Official Title: Developing a trauma-focused intervention for older adults living with HIV

NCT Number: NCT05287230

Date of Document: 10/13/2021

UNIVERSITY OF SOUTH CAROLINA

CONSENT TO BE A RESEARCH SUBJECT

Developing a trauma-focused intervention for older adults living with HIV – Phase III

KEY INFORMATION ABOUT THIS RESEARCH STUDY:
You are invited to volunteer for a research study because you are 50 years old or older living with HIV and report experiencing childhood sexual trauma. The study is being conducted by Dr. Monique Brown, an Assistant Professor in the Department of Epidemiology and Biostatistics, at the University of South Carolina. The National Institute of Mental Health is sponsoring this research study.

The purpose of this study is to determine the acceptability and feasibility of a new program designed to improve how individuals living with HIV take their antiretroviral or HIV medications. You are being asked to participate in this study. This study will involve approximately 40 volunteers.

The following is a short summary of this study to help you decide whether to be a part of this study. More detailed information is listed later in this form.

The expected duration of participation is approximately six months. You will participate in a weekly session with a facilitator for five weeks, and we will collect information about you at the beginning of the study, and again at 6-weeks, 3-months and 6-months. With your permission, we will review your medical records to obtain information about your latest viral load. There are two types of programs, and you will be assigned to one of them. In one program you will be asked to talk about your experience with childhood sexual trauma with a facilitator and discuss potential coping strategies. In the other program you will watch videos on improving your general health and talk with a facilitator about the videos and how the videos could be improved for someone aging with HIV.

You may not benefit directly from participating in this study; however, we hope to learn more about how to assist individuals living with HIV to better manage their medications and improve other aspects of their health. We do not anticipate any risk to you; however, there exists a slight chance of loss of confidentiality and emotional distress.

PROCEDURES:
If you agree to participate in this study, you will do the following:

1. *Participate in a program once a week for five weeks and attend five sessions (one session per week) where you will either discuss coping strategies you may use to deal with your childhood sexual abuse history or watch videos on how to improve general health. These sessions will take*

place at the HIV clinic or at the Discovery Building at the Arnold School of Public Health at the University of South Carolina in a private setting. A trained facilitator will deliver each session.

2. *You will also be asked to complete surveys (assessments) on social and behavioral factors associated with aging with HIV and adherence to antiretroviral therapy or HIV medication at the beginning of the study, at 6-weeks, 3-months and 6-months*, resulting in 4 questionnaires. These will be filled out using paper and pen format.

3. Give permission for the researcher(s) to review your medical records to gather information only about your viral load.

DURATION:
Participation in the study will last approximately six months. The first session will last approximately 90 minutes followed by four sessions lasting approximately 30 minutes. 6-week assessment – 60 minutes; 3-month assessment – 90 minutes; 6-month assessment - 60 minutes.

RISKS/DISCOMFORTS:

There is the risk of a breach of confidentiality, despite the steps that will be taken to protect your identity. Specific safeguards to protect confidentiality are described in a separate section of this document. Emotional distress is also a risk as you will be talking about your sexual abuse history as a child. However, the aim of this study is to help to improve coping with this history.

BENEFITS:
Taking part in this study may benefit you personally. It may help with depressive symptoms, coping strategies, and improve ART adherence. In addition, this research may help researchers understand the social and behavioral factors involved in the process of aging with HIV and childhood sexual trauma history, and adherence to antiretroviral therapy.

COSTS:
There will be no costs to you for participating in this study.

PAYMENT TO PARTICIPANTS:
You will be paid up to $230 in gift cards for taking part in the study. $40 for Session 1; $10 each for Sessions 2 to 5 and $50 each for the three follow-up assessments.

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH:

Signing this document means you allow us, the researchers in this study, and others working with us to use information about your health for this research study. You can choose whether you will participate in this research study. However, in order to participate you must sign this authorization.

This is the information we will use:

- Viral load information
- Name

The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Clinicaltrials.gov
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant; or
- Federal and state agencies and USC committees having authority over the study such as:
    - The Institutional Review Board (IRB) overseeing this study;
    - Committees with quality improvement responsibilities;
    - Office of Human Research Protections;
    - National Institutes of Health; or
    - Other governmental offices, such as a public health agency or as required by law.

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, USC may still use or disclose (release) health information already obtained about you as necessary to maintain the integrity or reliability of the research study. If you revoke this Authorization, you may no longer be allowed to participate in this research study. To revoke this Authorization, you must write to:

Dr. Monique J. Brown
915 Greene Street
Columbia, SC, 29208

You will not be allowed to see or copy the information described on this Authorization as long as the research study is in progress. When the study is complete, you have a right to see and obtain a copy of the information.

This authorization does not have an expiration date. After you sign this, you will be given a copy with your signature.

CONFIDENTIALITY OF RECORDS:
Information obtained about you during this research study will remain confidential and released only with your written permission. Study information will be securely stored in locked files and on password-protected computers. Results of this research study may be published or presented at seminars; however, the report(s) or presentation(s) will not include your name or other identifying information about you.

CONFIDENTIALITY CERTIFICATE:
To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you.

The Certificate cannot be used to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect, or harm to self or others.

VOLUNTARY PARTICIPATION:
Participation in this research study is voluntary. You are free not to participate, or to stop participating at any time, for any reason without negative consequences. In the event that you do withdraw from this study, the information you have already provided will be kept in a confidential manner. If you wish to withdraw from the study, please call or email the principal investigator listed on this form.

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study, I am to contact Dr. Monique J. Brown at 803-638-0155 or email (brownm68@mailbox.sc.edu).

Concerns about your rights as a research subject are to be directed to, Lisa Johnson, Assistant Director, Office of Research Compliance, University of South Carolina, 1600 Hampton Street, Suite 414D, Columbia, SC 29208, phone: (803) 777-6670 or email: LisaJ@mailbox.sc.edu.

I agree to participate in this study. I have been given a copy of this form for my own records.

If you wish to participate, you should sign below.

Signature of Subject / Participant	Date

Printed Name of Research Participant