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Enrollment Consent Form- Interventional

Study Title: Group Therapy in HIV for depression in Uganda: The Growth Study.

Study Purpose

Depression in HIV is associated with worse HIV outcomes including worse engagement in care, medication adherence, and retention in care. Depression is also three times more prevalent in those with HIV than in the general population. While there are complex reasons including psychosocial, there is a growing body of evidence that inflammation is linked to mental illness including depression although the underlying pathophysiology is not well understood. Better understanding of the pathogenesis will help identify new treatments. Better depression treatments may thereby lead to engagement/retention in care and better HIV outcomes including virologic control. Better HIV control will help achieve the UNAIDS 90/90/90 goals to diagnose 90% of all HIV-positive persons, HIV medication for 90% of those diagnosed, and achieve viral suppression for 90% of those treated.

The goal of this study is to determine if prevalence of depression at 12 weeks of HIV therapy is improved with group psychotherapy and determine if persistence of depression is associated with higher levels of innate inflammation.

Given you were screened and found to have depression and HIV we would like to follow you over 26 weeks.

A Ugandan researcher has found that group support psychotherapy is a culturally sensitive intervention, which enhances social support, teaching coping skills, and income-generating skills thereby treating depression. We will ask you to participate in the group therapy 1 time a week for 8 weeks.

You confirm that the following has been explained to you, and you have had a chance to ask questions:

1. You were previously screened for this study. You were found to be eligible and to have depression. As such we would like to follow you for 26 weeks. We are going to assess your stress levels and a questionnaire today.

2. We will ask you to participate in 8 weekly sessions of group therapy.
3. In 12 weeks we would like to have you back to clinic. We will ask you a few questions and screen you for depression again.
4. In 26 weeks we would like to have you back to clinic. We will again screen you for depression. We will again assess your stress levels, administer a questionnaire and take another plasma (blood) sample.
5. You also authorize study doctors or designated representative of the sponsor to acquire follow up information from your clinic including subsequent clinic attendance, adherence on your medications, CD4 counts, and viral load tests.
6. You may benefit from this study by having your depression improve. You may gain friends and job skills through the group therapy. You may also benefit by helping other people with depression and HIV in the future.
7. You will not be paid for participating in this study, but you will be given money to refund your actual transport expenses up to 30,000 Shillings/visit if you need to come to a visit outside your regular clinic visits.
8. Any information about you shall be kept private, and your data will be used without your name or identity.
9. Agreeing to participate in this study is voluntary and you can withdraw from the study at any time if you so wish by telling the study doctors. If you withdraw from the study, you can continue to receive your HIV medications freely at the clinic.
10. You will not be giving up any of your legal rights by signing this consent form.
11. You are going to be given a copy of this form.
12. As part of this study, the study staff will have access to your health information in your chart. However, as stated, this will be kept confidential and no identifying information will be shared with anyone without your consent.

Risks

The study has the following risks:

1. We will be discussing sensitive topics around your HIV disease and depression. This discussion will be private and the forms we will out will be confidential.
2. This is group therapy. By being in the group therapy people will know you have HIV and depression. The other participants will also have HIV and depression. This information will be expected to be confidential by all involved but there is a risk of disclosure. However, this intervention was developed in Uganda and has been judged by prior people with HIV and depression that the benefits outweigh the risks.

Study approval

Approval to conduct this study has been granted by the Uganda National Council for Science and Technology.

Contacts and Questions

You may ask any questions you have now. If you have questions later or any urgent health concerns, you are encouraged to contact:

Dr. Anita Arinda in Kampala on phone number **0788366132**.

In case of any questions regarding the Welfare and rights of participants, you should contact Vice Chair, Prof. Grace Ndeezi, telephone number 0702453191, email address gndeezi@gmail.com.

Informed consent

I hereby consent to participate in this study, Group Therapy in HIV for depression in Uganda: The Growth Study.



Participants thumb print

Participants full name

Signature of participant

Date

Full name of impartial witness

Signature of impartial witness

Date

Full name of person obtaining consent

Signature of person obtaining consent

Date