STUDY INFORMED CONSENT

HIV Engagement and Adolescent Depression Support (HEADS-UP)

NCT number NCT06173544
Document Date 5/22/2024

University of North Carolina at Chapel Hill
Assent to Participate in a Research Study
Minor Subjects Ages 13-14

Consent Form Version Date: Version 2.0, May 22, 2024
UNC IRB Study #23-2439: NHSRC Study #: 23/09/4187

Title of Study: UNCPM 22319 - HIV Engagement and Adolescent Depression Support (HEADS-UP) Pilot Trial

Malawi Principal Investigators: Kazione Kulisewa, MBBS, MMed
US Principal Investigator: Bradley N. Gaynes, MD, MPH
UNC-Chapel Hill Department: Psychiatry

Funding Source and/or Sponsor: National Institute of Mental Health

Study Contact telephone number: +265 999 272 759

CONCISE SUMMARY

The purpose of this project is to enroll 105 young people to learn how successful, helpful, and appropriate a changed program is for helping young people living with HIV and depression feel less depressed and go to their HIV care appointments. Some young people in this project will go to counseling sessions, some will go to counseling sessions plus group meetings with other young people with HIV and depression, and some will get their regular HIV and depression care. The study will last 12 months.

Being in this study has few risks like the loss of confidentiality or of discussing uncomfortable things. Being in the study will help the investigators to better design treatments to help young people living with HIV. Some young people in this study might feel less depressed, but it's possible there will be no change in the way they feel.

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

Your parent, or guardian, needs to give you permission for you to be in this study. You do not have to be in this study if you do not want to, even if your parent has already given permission. You may stop being in the study at any time. If you decide to stop, no one will be angry or upset with you. Sometimes good things happen to people who take part in studies, and sometimes things happen that they may not like. We will tell you more about these things below.

Why are they doing this research study?

The reason for doing this research is to find out how successful, helpful, and appropriate an adult treatment of depression works to help depressed adolescents with HIV, and improve their depression and participate more in their HIV care. Some young people in the study will go to

counseling sessions, some will go to counseling sessions plus group support sessions, and some will get their regular HIV and depression care. All participants will answer some questions at the beginning, middle (6 months), and end of the study (12 months). Viral load data (the amount of HIV in the blood) will be collected at the beginning and end of study.

You are being asked to be in the study because you are a young person with HIV and depression.

Are there any reasons you should not be in this study?
You should not be in this study if you are not comfortable discussing sensitive topics like depression or HIV.

How many people will take part in this study?
There will be approximately 105 young people with HIV and depression in this research study.

How long will your part in this study last?
Your participation will last approximately 1 year.

What will happen if you take part in the study?
If you take part in this study, you will be asked to complete a questionnaire that will ask about your experience with mental health care and HIV care. You will also be asked to have your viral load tested at the beginning of the study, six months, and at the end of the study (12 months). To test viral load, the study staff will collect 3-5 drops of blood by sticking your finger one time.

In addition to the questionnaire and viral load testing, you might be asked to participate in 6 individual counseling sessions over the course of 2 months led by counselors at one of our HIV clinics. One of your six counseling sessions will be recorded . If you do not want to be recorded, you will not be able to participate. You may also be asked to participate in monthly peer support sessions that are in person group meetings for 6 months for a total of 6 meetings. One of your peer support sessions will be recorded. If you do not want to be recorded, you will not be able to participate. If you participate in the counseling sessions and/or peer support sessions, you will be asked to complete a brief exit interview once the study is completed. If you do not want to be recorded, youwill not be able to participate in the interview. If you are not asked to interact with the counseling sessions or peer support sessions, you will continue to receive your medical care as usual.

You may choose not to answer a question for any reason. All questionnaires will be available in Chichewa.

What are the good things that might happen from being in this study?
This research study is designed to help doctors improve efforts to monitor engagement in HIV care and manage depression for others, like you, in the future. This research will improve our understanding of how to deliver a counseling and peer support intervention for ALWH. Some people in the study might feel less depression, but it's also possible that you will not have any benefit.

What are the bad things that might from being in this study?

Sometimes things happen to people in research studies that may make them feel bad. These are called "risks."

Not all of these things may happen to you. None of them may happen or things may happen that the researchers don't know about. You should report any problems to the researcher.

During this study, we will ask some personal questions that may make you feel embarrassed or emotional. We will refer you to existing counseling and support services, if needed. This is also optional and you may choose to refuse to answer particular questions.

If you are participating in a peer support session group, other participants in that session may be aware of your HIV or depression status. We will make every effort to protect your privacy and information about you while you are participating in this study. All of the information you give will be kept secure and will not be shared with anyone without your permission unless there is something that could be dangerous to you or someone else. The information we collect will only be identified with a code or number, not with your name. Any information about you will be removed from the information collected in the audio recording

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.

Who will be told the things we learn about you in this study?

Efforts will be made to keep your personal information confidential to the extent allowed by law. However, there may be times when Malawi or US law requires the release of such records, including personal information. All data will be kept in a locked cabinet at UNC project or on a secure server at UNC Project accessible only to approved study staff. All study data will be destroyed 1 year after the completion of all study-related activities. You will not be personally identified in any publication about this study. We will not tell anyone outside of the research and medical team what you tell us without your permission unless there is something that could be dangerous to you or someone else. We will not share your information with anyone outside of this study for future research studies.

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

You may stop being in the study at any time. If you decide to stop, no one will be angry or upset with you. The doctors may also choose to stop your participation at any time, maybe because the entire study has stopped.

If you are in a focus group and decide to leave during the focus group, we will only use the parts of the audio recordings without you for transcription and translation.

Will you get any money or gifts for being in this research study?

You will not receive anything for taking part in this study. However, at the enrollment visit, 6-month visit, and 12-month visit your parent or legal guardian (if they are with you) will receive the equivalent of US $10. You parent or legal guardian will receive transport imbursement for attending each of the six peer support sessions. They will not receive any payment for counseling sessions.

Will it cost you anything to be in this study?
It will not cost you or your parents anything to be in this study.

Who is paying to do this study?
This research is funded by the National Institute of Mental Health from the United States. 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. You can talk to the study doctor about any questions or concerns you have about this study. Contact the study doctor Dr Kulisewa at +265 997 21 03 81.

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 participant, or if you would like to obtain information or offer input, you may contact the NHSRC Director, Dr. Evelyn Chitsa Banda at +265 999 936 937.

SIGNATURE PAGE

UNC IRB Study #:23-2439; NHSRC Study #: 23/09/4187

Title of Study: UNCPM 22319 - HIV Engagement and Adolescent Depression Support (HEADS-UP) Pilot Trial

Malawi Principal Investigators: Kazione Kulisewa, MBBS, MMed
US Principal Investigator: Bradley N. Gaynes, MD, MPH

Participant's Agreement:

If you have read this informed consent, or have had it read and explained to you, and understand the information, and you voluntarily agree to participate in this research study, **please print and sign your name and write the date** in the signature area below**.**

PART A: LITERATE PARTICIPANT

Participant is literate: ☐

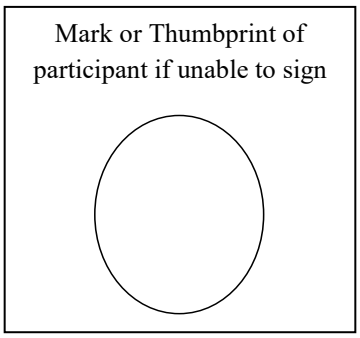
_____	_____	_____
Participant Name (print)	Participant Signature	Date
_____	_____	_____
Study Staff Conducting Consent Discussion (print)	Study Staff Signature	Date

If you have read this informed consent, or have had it read and explained to you, and understand the information, and you voluntarily agree to participate in this research study, **please make your mark or place your thumbprint** in the signature area below.

PART B : ILLITERATE PARTICIPANT

Participant is illiterate: ☐

The study staff must complete this section, ONLY if an impartial witness is available.
The **impartial witness 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
_____	_____	_____
Impartial Witness Name (print)	Impartial Witness Signature	Date

University of North Carolina at Chapel Hill
Parental/Legal Guardian Permission Form for a Minor to Participate in a Research Study

Consent Form Version Date: Version 2.0, May 22, 2024
UNC IRB Study #:23-2439 NHSRC Study #: 23/09/4187

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UNC-Chapel Hill Department: Psychiatry

Funding Source and/or Sponsor: National Institute of Mental Health

Study Contact telephone number: +265 999 272 759

CONCISE SUMMARY
The purpose of this project is to enroll 105 participants to determine the feasibility, fidelity, and acceptability of the adapted and enhanced Friendship Bench (FB) counseling interventions to improve depression and engagement in HIV care among adolescents living with HIV. Some participants will receive the adapted FB, some will receive the enhanced FB, and some will receive care as usual. Participants will be recruited and followed for 12 months.

Participation in this study has few risks. There is a risk of loss of confidentiality or of discussing uncomfortable things. Participation will help the investigators to better design treatments to help young people living with HIV. Some participants may experience reduced depression, but it's possible that there will be no benefits to participants.

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

You are being asked to allow your young person to take part in a research study. To join the study is voluntary. You may decide not to allow your young person to participate, or you may withdraw your permission for your young person to be in the study, for any reason, without penalty. Even if you give your permission, your young person can decide not to be in the study or leave the study early.

Research studies are designed to obtain new knowledge. This new information may help people in the future. Your young person 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 or your young person's relationship with the researcher, your health care provider, or the University of North Carolina Project, Lilongwe. If your young person is a patient with an illness, your young person does 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 and your young person understand this information so that you and your young person can make an informed choice about being in this research study.

You will be given a copy of this consent form. You and your young person 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 better understand if the adapted and enhanced Friendship Bench counseling interventions for improving depression and HIV care engagement among adolescents living with HIV (ALWH) are feasible, acceptable, and able to be delivered to participants as planned. Another purpose of this study is to compare how well the adapted and enhanced FB counseling interventions work to improve depression and engagement in HIV care among ALWH.

Your young person is being asked to be in the study because your young person has HIV and is depressed.

Are there any reasons you should not be in this study?
Your young person should not be in this study if you are not comfortable discussing sensitive topics like depression or HIV.

How many people will take part in this study?
There will be approximately 105 adolescents with HIV and depression in this research study. The study is being done at 4 different clinics in Lilongwe.

How long will your part in this study last?
Your young person's participation will last approximately 1 year.

What will happen if you take part in the study?
All participants who take part in this study will be asked to complete a questionnaire that will ask about their experience with mental health care and HIV care and be asked to have their viral load tested by finger prick at enrollment, six months, and at the end of the study (12 months). The questionnaire and viral load testing will take approximately one hour.

For the HIV viral load testing, the study staff will collect 3-5 drops of blood by a finger stick. The blood will be placed on a collection card which will be sent to a laboratory to measure the amount of HIV in your blood. The blood collection card will be stored in the laboratory until the end of the study. It will not have your young person's name or other identifying information on it.
In addition to the questionnaire and viral load testing, some participants might also receive counseling sessions. Other participants will receive standard support services for mental health. You will not be able to choose whether your young person receives standard care or the counseling services.

One group of participants will be asked to participate in 6 individual counseling sessions over the course of 2 months facilitated by counselors at one of our HIV clinics. The counseling sessions will focus on experiences with stigma, disclosure of HIV status, social relationship issues, and health care access. Each session last about 30-45 minutes and will be conducted in a private room. Of the 6 total counseling sessions per participant, 1 will be recorded. Recordings will not be transcribed.. Participants who do not want to be recorded will not be able to participate.

Another group of participants will be asked to participate in 6 individual counseling sessions and will also participate in monthly peer support sessions via in person group meetings for 6 months for a total of 6 meetings. Discussions will include Mental Health and HIV, status communication, adherence and viral load testing, sex and relationships, stigma, and planning for the future. Of the 6 total peer support sessions per participant, 1 session will be recorded. Recordings will not be transcribed. Participants who do not want to be recorded will not be able to participate.

If your young person participates in the counseling sessions and/or peer support sessions, they will be asked to complete a brief exit interview once the study is completed. The interview is expected to take 1 hour. During the interview your young person will meet with a member of the study staff who will ask questions about their experience with the counseling sessions, such as what they liked and did not like about the sessions. The interview will be recorded and the recording transcribed (written down) in order to have accurate information. Any information that could identify your young person will be deleted.

People who do not want to be recorded will not be able to participate in the interview.

Another group of participants will receive basic supportive counseling by a primary provider or nurse, medication management, and a referral to a mental health facility. This will also include a mental health evaluation by a study nurse, and supportive counseling. The study nurse may follow-up with your young person 3 times.

All participants will continue to receive medical care as usual.

Your young person may choose not to answer a question for any reason. All questionnaires will be available in Chichewa.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. This research will improve our understanding of how to deliver a counseling and peer support intervention for ALWH. Long-term, supporting ALWH with depression through a counseling intervention carried out by counselors is expected to reduce depression, improve engagement in HIV-care, and ultimately improve adolescent health and HIV outcomes. Therefore, the risk to individual participants in our study is small and the potential benefit to society is substantial.

Some individuals may experience reduced depression by engaging in the counseling sessions; however we cannot guarantee this. It is possible that your young person may not benefit from participation.

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

We do not anticipate any significant risks associated with this study. With research, there is always the possibility that your young person's private information (in this case, information about your young person's HIV or depression status) could be disclosed unintentionally. In particular, if your young person participates in a peer support session group, other participants in that group may be aware of your young person's HIV or depression status. We will make every effort to protect their privacy and confidentiality while they are participating in this study. All the information they give will be kept confidential and all personal data will be kept secure. The information we collect will only be identified with a code or number, not with their name. We will not share the information they give us with anyone not involved in the study.

The surveys, counseling sessions, and peer support activities may cause discomfort for some participants. Study staff are trained to work with people in this setting. Study staff may also refer your young person to additional mental health professionals if they feel it is needed. Your young person does not have to answer any questions they don't want to answer.

There is a small risk of some discomfort from the routine finger stick for viral load testing.

There may be uncommon or previously unknown risks that might occur. You should report any problems to the researchers.

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

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

A description of this clinical trial will be available on 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.

How will information about your young person be protected?

Efforts will be made to keep your young person's personal information confidential to the extent permitted by law. However, there may be times when Malawi or US law requires the disclosure of such records, including personal information. Your young person will be identified by a code (a number), and personal information from your records will not be released without your written permission. All data will be kept in a locked cabinet at UNC project or on a secure server at UNC Project accessible only to approved study personnel. All study data will be destroyed 1 year after the completion of all study-related activities. Your young person will not be personally identified in any publication about this study. However, your young person's records may be reviewed, under guidelines of the sponsor of the study; the National Institutes of Mental Health (NIMH), the University of North Carolina Institutional Review Board (IRB), the National Health Sciences Research Committee in Lilongwe, Malawi, study staff, or study monitors.

The study staff will also use your young person's personal information, if needed, to verify that your young person is not taking part in any other research studies. This includes other studies conducted by UNC Project and studies conducted by other researchers that study staff know about.

De-identified data may be used in future research without additional consent.

What is a Certificate of Confidentiality?
Most people outside the research team will not see your young person's name on your research information. This includes people who try to get your young person's information using a court order in the United States. One exception is if we are concerned for their safety or the safety of someone else, we may share limited information to ensure their safety or the safety of that other person. 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 young person's involvement in the research study.

What if you want to stop before your part in the study is complete?
You can withdraw your young person from this study at any time, without penalty. The investigators also have the right to stop your young person's participation at any time. This could be because your young person has had an unexpected reaction, or has failed to follow instructions, or because the entire study has been stopped.

Will you receive anything for being in this study?
Your young person will receive the equivalent of US $10 for the enrollment visit, 6-month visit, and 12-month visit. Your young person will receive transport imbursement for attending each of the six peer support sessions. Your young person will not receive any payment for counseling sessions.

Will it cost you anything to be in this study?
It will not cost you anything for your young person to be in this study.

Who is sponsoring this study?
This research is funded by the National Institute of Mental Health from the United States. This means that the research team is being paid by the sponsors 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 and your young person have the right to ask, and have answered, any questions you may have about this research.

You and your young person can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries. Contact the study doctor Dr. Kulisewa at +265 997 21 03 81.

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 participant, or if you would like to obtain information or offer input, you may contact the NHSRC Director, Dr. Evelyn Chitsa Banda at +265 999 936 937..

SIGNATURE PAGE

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Malawi Principal Investigators: Kazione Kulisewa, MBBS, MMed
US Principal Investigator: Bradley N. Gaynes, MD, MPH

Participant's Agreement:

If you have read this informed consent, or have had it read and explained to you, and understand the information, and you voluntarily agree to participate in this research study, **please print and sign your name and write the date** in the signature area below**.**

PART A: LITERATE PARTICIPANT

Participant is literate: ☐

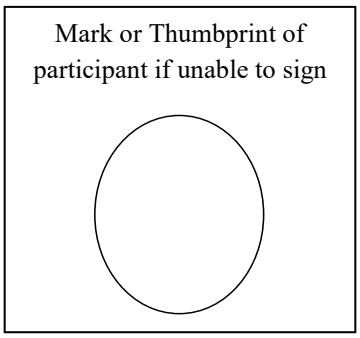
_____	_____	_____
Participant Name (print)	Participant Signature	Date
_____	_____	_____
Study Staff Conducting Consent Discussion (print)	Study Staff Signature	Date

If you have read this informed consent, or have had it read and explained to you, and understand the information, and you voluntarily agree to participate in this research study, **please make your mark or place your thumbprint** in the signature area below.

PART B : ILLITERATE PARTICIPANT

Participant is illiterate: ☐

The study staff must complete this section, ONLY if an impartial witness is available.
The **impartial witness 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
_____	_____	_____
Impartial Witness Name (print)	Impartial Witness Signature	Date