Research Consent Form

Boston ARCH 4F Fall Prevention Intervention Pilot Study

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RESEARCH CONSENT FORM

Basic Information

Title of Project: Boston ARCH 4F Fall Prevention Intervention Pilot Study

IRB Number: H-41041

Sponsor: National Institute of Health, National Institute on Alcohol Abuse and Alcoholism

Principal Investigator: Theresa Kim, MD
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Study Phone Number: (617) 358 -1498

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. We are asking you to be in this study because you are a participant of the Boston ARCH 4F study, have used alcohol, and are at risk for experiencing a fall. We have developed an intervention to help reduce a person's risk of falling. We are doing the research to test the acceptability (if the participants like the intervention) and feasibility (if it is possible to do the intervention and carry out the study). If you agree, you will be interviewed, complete a physical assessment, and be assigned to one of two groups: 1) 10-week fall prevention intervention group, and 2) control group that will be provided with educational materials on fall prevention and alcohol consumption. Assignment to the group will be random (by chance, like the flip of a coin). You will be in the study for about 14 weeks 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 is loss of confidentiality. You will find more information about risks later in this form.

You might benefit from being in the study because the intervention may improve your risk for experiencing a fall. You will find more information about benefits later in this form.

You could get these benefits without being in the study by discussing fall prevention options with your doctor or an occupational therapist. You will find more information about alternatives 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. Your doctor's goal as an investigator is to collect information to answer the scientific questions asked in this research study, in order to help future patients. This is

different from their role as your doctor, where their goal is to treat you as a patient. You may want to get another opinion about being in the study from a doctor who is not an investigator in this study. You can do so now or at any time during the study. You do not have to agree to be in this study even though it is offered by your doctor.

Purpose

We have developed a 10-week long virtual intervention that is designed to improve balance and strength and provide participant support to prevent falls in people living with HIV who drink alcohol. In order to know if this intervention works to decrease falls, we will need to conduct a large-scale version of this study. The purpose of conducting this small-scale study is to help us know if it is possible and acceptable to conduct the large-scale version of the study.

What Will Happen in This Research Study

You will be one of approximately 50 people in this research study. The research will take place both virtually and at the Boston University Medical Campus.

If interested in participating, a research team member will call you via phone or video call to assess eligibility. If you're deemed eligible, the research team member will schedule your in-person baseline visit.

In-person visits: A baseline and post-study follow-up visit will take place in-person at the Boston University Medical Campus. These in-person visits will occur before and after the intervention. During these visits, a research team member will interview you using standardized interview questions and assess grip strength, vision, and conduct a series of other tests to measure balance and strength. We will also use an assessment tool to identify specific exercises that will be tailored to meet your own customized goals for strength and balance. These visits will take approximately two hours to complete.

Intervention: If you decide to participate in the study you will be assigned to one of two groups for the intervention: 1) Fall prevention intervention group, and 2) Control group. Assignment to the group will be random (by chance, like a flip of a coin). You will have an equal chance to be assigned the fall prevention intervention group or the control group.

Fall Prevention Intervention Group: The intervention has 3 main parts: 1) Virtual Group Sessions 2) Home Exercises, and 3) Weekly Phone Check-Ins.

1) The weekly virtual group sessions will be led by a member of the research team. The sessions include a discussion about challenges related to falls and how to prevent falls. You will be able to ask questions to other participants and the group leader.
2) The home exercises include activities to work on strength (like lifting items) and balance (like standing with one leg raised). The exercises will be customized for you (based on your assessments and goals) to match your current fitness level. You will be asked to complete the home exercises on your own 3 times per week for approximately 30 – 60 minutes each time you exercise.
3) Phone check-ins will happen once per week. A member of the research team will call you once per week. The member of the research team will answer your questions, provide feedback on

your exercises, set up any reminders for the upcoming week, and ask about falls and alcohol use during the week.

Control Group: If you are assigned to the Control group, you will receive an educational pamphlet on fall prevention and alcohol use.

Contacts: Members of the research team are people who work for the study but are not your healthcare providers. The members of the research team will contact you for follow-up assessment by phone or mail. We will ask for your permission to use the contact information (about yourself and alternative contacts) that you have already provided as part of your enrollment in the Boston ARCH 4F cohort study. We will review this contact information with you to make sure the information that we have on file is still accurate. We will also ask you to call us if your contact information changes. If we have to call one of your contacts to find you, we will not tell them about the purpose of the study or any of the information you have given us as a part of the study.

Data Repository: We will keep electronic research data on computers at the Boston University (BU) School of Public Health Biostatistics and Epidemiology Data Analytics Center (BEDAC). These data are locked behind two card-access doors with access to the main door restricted to key staff in charge of computers for Boston University.

Data are labeled and identified with a study number, but not your name or other information that can be connected to you. A master list of study numbers linked to identifying information will be kept separately. Using a study number and separate master list helps protect your privacy. If you leave the study, we will keep the information already collected.

The study number that we use to identify your data will be the same study number that we use in the Boston ARCH 4F study. This means that we will be able to link the data collected in the Boston ARCH 4F study to the information that we collect in this study.

If you agree, these data will be stored indefinitely and may be made available to other researchers (at BMC, BU or elsewhere) for future studies. Requests by other researchers to use these data will be reviewed by the study investigators. Data shared with other researchers will only be labeled with the study number, and they will not have any access to information that could identify you. The retention of data is optional, and you may agree to participate in the main study without agreeing to have your data retained after the conclusion of this research study.

Because the information we collect from you may be sensitive (like drug and alcohol use) it could be embarrassing or affect your ability to get a job if someone who wasn't supposed to know, found out. For that reason we put in place extraordinary measures to protect the information and keep it private. We do not have plans to use these data for commercial reasons and will not sell or transfer your data to for-profit companies.

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

Risks and Discomforts

Visits/ phone calls: You may have stress from talking about your health or from recognizing health disorders during the assessments or intervention sessions. If you become extremely upset during the visits we will refer you for psychiatric help. You may get tired during the visits. You may find it inconvenient to take time for the visits, especially on a day when you have other appointments. You may find it inconvenient to be contacted by study staff reminding you of a research visit.

Exercise Assignments: If you are randomly assigned to the intervention group, common risks from doing exercises include muscle soreness, discomfort, and fatigue. These are temporary and usually go away quickly. There is the unlikely risk that you could get injured while doing the exercises. For this reason, you will only be assigned exercises that have been tailored to your individual needs and skill level. We will ask that you do the exercises exactly as we tell you to do them, and you should not do any exercises that you feel uncomfortable doing. You should discuss any discomforts that have resulted from exercise assignments with members of the research team during weekly virtual group meetings and phone check-ins.

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. These are described below.

Potential Benefits

If you are randomly assigned to the control group, you may benefit from receiving educational materials on falls and alcohol use.

If you are randomly assigned to the intervention group, you may benefit from the intervention components of the study. You may gain strength and balance from weekly exercises, which may make you less likely to fall. You may benefit from discussing your experiences related to falls and alcohol use with other peers during weekly virtual group meetings. Additionally, you may benefit from discussing your experiences and concerns related to falls and alcohol use with an occupational therapist member of the research team during weekly phone check-ins.

The primary goal of this research is to collect information about the scientific questions asked in this study. Your being in the study may help the investigators learn whether a fall prevention intervention with this study design is possible and/or well-received by its participants.

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. Peer support groups, educational materials, and physical and occupational therapy for reduction of fall risk are also available through clinical services.

Costs

You may have costs related to travel or parking during the in-person visits. Your mobile phone company may charge you more if you use more data or telephone minutes to participate in weekly virtual group sessions and phone check-ins.

Payment

You will be paid up to $130 in cash for completing the baseline and post-study assessments. You will receive $50 in cash for completing the baseline assessment and $80 in cash for the post-study assessment. If you have to be re-screened for eligibility in-person before your baseline assessment and we find you are ineligible at that time; we will not continue with the baseline assessment. We will compensate you $15 for your time.

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. The procedures in place to assure confidentiality include the following: you will have a unique study identification (ID) number; research data collection and data entry forms will be labeled only with this number, not your name; and interview forms will not contain any other identifiable information (for example, your name and date of birth). However, we cannot guarantee complete confidentiality.

Only the written informed consent forms, your contact information, and a master list of people in the study will have your study ID number and identifying information on them. These documents will be kept in locked filing cabinets accessible only to the research staff on an as needed basis or on secure computers. Computer data will be password protected and accessible only to research staff needing the information to contact you.

When research assistants attempt to make any contact with you, all communications will be identified as coming from a Boston University Medical Campus “health study,” not a study about HIV or alcohol use, and will be made by phone, secure email, or mail. Study staff will only send non-secure emails to you if you provide express permission for us to do so. If you are in an institution such as a rehab facility or hospital at the time of a scheduled follow up assessment, the researchers will provide the institution’s staff with information about the study (for example, the name of the study and a copy of the study protocol) and about who you are (so they know who we are looking for) but not any information that you have given the study staff during the study assessments.

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 are covered by a CoC. The CoC provides how we can share research information. Because we have a CoC, we cannot give out research information 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 in connection with a legal proceeding, we cannot give it to them. The CoC does not prevent you from sharing your own research information.

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.
- 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.

We will ask everyone in the weekly group meetings not to talk about the discussions outside the group. However, we can't promise that everyone will keep what you say confidential.

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.

Special Permissions

Data Storage

We would like to ask you to give your permission to store your data for future research. Saying no will not affect your ability to participate in the study.

___Yes ____No My research data may be kept for future studies.

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. You will only be paid for the study activities that you complete before withdrawing.

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 Theresa Kim, MD at 855-414-2724 (Toll Free). This line is staffed during the day Monday through Friday. Please leave a message after 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 sharing of information that may identify you as described

_____ _____
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

BMC and BU Medical Campus IRB
IRB NUMBER: H-41041
IRB APPROVAL DATE: 06/13/2022