STUDY INFORMED CONSENT

Adaptation of the Friendship Bench counseling intervention to improve mental health and HIV care engagement outcomes among people living with HIV who inject drugs in Vietnam

NCT number NCT04790201
Document Date 04/01/2022

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: version 2.0 dated 18 February, 2022
IRB Study #: 20-1689

Title of Study: IGHID 12028 - Adaptation of the Friendship Bench counseling intervention to improve mental health and HIV care engagement outcomes among people living with HIV who inject drugs in Vietnam

US Principal Investigator: Bradley Gaynes, MD, MPH
Psychiatry – General, The University of North Carolina at Chapel Hill
Phone number**:** 919-445-0214
Email Address: bradley_gaynes@med.unc.edu

Investigator of Record: Tran Viet Ha, MD
The University Of North Carolina Office in Vietnam
Phone number: 84-24-3211-5839
Email Address: vietha@live.unc.edu

Local Principal Investigator: Associate Professor Le Minh Giang, PhD
Global Health, Institute for Preventive Medicine and Public Health, Hanoi Medical University
Phone number: 84-24-3574-1596
Email Address: leminhgiang@hmu.edu.vn

Funding Source and/or Sponsor: National Institutes of Health (NIH)

Study Contact Telephone Number: Dr. Tran Viet Ha at 84-24-3211-5839
Study Contact Email: vietha@live.unc.edu

CONCISE SUMMARY

This study is being done to test the feasibility of the Adapted Friendship Bench intervention to improve mental health treatment and engagement for those receiving methadone maintenance therapy and HIV treatment who also have a common mental disorder, meaning depression, anxiety, or a stress-related disorder. Subjects will be randomized to one of three groups: Friendship Bench by a professional counselor, Friendship Bench by lay counselor, or enhanced usual care (EUC). Friendship Bench is a problem-solving based therapy technique. There is no cost to participate and compensation will be provided per local policies. There are no direct benefits from being in the research study. Subjects may experience discomfort from answering questionnaires. Study participation lasts approximately 12 months.

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary.
You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this research study is to assess the feasibility, fidelity, and acceptability of the Adapted Friendship Bench interventions to improve psychiatric disorders and engagement in HIV care.

You are asked to be in this study because: 1) you have screened positive for a common mental disorder, such as depression, anxiety, or stress; 2) you are at least 18 years of age; 3) you are HIV positive

How many people will take part in this study?
If you decide to be in this study, you will be one of approximately 75 adults in this research study.

How long will your part in this study last?
Your participation in the study could last up to 12 months.

What will happen if you take part in the study?
If you decide to be in this study, we will:

- Ask you to complete a baseline research assessment to assess a series of health related questions to confirm your eligibility for the study
- Collect sociodemographic information
- Perform a psychiatric interview (called the "MINI") to clarify the diagnosis of a common mental disorder
- Use a questionnaire to assess substance abuse (called the "ASSIST")
- Randomly assign to one of 3 arms listed below. You will know which group you are in.

- Additionally, we will collect information from your medical record, including results from your clinic urine drug screen. If this information is not available in your chart, we may ask you to complete a urine drug screen for the study.

Arm 1 - Adapted Friendship Bench counseling intervention delivered by a professional counselor
If you are assigned to this arm, we will:

- Ask you to participate in approximately 6 counseling session over a 6-week period. Each session will last 45 minutes. During these sessions, the study counsellors will work with you to help with depressive, anxiety, or stress-related symptoms.
- Ask you to complete a follow-up assessments at approximately 6 weeks, 3, 6, and 12 months post-baseline assessment. We will use the same assessments used at baseline described above

Arm 2 - Adapted Friendship Bench counseling intervention delivered by a lay counselor
If you are assigned to this arm, we will:

- Ask you to participate in approximately 6 counseling session over a 6-week period. Each session will last 45 minutes. During these sessions, the study counsellors will work with you to help with depressive, anxiety, or stress-related symptoms. We will use the same assessments used at screening described above.
- Ask you to complete a follow-up assessments at approximately 6 weeks, 3, 6, and 12 months post-baseline assessment. We will use the same assessments used at screening described above

Arm 3 - Enhanced usual care (EUC) intervention
If you are assigned to this arm, we will:

- Train your clinic providers and clinics about identification and management of depressive, anxiety, and stress symptoms, in general.
- Give feedback to your provider of what symptoms you have. They will provide their usual care for these symptoms without any help by a counsellor.
- Ask you to complete a follow-up assessments at approximately 6 weeks, 3, 6, and 12 months post-baseline assessment.

Additionally, regardless of which arm you are in, we will collect information from your medical record, including results from your clinic urine drug screen and any HIV viral load tests. If this information is not available in your chart, we may ask you to complete a urine drug screen or HIV viral load test for the study.

If you receive counseling, these counseling sessions may be recorded. After the last counseling session, we will interview to seek your perception on how easy the counseling intervention was to participate in, the usefulness of the intervention and suggestions for improvement. The interview will be recorded and transcribed for analysis. These recordings will not be linked to your name and will not be shared with anyone outside the research team. If you do not want your counseling sessions and interview recorded, you can still participate in the study.

At any time, you may decline to answer questions in an interview. If you have questions or concerns, you may contact the study doctor Tran Viet Ha at 84-24-3211-5839 or vietha@live.unc.edu.

What are the possible benefits from being in this study?

By participating in counseling, your feelings of sadness or worry may improve, though this cannot be guaranteed. At a societal level the results of this study will improve our understanding of how an adapted and enhanced counseling intervention may improve HIV, mental health, and drug use treatment.

What are the possible risks or discomforts involved in being in this study?

The risks of taking part in the interview are small, if any. Some questions could make you feel uncomfortable or embarrassed. You may choose not to answer any question for any reason and you can leave the interview at any time.

There is a potential for breach of confidentiality if during these interviews you indicate to study staff you may harm yourself or someone else. Legal mandates for reporting and appropriate treatment plans and referrals will be made if this occurs.

You may feel pain, discomfort, dizzy when your blood is drawn. You may decline blood collection with no consequence to your care.

If you choose not to be in the study, what other treatment options do you have?

You do not have to be in this research study in order to receive treatment. If you do not participate in this study, you will continue to receive your regular medical care.

What if we learn about new findings or information during the study?

You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will your privacy be protected?

The study team will try to protect the privacy of your study records and test results, to the extent permitted by law, but cannot guarantee that your study records and test results will never be released to others. Unless required by law or unless you give written permission, study records that identify you will not be released to other parties or entities. However, your study records may be reviewed by various government agencies that have a legal right to do so, such as the sponsor of the study (US National Institutes of Health (NIH), the University of North Carolina at Chapel Hill Institutional Review Boards and the Hanoi Medical University Institutional Review Board, study staffs and study monitors. It is also possible that a court or other government agency could order that study records identifying you be released to others. Any publication or presentation of the results of findings of this study will not use your name and will not include any information that will identify you.

Participants will not be identified in any report or publication about this study. We may use de-identified data and/or specimens from this study in future research without additional consent.

A description of this clinical trial will be available on http://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.

What is a Certificate of Confidentiality?

Most people outside the research team will not see your name on your research information. This includes people who try to get your information using a court order in the United States and/or Vietnam. One exception is if you agree that we can give out research information with your name on it or for research projects that have been approved under applicable rules. Other exceptions are for information that is required to be reported under law, such as information about child or disabled abuse or neglect or certain harmful diseases that can be spread from one person to another. Personnel of a government agency sponsoring the study may also be provided information about your involvement in the research study.

What will happen if you are injured by this research?

If you have any health problem, please contact the study staff. If you have a medical emergency that requires immediate care, please call 115. If you are injured as a result of being in this study, the District Health Center will give you immediate necessary treatment for your injuries. You *will* have to pay for this treatment. You will be told where you can get additional treatment for your injuries. There is no program for monetary compensation or other forms of compensation for such injuries either through this institution or the NIH.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

Will you receive anything for being in this study?

You will be compensated for your lost work time and expenses for your travel from your house to the study site and back home with:

- An amount of VND 50,000 at screening visit.
- An amount of VND 100,000 at enrollment and follow-up visits.
- An amount of VND 100,000 for having your viral load tested at 6 month and 12 month follow-up visits.

Will it cost you anything to be in this study?

It will not cost you anything to be in this study.

Who is sponsoring this study?

This research is funded by the National Institutes of Health (NIH). This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?
You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research participant?
All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Hanoi Medical University Institutional Ethical Review Board at 024-388-527-622 or by email to irb@hmu.edu.vn. Or you may contact the University of North Carolina at Chapel Hill Institutional Review Board at +1-919-966-3113 or by email to IRB_subjects@unc.edu.

SIGNATURE PAGE:

Title of Study: IGHID 12028 - Adaptation of the Friendship Bench counseling intervention to improve mental health and HIV care engagement outcomes among people living with HIV who inject drugs in Vietnam

US Principle Investigator: Bradley Gaynes, MD, MPH
Investigator of Record: Tran Viet Ha, MD
Local Principal Investigator: Associate Professor Le Minh Giang, PhD

Participant's Agreement:
Please indicate below by writing your initials or make your mark below if you agree or not to having your counseling sessions and your interview audio-recorded

I agree _____

I do not agree _____

If you have read this informed consent, or have had it read and explained to you, and you understand the information, and you voluntarily agree to enroll into this study, please sign your name or make your mark below.

_____ _____
Participant's Name (print) Participant's Signature or Thumbprint and Date

For staff: I have explained the purpose of the study to the volunteer and have answered all of his/her questions. To the best of my knowledge, he/she understands the purpose, procedures, risks and benefits of this study.

_____ _____
Study Staff Conducting Consent Discussion (print) Study Staff Signature and Date

For witnesses for illiterate volunteers: I attest that the information contained in this written consent form has been read and explained to the participant. He/she appears to understand the purpose, procedures, risks and benefits of the study and has voluntarily accepted to participate in this study.

For those placing thumbprint only: I attest that the participant who states that his/her name is _____ has placed his/her thumbprint on this consent form of his/her

own free will on this day _____.

_____ _____
Witness' Name (print) Witness's Signature and Date