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

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Study Title: **Developing a trauma-focused intervention for older adults living with HIV - Phase III**

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A. SPECIFIC AIMS

1) To determine the feasibility and acceptability of a pilot intervention addressing childhood sexual abuse among older adults living with HIV.

B. BACKGROUND AND SIGNIFICANCE

HIV/AIDS continues to be a major public health issue for older adults, locally, nationally and globally. In 2018, over half of people diagnosed with HIV were aged 50 and older (1). Around 1 in 6 new HIV diagnoses in 2018 were among people aged 50 and older (1) Based on data from the South Carolina Department of Health and Environmental Control and the Census, the case rate among adults 50 and older living in South Carolina was 521.1 cases per 100,000 population in 2016 (n=9,925 cases) and this population accounted for half of all people living with HIV (2). The prevalence of childhood sexual abuse (CSA) among older adults living with HIV may range from 16-22%. Older adults with CSA history had three to four times higher odds of reporting depression compared to older adults who did not experience CSA (3). Addressing CSA among older adults living with HIV (OALH) may help to reduce depression, which may help to improve ART adherence, viral suppression, and overall health-related quality of life (HRQoL).

C. PRELIMINARY STUDIES

This is Phase III of a 3-phase research project. The research team and PI have completed data collection for Phases I (qualitative study) and II (quantitative study) and are currently analyzing the data.

D. RESEARCH DESIGN AND METHODS AND DATA ANALYSIS

Phase III (Pilot intervention): A baseline assessment will be used to garner data on these relationships. ART adherence and viral suppression will be obtained by viral load data via assessment of medical record copies from recruitment sites, via informed and HIPPA consent. The data will then be deidentified and Dr. Sharon Weissman will assist in the interpretation of viral load data to determine ART adherence and viral suppression of participants. HRQoL will be measured by the CDC Healthy Day Cores Module (HRQOL-4), (4) and CSA using 15 related items from the Early Trauma Inventory – Self Report (ETI-SR) (5). Concepts related to aging with HIV will include data on comorbidities using the Self-Administered Comorbidity Questionnaire (6); AIDS diagnosis using medical records; loneliness using the UCLA Loneliness Scale (7); HIV-

related stigma using the Berger Stigma Scale (8); and the role of caregivers in ART adherence. For potential mediators, coping strategies will be measured by the Brief Cope Scale (9); substance use using the Substance Abuse and Mental Illness Screener (10); and depressive symptoms using the 20-item Center for Epidemiologic Studies – Depression Scale (11). Data will also be collected on condomless sexual intercourse [vaginal, anal (receptive and/or insertive), oral] in the past 6 months (12); IPV victimization and/or perpetration using the Partner Violence Screen (13) and the Conflict Tactics Scale (14), respectively; and on sociodemographics including age, sex, race/ethnicity, education, income, sexual orientation, and time since diagnosis.

This phase is proposed so as to determine the feasibility and acceptability of the **Coping with Childhood Sexual abuse, HIV and Aging (CoSHA) intervention**. The CoSHA one-on-one intervention will be developed by drafting a manual, and having it reviewed by experts and
potential users. Findings from Phase I will be the formative phase of providing input from the population for which the intervention will be designed. Input will also be sought from stakeholders (healthcare providers and ASO staff). Facilitators will be systematically trained using a criterion of successful implementation based on the REFLECT and the LIFT interventions. Implementation of treatment will be monitored to determine if the facilitator follows the approaches appropriately. CoSHA will be pilot-tested among OALH with CSA history and will use some of the main concepts from the REFLECT and LIFT interventions. Components to be used from REFLECT will include: appraisal and changeability of stressors related to aging with HIV; implementing adaptive problem- and emotion-focused coping skills; optimizing coping efforts by using interpersonal supports. Concepts from the LIFT intervention will include: identifying and expressing emotion related to CSA and perceptions of being a victim; identifying stressors and coping difficulties in relation to CSA; and developing adaptive strategies to reduce psychological stress. We will do theater/usability testing with 5 individuals to examine the preliminary intervention. Individual usability interviews with OALH will be conducted with the same recruitment procedures below. During the interviews, the moderator will walk the participant through each portion of the manual. Participants will be asked to reflect on whether the intervention met expectations. CoSHA will be a 5-session intervention with each session conducted weekly for five weeks. During the first session, baseline data will be collected and participants (N=40) will be randomly assigned to the intervention or to the 5-session attention control case management (ACCM) control group. For ACCM, participants will be given resources and will be able to talk about any issue of their interest. Sessions 2 and 3 for the intervention will focus on improving CSA coping strategies, and sessions 4 and 5 will focus on aging with HIV. Assessments will be done post session 5 (6-weeks post baseline), at 3 months, and at 6 months post baseline. A 3-month booster will be also
given. After each session, the facilitator will complete quality assurance forms. The graduate research assistant or the PI will deliver the intervention.

Fidelity checks will be done by recording the sessions. Selected parts of the recordings of sessions will be reviewed and feedback will be provided to the facilitators. An

independent coder (undergraduate student) will estimate level of adherence to the CoSHA protocol. He/she/they will be trained to evaluate sessions using a checklist. Twenty percent (20%) of all recoded sessions will be coded to ensure the intervention is delivered as intended. Fidelity will be measured by calculating the percent performance of desired and undesirable behaviors during intervention delivery and will be done on a continual basis. If more focused training is required to improve fidelity, additional supervised sessions will be done until acceptable levels of fidelity are obtained.

Location: Recruitment will occur at the University of South Carolina Immunology clinic. After screening, and informed consent is obtained in person, data collection will be conducted in-person. Analysis will occur in the Department of Epidemiology and Biostatistics at the Arnold School of Public Health (ASPH). The five sessions will occur at the HIV clinic or in the Discovery Building at ASPH.

Analytic approach. Data collected will not be enough to perform advanced statistical analyses (N=40). Therefore, analyses will be for exploratory and informational purposes. For example, these data will inform on the length and burden of items asked. Evaluation of the intervention will occur throughout the pilot testing at each session, at post-intervention, and at three- and six-month follow-up.

The pilot study will be used to test recruitment methods, willingness of participants to participate, feasibility of the protocols, training staff, and examining data collection and retrieval methods. As a result, participants will be requested to evaluate each part of the intervention on the following criteria: suitability, impact, enjoyment, importance, interest, innovativeness, uniqueness, acceptability, and clarity. Participants will be asked to rate each portion on a 5-point Likert-type scale (e.g., 1 = very clear and 5 = not clear at all) as well as provide open-ended feedback. The goal is to assess the suitability, appropriateness, and tolerability of each component utilized. A modified version of the 8-item Abbreviated Acceptability Rating Profile (AAR) will be used to assess the intervention acceptability.

Participants will also be asked to evaluate the feasibility of recruitment methods and provide input on additional methods to be examined. As part of the evaluation of the study protocol and tasks, participants and facilitators will rate the extent to which the study protocol was presented in a logical, iterative, and cogent manner. Participants will also complete information about the facilitator and his/her training and professionalism. Having audiotapes of the sessions will also help to ensure the validity of protocol and serve as qualitative data for the evaluation of the project. Near the conclusion of the pilot, evaluation data will be analyzed and used to modify the intervention further for use in preparation of a R01 application to conduct a larger scale trial. Specifically, the outcome data will be analyzed using generalized estimating equations (GEE) in order to generate estimates of effect sizes for future large scale studies. It is important to note that once the intervention begins, no changes will be made to intervention materials for the pilot. Differences in feasibility and acceptability of the intervention by sex will also be noted.

E. PROTECTION OF HUMAN SUBJECTS

1. TARGET POPULATION:

Discuss the population you are targeting for the study (e.g., college students, elementary school students, adults with aphasia), the demographics of the population, any inclusion or exclusion criteria, and your anticipated sample size including method used to determine sample necessary to accomplish aims.

Inclusion/Exclusion criteria. To be eligible, participants will be 50 years or older, HIV-positive, give informed and HIPAA consent to access medical records so as to obtain viral load measurements, not have significant cognitive impairment, <100% ART adherence in the past month, and score

Sample size: N=40. We will determine the feasibility and acceptability of the intervention, and preliminary efficacy.

2. RECRUITMENT PLANS:

Advertisements will be placed in the waiting room at the immunology clinic. The clinic staff will inform the research staff of people who are 50 and older and then the research staff approaches these participants and determine their interest. If they are interested, we will determine eligibility in a private room. If eligible, we will obtain informed consent and HIPAA authorization. We have already obtained approval from the immunology clinic. Research staff will be at the clinic for recruitment.

3. EXISTING DATA/SAMPLES:

N/A

4. CONSENT/ASSENT:
Describe procedures to be used to obtain consent/assent of subjects, including means that will be used to minimize any risks of coercion or undue influence.

Research staff will obtain informed consent and HIPAA authorization. Potential participants will be informed about the study and we will garner their interest and eligibility before obtaining informed consent and HIPAA authorization. Participants will also be informed that they are free to leave the study at any time.

5. POTENTIAL RISKS:

Risks to participants may include breach of confidentiality and emotional distress. Breach of confidentiality could result in emotional consequences for the subjects in the study. Emotional distress for the participants could occur due to remembering childhood traumatic experiences. Nevertheless, research staff will be trained so as to keep data and information on participants confidential. All data will be stored on a password-protected server.

A. Protection of Human Subjects

A.1. Protection against breach of confidentiality. Research staff will undergo human subjects protection training from the Collaborative Institutional Training Initiative (CITI) program and will also sign a contract to maintain confidentiality of study participants. The graduate research assistant will also be consistently reminded and monitored to maintain the confidentiality of the participants. In remembering experiences with

childhood sexual abuse, in the event a participant indicates to be an imminent threat to harm himself or someone specific, a clinical psychologist will be consulted, and he/she will advise on next steps.

6. POTENTIAL BENEFITS:

Findings retrieved will help in the design and implementation of a coping intervention for older adults who may still be struggling with the effects of childhood trauma.

7. CONFIDENTIALITY

B.1. Participant materials and lap-tops will be kept in a locked file cabinet. The laptop for data analysis will be password-protected and encrypted. Electronic materials will be stored on a computer network, which is also password-protected and encrypted. The electronic materials and files will also be stored based on USC procedures for HIPAA-protected data. Only the PI and research staff will have access to the data.

Data will be confidential. The investigator will maintain a key linking participants to ID numbers.

8. COMPENSATION:

Participants will be compensated $230 in gift cards: $40 for Session 1; $10 each for Sessions 2 to 5; 6-week assessment - $50; 3-month assessment - $50; 6-month assessment - $50.

9. WITHDRAWAL:

Participants will be able to withdraw from the study at any time.

F. REFERENCES/LITERATURE CITATIONS

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