IGHID 12230 - Scaling up the brief alcohol intervention to prevent HIV infection in Vietnam: a cluster randomized, implementation trial (EBAI)

NCT number NCT06358885
Document Date 07/15/2024

University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants - Enrollment - People with HIV (PWH) - Subsample Cohort

Consent Form Version Date: 15 July 2024
IRB Study #: 22-3123

Title of Study: IGHID 12230 - Scaling up the brief alcohol intervention to prevent HIV infection in Vietnam: a cluster randomized, implementation trial (EBAI)

Local Principal Investigator: Associate Professor Phan Thi Thu Huong, PhD
Vietnam Administration of HIV/AIDS Control, Ministry of Health
Tel: +84 243865578
Email: huongphanmoh@gmail.com

Local Principal Investigator: Associate Professor Le Minh Giang, PhD
Department of Epidemiology, Institute for Preventive and Public Health
Hanoi Medical University
Tel: +84 2435741596
Email: leminhgiang@hmu.edu.vn

US Principal Investigator: Professor Vivian Go, PhD
Health Behavior Department, The University of North Carolina at Chapel Hill
Tel: +1-919-966-3908
Email: vgo@unc.edu

Study Sponsors: US National Institute on Alcohol Abuse and Alcoholism (NIAAA), US National Institutes of Health (NIH)

Study Contact telephone number: Dr. Le Minh Giang at +84 2435741596

You enrolled in the part of the study allowing us to access your ART information and you have been selected to take part in a subsample cohort to allow us to re-contact you at a later date.

You will be asked to take part in an interview by phone at baseline, 3 and 12 months where a brief questionnaire will be given. We will collect a dried blood specimen for viral load and alcohol use testing at baseline. You will also be asked to return 12 months later to the test site where a dried blood spot specimen will again be collected for viral load and alcohol use testing.

You may also be selected to take part in a qualitative in-depth interview 12 months after you enroll in this study to assess characteristics of high and low performing sites in depth. We will ask you about knowledge of alcohol use and effects on HIV; motivators to consume, reduce or abstain from alcohol; behavioral skills to cope with high-risk moods and situations for drinking; and attitudes and experiences in the ART clinic. The interview will take about 1 hour and will be audiotaped.

While you may likely benefit from the Brief Alcohol Intervention (BAI), you may not directly benefit from taking part in the study. You may have problems if people learn that you are here for this study and think that you are infected with HIV or have unhealthy alcohol use. There may be a small risk of psychological distress due to study questions, and you may have slight pain and possible bruising when the blood is collected, and there is a risk of breach confidentiality. You can withdraw from this study at any time, without penalty.

If you are interested in learning more about this study, please continue reading below.

What are some general things you should know about research studies?

You are being asked to take part in a research study because you are living with HIV and you are on antiretroviral therapy; you are 18 years or older; and you report unhealthy alcohol use. 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 study is to assess two implementation strategies for the brief alcohol reduction intervention (BAI) for People with HIV (PWH) attending the study ART clinics, and it is designed to help PWH reduce alcohol use and increase ART adherence.

We will compare the BAI implementation using facilitation only (FAC) to facilitation plus experiential brief alcohol reduction intervention (EBAI+FAC) in ART clinics to determine their relative effectiveness and cost for scaling-up the BAI as well as the characteristics of high and low performing ART clinics.

You enrolled in the part of the study allowing us to access your ART information and you have been selected to take part in a subsample cohort to allow us to re-contact you at a later date.

Are there any reasons you should not be in this study?
You should not be in this study if you are suffered from psychological disturbance preventing your participation to the study, or you have cognitive impairment, threatening behavior or you are identified to be at substantial risk for alcohol withdrawal based on our assessment. You may be rescreened, consented, and enrolled after treatment.

How many people will take part in this study?
Approximately 810 PWH will be asked to take part in this subsample cohort.

How long will your part in this study last?
You will be in this study for 15 months.

What will happen if you take part in the study?
In this part of the study, you will:

- Be asked to provide contact information to allow us to re-contact you at a later date and to obtain your locator information including a family member's contact information.
- Be asked to take part in an interview by phone at baseline, 3 and 12 months where a brief questionnaire will be given. The questionnaire will address your views of BAI and factors that may affect your ART adherence, including sociodemographic characteristics, injecting behaviors, HIV-related questions, alcohol use, social support, quality of life, provider relationships, mental health, and costs.
- Be asked to have dried blood spot specimen collected for viral load and alcohol use testing at baseline and 12 months.

We will call you every 3 to 4 months to ensure your contact information has not changed. If we are unable to reach you, we will contact a family member or friend, using the contact number that you had provided, to try to update your locator information.

If we are not able to contact you within 2 months from when you joined the study, you will not have the follow-up visits or phone interviews at 3 and 12 months.

We also want to keep your contacts so that we can contact you in the future if needed. You will be asked to give consent to be contacted for future studies.

You may also be asked to take part in a qualitative in-depth interview 12 months after you enroll in this study. If you are selected to take part in this qualitative in-depth interview at 12 months to assess characteristics of high and low performing sites in depth, we will ask you

about your knowledge of alcohol use and its effects on HIV; motivators to consume, reduce or abstain from alcohol; behavioral skills to cope with high-risk moods and situations for drinking; and attitudes and experiences in the ART clinic. The interview will take about 1 hour and will be audiotaped. You may benefit from being able to share your experiences and opinions about the BAI intervention. There may be a small risk of psychological distress due to the study questions. You can terminate the interview at any time. Approximately 32 people will take part in the qualitative in-depth interview.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. All PWH presenting at the 30 ART clinics will be offered the BAI intervention. While you may likely benefit from the BAI intervention, you may not directly benefit from taking part in the study. Participants may benefit from being able to share their experiences and opinions about the BAI intervention. Participants in the EBAI+FAC implementation arm may benefit from potentially more effective implementation of BAI.

You will not receive any direct benefit from sharing your data and biospecimens. However, sharing your data and biospecimens may contribute to research that could help others in the future.

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

Social Impact Reporting

- We will make every effort to protect your privacy and confidentiality while you are in this study. However, it is possible that you could have problems if people learn that you are here for this study. People may think that you are infected with HIV or at risk of HIV because of sexual behavior or drug use. It is also possible that others may find out that you have been screened for this study and assume that you are a person with unhealthy alcohol use. If people think you are infected with HIV or a person with unhealthy alcohol use, this could cause you problems finding or keeping a job. Others may treat you unfairly, including your family and community.
- Further, it is possible that those you tell, will tell others that you are HIV-positive and have unhealthy alcohol use.

We will do our best to protect your data and biospecimens during storage and when they are shared. However, there remains a possibility that someone could identify you. There is also the possibility that unauthorized people might access your data and biospecimens. In either case, we cannot reduce the risk to zero.

Blood collection

Dried blood spots (DBS) will be collected by a finger prick or blood draw. You may have a slight pain and possible bruising when the blood is collected. To reduce the possibility of pain and bruising, blood draws or finger pricks will be taken by trained phlebotomists. Additionally, if the DBS is collected via blood draw, you will be asked to rest and take water following the blood draw. You may decline the dried blood spot collection with no consequence to your care.

Specific and appropriate protocols will be in place to ensure a participant's safety should a research staff member feel that a participant is in danger of harming himself or others during the course of a study visit. We will also remind participants that they can terminate the interview at any time.

In-depth interview (if you are selected):
If you participate in in-depth interview, there may be a small risk of psychological distress due to study questions such as those concerning HIV risk, drug use, alcohol use and disclosure of HIV serostatus. You may find answering questions about these issues upsetting. These questions will be asked in as sensitive a manner as possible, and you may decline to answer at any time. If you experience emotional upset during the interview, the research staff will be trained on how to handle these situations and the principal investigators will be available to speak with you if needed.

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?
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.

All study interviews and procedures will be administered by trained study staff in a private room. If names and identifying information are collected, a logbook will be used to link a participant's identifying information with his/her study identification number (PID); personal identifiers will not be stored in the data set. The logbook will be kept in a locked cabinet, separate from all other study file cabinets, in a locked project office room; an electronic copy will be saved on a password-protected, encrypted computer. All data, notes, and audio-recordings will also be kept on a password-protected, encrypted computer. Access to the locked files and security passwords will be given only to the PIs, UNC-Vietnam In-Country Director, Research Manager and select well-trained project staff. The logbook will be destroyed and the electronic copy deleted one year after the end of data collection. Tapes of qualitative interviews will be destroyed within one year of being transcribed electronically. Raw data files will be destroyed one year after electronic coding.

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 Institute on Alcohol Abuse and Alcoholism (NIAAA), US National Institutes of Health (NIH), the University of North Carolina at Chapel Hill Institutional Review Boards and the Institutional Review Board for Ethics in Biomedical Research – Hanoi Medical University, the Vietnam Administration for HIV/AIDS Control (VAAC), study staff 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.

This study is collecting data and biospecimens from you. We would like to make your data and biospecimens available for other research studies that may be done in the future. The research may be about similar diseases or conditions to this study. However, research could also be about unrelated diseases, conditions, or other types of research. These studies may be done by researchers at this institution or other institutions, including commercial entities. Our goal is to make more research possible. We plan to keep your data for five years after coding.

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. 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.

By signing this consent form, you authorize the collection and use of information about you. The Sponsor will not share individual participant data with you in order to maintain the scientific integrity of the study.

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. 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.

Will you receive results from research involving your specimens?

Most research with your specimens is not expected to yield new information that would be meaningful to share with you personally. There are no plans to re-contact you or other subjects with information about research results.

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. You do not give up any legal rights by signing this consent form.

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.

If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal.

If you do not want your data or biospecimens used for other projects, you should not participate in this study.

If you choose not to be in the study, what other treatment options do you have?
If you choose not to take part in this study, it will have no effect on your access to regular services at this site.

Will you receive anything for being in this study?
You will receive VND 100,000 (USD 4.35) at the end of each study visit to compensate for your time and travel.

In addition, if you are selected to take part in a qualitative in-depth interview at 12 months, you will receive an amount of VND 200,000 (USD 8.70) at the end of the in-depth interview to compensate for your time and effort in this study, and/or be reimbursed for travel to the interviews and time away from work.

Will it cost you anything to be in this study?
There will be no cost to you for study-related visits or other procedures.

Who is sponsoring this study?
This research is funded by the US National Institute on Alcohol Abuse and Alcoholism (NIAAA), US National Institutes of Health (NIH). This means that the research team is being paid by the sponsor. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

NIAAA Data Archive (NIAAADA)
Data from this study will be submitted to the National Institute on Alcohol Abuse and Alcoholism Data Archive (NIAAADA) at the United States National Institutes of Health (NIH). NIAAADA is a large database where deidentified study data from many NIAAA studies is stored and managed. Deidentified study data means that all personal information about you (such as name, address, birthdate, and phone number) is removed and replaced with a code number. During and after the study, the study researchers will send deidentified study data about your health and behavior to the NIAAADA. Other researchers across the world can then request your deidentified study data for other research. You will not be contacted directly about the study data you contributed to NIAAADA.
Every researcher (and institutions to which they belong) who requests your deidentified study data must promise to keep your data safe and promise not to try to learn your identity. Sharing your study data does have some risks, although these risks are rare. Your study data could be accidentally shared with an unauthorized person who may attempt to learn your identity. The study researchers will make every attempt to protect your identity. You may not benefit directly from allowing your study data to be shared with NIAAADA. The study data provided to NIAAADA may help researchers around the world do more powerful research.
You may decide now or later that you do not want your study data to be added to the NIAAADA. **You can still participate in this research study even if you decide that you do not want your data to be added to the NIAAADA.** If you decide any time after today that you do not want your data to be added to the NIAAADA, inform the study staff, and they will not share your data collected on or after that date. The study researchers cannot remove the study data that was shared before they were notified that you changed your mind. If you would like more information about NIAAADA, this is available on-line at https://nda.nih.gov/niaaa.

Contact Information

You will be asked to provide your address and phone number(s). The staff will ask you for names of people who will always know how to find you and places where you can be found. It is possible that the staff may visit you at your house or contact one of the people on your contact list if you are not able to attend your visits or if the staff have important information for you. If we talk to people on this list, we will not tell them why we are trying to reach you. If you are not willing to give us this information, you should not agree to be in this study. We will also ask you to give us contact information at the last study visit so we can contact you and share with you the results of this 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, 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, please contact:

- Dr. Le Minh Giang, Head of Department of Epidemiology, Institute for Preventive and Public Health, Hanoi Medical University at +84 2435741596 or at leminhgiang@hmu.edu.vn
- Hanoi Medical University Institutional Ethical Review Board in Biomedical Research at +84 2438527622 or by email to irb@hmu.edu.vn

Or you may contact the University of North Carolina at Chapel Hill Institutional Review Board (IRB) at +1-919-966-3113 or by email to IRB_subjects@unc.edu.

SIGNATURES - ENROLLMENT CONSENT FOR PWH - SUBSAMPLE COHORT

Participant's Agreement:

Please indicate by writing your initials or making your mark below if you agree or not to be contacted by the study team for future studies, when appropriate.

I agree _____

I do not agree_____

Please indicate by writing your initials or making your mark below if you agree or not to having an in-depth interview audio recorded.

I agree _____

I do not agree _____

Please indicate below by writing your initials or make your mark if you agree or not to have your study data, including information collected during the study screening assessment, submitted to the NIAAA Data Archive.

I agree _____

I do not agree_____

If you have read this consent form, or had it read and explained to you, and you understand the information, and you voluntarily agree to take part in this study, please check this box:

☐

And please sign your name, make your mark or place your thumbprint below.

PART A: LITERATE PARTICIPANT

Participant is literate ☐

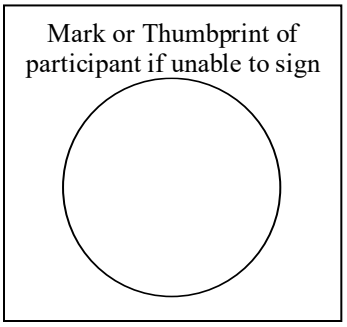
_____	_____	_____
Participant Name (print)	Participant Signature	Date
_____	_____	_____
Study Staff Conducting Consent Discussion (print)	Study Staff Signature	Date

---

PART B : ILLITERATE PARTICIPANT

Participant is illiterate ☐

The study staff must complete this section, ONLY if an impartial witness is available.
The **study staff must write participant's name and date of consent** below**.**



Participant Mark or Thumbprint

_____	_____
Participant Name (print)	Date

Participant name and date written by _____ on _____

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

_____	_____	_____
Witness Name (print)	Witness Signature	Date