Brief Acceptance-Based Retention Intervention for Newly Diagnosed HIV Patients

NCT04201288

Master Informed Consent Form – 12/13/22

CONSENT FOR RESEARCH PARTICIPATION

Sponsor / Study Title: **National Institute of Mental Health / "Brief Acceptance-Based Retention Intervention for Newly Diagnosed HIV Participants ("HIV Engage")"**

Principal Investigator: **«PiFullName»**

Telephone: **«IcfPhoneNumber»**

Address: **«PiLocations»**

KEY INFORMATION:

You are invited to take part in a Brown University research study in collaboration with your clinic. Your participation is voluntary.

- PURPOSE: The study is about understanding and potentially improving medical care for new HIV patients using an intervention.
- PROCEDURES: You will be asked to answer personal health questions including on your alcohol and drug use, complete electronic surveys, and you will be provided with education materials on HIV during an individual meeting with a researcher. You may complete 1 of the sessions over the phone, provide a blood sample, and have your sessions audio-recorded. You will need to provide us with access to your medical records to monitor your HIV health and medical appointment attendance for 1 year.
- TIME INVOLVED: The study is 8 appointments long (baseline, 2 sessions within the first month, 1-, 3-, 6-, 9-, 12- month follow-up) and each session may last up to 70 minutes.
- COMPENSATION: You may receive up to $375 total for your time. You will be paid $75 for completion of the baseline appointment. You will be paid $25 for each of the two sessions ($50 total) with the interventionist. At each follow-up survey appointment, you will be paid $50. All payments will be in the form of a pre-paid Mastercard.
- COSTS: There will be no cost to you for your participation in this study.
- RISKS: You may experience emotional distress from sensitive questions asked, discomfort from disclosing personal information in a group session, loss of confidentiality from group session, and feel coerced to participate.
- BENEFITS: You may not directly benefit from participating in this research study.

- ALTERNATIVES TO PARTICIPATION: You do not have to participate in this research study. You will not be penalized for not participating.

What is this study about?

The study is about medical care for new HIV patients. This study is designed to help patients with HIV better engage in primary care, which means regularly attending medical appointments over time. Engagement in primary care is a significant public health concern because regular medical care is essential to maintaining one's health when living with HIV and because it can reduce the risk of transmitting HIV to others.

You are being asked to take part in a research project because you are 18 years old or older, you were recently diagnosed with HIV, and you are a new patient.

We expect to enroll 270 participants in this study between three study sites. The study is being conducted under a grant sponsored by The National Institute of Mental Health through Brown University.

What will I be asked to do?

Baseline (Day 1):

- You will be asked about your mood, alcohol and drug use, experiences with the healthcare system, stigma, social support, acceptance, and disclosure. Your responses to these questionnaires will not be shared with your medical providers.

Intervention (2 sessions within 1 month):

- Next, you will be randomly assigned (like the flip of a coin) to one of two groups. Which group you are put in is done by a computer. Neither you nor the researcher will choose what group you will be in. You will have an equal chance of being placed in either group. The groups are different only in regard to the content of theconversation.

  You will not know which group you are in. Neither will the researchers. This information needs to be kept secret so that the study is based on scientific results, not on peoples' opinions.

- Both groups meet with the interventionist two (2) times. As with anyone starting HIV care, these visits will occur during the first month of HIV treatment. The conversations could last 45 minutes in total. The second meeting can occur by telephone if you prefer.

- Group One: Interventionists will provide HIV education and help you address

the day- to-day needs of your new diagnosis, including how to reduce HIV transmission risk and guidelines for safe sex practices.

- Group Two: Interventionists will provide HIV education and help you address the day- to-day needs of your new diagnosis. In addition, the interventionist will also spend time during these first two visits discussing your life goals and offering ways to cope with your diagnosis.

- Both groups will have the visits with the interventionist audiotaped. Audio recording can be stopped at any time, upon your request. You may also "opt out" of being recorded. Audiotapes will be maintained for 3 years.

Follow-up sessions (1-, 3-, 6-, 9-, 12- month):

- Both groups will have five (5) follow-up visits after the interventions. Follow-up visits are usually less than 1 hour. Study staff will contact you one (1) month, three (3) months, six (6) nine (9), and 12 months after your interventions to ask a series of questions similar to those at your first appointment. There is no questionnaire at the second intervention. A brief exit questionnaire in which you are asked to provide feedback about the research project will be administered at the 1-month follow-up. Depending on your preference, you will be asked to complete these follow-up surveys electronically using a system called REDCap.

- If you have not recently completed a medical visit around the time of a follow-up assessment, you will be asked to provide a small blood sample (1-3 ml) at your clinic's phlebotomy lab. This will allow study staff to determine your HIV viral load at each assessment.

- Additionally, you will give study staff permission to access your electronic medical record to allow staff to monitor your HIV health and attendance of medical appointments up to 12 months after you enroll in the study.

How much time is involved?

Given the number of sessions involved in the study, we estimate the 8-session study will take approximately 7 hours of your time over the course of 12 months, but could take up to 10 hours total.

Will I be paid?

«Compensation»

You will receive up to $375 for your time. You will receive $75 for completing the baseline assessment appointment. You will be paid $50 for each study follow-up assessment appointment (1-, 3-, 6-, 9-, and 12-month follow-up). This can occur in person or by telephone. You will be paid for completing intervention sessions ($25 each; $50 total).

- Payment for participating in this study will be made using ClinCard, a pre-paid Mastercard that works like a debit card. We will give you the card. You will be given one card for the entire time of your participation and this card may be used to pay you in any future Brown University studies that use ClinCard. You will also get information about how to use this card and whom to call if you have any questions. Be sure to read this information, including the cardholder agreement from Greenphire.

  Money will be added to your card based on the study's payment schedule. You may use this card online or at any store that accepts Mastercard. Please read the FAQ information sheet from your study coordinator for details about the ways you can use the card, some of which may involve fees that will reduce the amount of money on the card.

  If you earn $600 or more from the study site in a single calendar year (either in a one study or across multiple studies), the study site will ask for your social security number to correctly identify you in the payment system and send you an IRS 1099 Form. You may also be asked to complete a Form W9. This may affect your taxes. Only payments for being in research studies will be used to decide if you should receive the IRS form. Money for study-related parking, food, and other expenses are not included in this IRS disclosure.

  This card is administered by an outside company called Greenphire. Greenphire will be given your name, address, and date of birth. They will use this information only as part of the payment system, and it will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating.

  If your card is lost or stolen, please call the study coordinator for a free replacement card. If you request a replacement card from Greenphire directly, you may be charged a fee.

What are the risks?

- No side effects from the interviews are known or anticipated. Some interview questions may be considered sensitive and may cause emotional distress. Psychological risks of the intervention sessions may include discomfort when discussing disclosure of HIV status to others as well as other HIV-related topics. It is possible that you might feel coerced to participate in this study.
- Loss of confidentiality is also a risk when participating in this project. Research staff will be trained to protect this confidentiality, and all data will be stored in locked cabinets and/or password-protected electronic files. None of your questionnaire responses will be shared with your medical providers.
- If you agree to be part of this study and believe you are sick or have been injured from being in this study, you should call the study investigator at the phone number listed on page one of this form. Medical care for any study-related sickness or injury will be available to you at the clinic. Financial compensation for lost wages, disability, and discomfort is not routinely available.

  The cost of this medical care will be billed to you or your insurance company.
- Lastly, it is possible that participation in the study and the intervention you receive might be ineffective at increasing your engagement in medical care.

What are the benefits?

- You may not directly benefit from being in this research study. However, you may acquire an increased awareness of connections between acceptance of HIV status and general well-being, and how these connections may help or hinder your HIV care. You may also benefit by increasing your knowledge of general HIV health issues.

How will my information be protected?

- This study is a clinical trial. A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

- Data will be coded so that any identifying information will not be directly linked to your information. You will be assigned a numeric participant ID. Paper copies of any assessments you complete will be stored in locked file cabinets, accessible only to study staff. Electronic information will be securely stored on protected research servers.
- Brown University sometimes review studies like this one to make sure they

are being done safely and correctly. If a review of this study takes place, your records may be examined. The reviewers will protect your confidentiality.

- After three (3) years following study completion, all paper-based identifying information will be destroyed via shredding and secure disposal.

- If you provide blood samples for study purposes, these biospecimens will not be used for any other purpose than determining your current HIV viral load. The phlebotomy clinic will safely dispose of your blood sample immediately.

- Your research records will be treated as private health care records and will be protected according to privacy practices and policies that are based on state and federal law. In particular, federal law requires us to get your permission to use or disclose (release your information to someone outside of Brown or your clinic) your health information for research purposes. If you sign this consent and the separate HIPAA Authorization form that we have provided and discussed, you agree to be in this research study and you permit the use and disclosure of your health information for the purpose of conducting the research, collecting payment and running the business of the clinic. You may withdraw from the study at any time. However, if you do not want the researchers to use or disclose any further information in this study you must cancel permission in writing and may do so at any time. If you cancel your permission, you will stop taking part in the study and no new information will be collected about you. However, if you cancel your permission, it will not apply to actions already taken or information already collected about you by the hospital or the researchers before you canceled your permission.

- All researchers and health care providers are required to protect the privacy of your health care information. Other people and businesses/organizations that are not health care providers are not required by law to do that so it is possible they might re-release your information.

- 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, except as explained below.

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

PLEASE NOTE:

If we learn about excessive use of alcohol or use of controlled substances for non-medical reasons during pregnancy, we may be required or permitted by law or clinic policy to report this information to the appropriate authority.

If we learn about current or ongoing child or vulnerable adult abuse or neglect, we may be required or permitted by law or clinic policy to report this information.

Are there any alternatives to this study?

- ALTERNATIVES TO PARTICIPATION: No alternative is offered. A decision not to participate in this research study will in no way prevent you from receiving the standard services at your clinic or from seeking medical or psychiatric services where the study staff work. You will receive the standard medical care at your clinic regardless of your participation in this study.

New findings

- Any new important information that is discovered during the study and which may influence your willingness to continue participation in the study will be provided to you.

Future research studies

- Your private information or biospecimens collected during this study will not be used or distributed for future research studies, even if identifiers are removed.

Clinically relevant results

- Research results that are clinically relevant, including individual research results, will not be disclosed to you.

What if I want to stop?

- You do not have to be in this study if you do not want to be. Even if you decide to be in this study, you can change your mind and stop at any time.

- If you refuse to participate in or leave the study, your current or future relationship with Brown University or your clinic will not be affected.

- The investigator may end your participation in the study without your consent.

Whom to contact about this study

During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research subject;
- Eligibility to participate in the study;
- The Investigator's or study site's decision to exclude you from participation;
- Results of tests and/or procedures;

Please contact the Investigator at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. If you have any questions about your rights as a research subject, contact:

- By **mail**:
  Study Subject Adviser
  Advarra IRB
  6100 Merriweather Dr., Suite 600
  Columbia, MD 21044
- or call **toll free**: 877-992-4724
- or by **email**: adviser@advarra.com

Please reference the following number when contacting the Study Subject Adviser: Pro00059418.

Consent to Participate

Your signature below shows that you have read and understood the information in this document, and that you agree to volunteer as a research participant for this study.

You will be offered a copy of this form.

Participant's Signature and Date / PRINTED NAME

Research Staff Signature and Date / PRINTED NAME