BROWN

BROWN UNIVERSITY
CONSENT FOR RESEARCH PARTICIPATION

Supporting Trans Affirmation, relationships, and Sex (STARS), Phase 3
Full Consent
Version 1, March 13, 2023

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

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- PURPOSE: The purpose of this research study is to evaluate and test a newly developed gender-affirming intervention that addresses the dual and interconnected risks of HIV and intimate partner victimization (IPV) among transgender women. You are being asked to be in this study because you expressed interest and may meet the entrance eligibility criteria.

- PROCEDURES: There are several components to this research study (refer to Table 1 on p.3 for an overview of all study procedures and the time involved).

  1) *Screening* -- The first step in this study is to determine your eligibility. This screening process can be completed online or by phone with a trained researcher (note that this step has already taken place). If eligible, you will be asked to provide your contact information, so that we can follow up with you regarding next steps and determine your final eligibility.

  2) *Baseline Evaluation* -- Next, we will invite you to meet in-person or online via Zoom with a trained researcher (that is the step you are completing now). During this meeting we will: (a) go over the informed consent form and answer any questions you might have; (b) have you complete an HIV test to determine your final eligibility; and (c) have you complete the baseline assessment (details below). Note that if you are unable to complete an HIV test in-person, we may be able to connect you with a local health clinic that provides free or low-cost testing. If that option is unavailable, we may be able to mail you a free HIV self-test kit to an address of your choosing. We would then work with you (by Zoom or phone) to go over the testing instructions and results. Alternatively, if you have received HIV testing in the past three months, we would allow for those results to be used to determine eligibility.

3) *Online Assessments* – You will be asked to complete an online survey that asks questions concerning HIV, safety, and IPV. This survey takes around 60-90 minutes to complete and will be administered at four time points throughout the study: (1) baseline; (2) after the intervention is complete; (3) at 4-months follow up; and, lastly, (4) at 6-months follow up.

4) *STI Testing* – After completing the baseline survey, we will work with you to find a local gender-affirming clinic where you can go to for sexually transmitted infections (STI) testing (gonorrhea, chlamydia, syphilis). This testing is optional and will be provided at no cost to you. If you agree to get tested, we will invite you to share your STI test results with us during a confidential Zoom call.

5) *Study Interventions and Program Assignment* – Regardless of your decision to get tested for these sexually transmitted infections, you will be invited to participate in one of two study interventions: (1) a newly developed gender affirming intervention, known as Program STARS (Supporting Trans Affirmation, relationships, and Sex) OR (2) a program that offers free training in relaxation and stress reduction techniques. Both interventions offer unique components and we do not yet know the impact the programs may have on your overall well-being.

   To decide which of the two programs you will complete, we will use a method of chance, much like flipping a coin. The researcher that will work with you to complete your study assessments will not know which of the two programs you completed, so please keep this information a secret. This information needs to be kept secret so that the study is based on scientific results, not on peoples' opinions.

   Both Project STARS and the alternative relaxation and stress-reduction program will be offered to you at no cost and will consist of two hour-long one-on-one peer-led counselling sessions held approximately one week apart as well as two brief 20-30 minute "booster" sessions administered around two- and four-weeks after the 2nd hour long session. You can choose to complete these programs in-person with the peer counselor or online via Zoom. Both programs will be led by trans women who have been trained as peer counselors.

6) *Zoom Requirements and Recordings* – Online sessions will occur using the free online Zoom video conferencing platform that can be accessed using a smartphone, tablet or computer. To participate remotely, you must have access to WiFi or internet. If you do not have WiFi/internet, we will work with you to find a private room in a safe location (such as a public library) that will provide you internet access to the sessions. During these sessions, counselors may discuss sensitive topics concerning

HIV-risk, safety, and your relationship with sexual and intimate partners. Counselors will provide you with information about and referrals to accessible and gender-appropriate community resources based on your needs.

All Zoom sessions will be recorded for research and training purposes and the recordings will be stored on a secure server. The recordings will be destroyed once the study is complete. The recordings for the exit interviews (see item #7 below) will be transcribed for research and the final transcription and coded data will not contain any personally identifiable data (ID only).

Table 1. Timeline and Outline of Study Procedure	**Estimated Time Commitment**
Screening process – online or by phone (already completed)	15 minutes
Baseline research assessment (in-person or by Zoom) - $50 *Includes final eligibility screening / HIV self-testing, safety assessment, baseline assessment, and optional STI testing plan.*	2-3 hours
Randomization to one of two study programs – results will be communicated to you by a research team member	n/a
Peer-counseling Sessions (two sessions, 1hr each)	1 hour (x2 total)
Booster sessions (two 30-minute sessions)	30 minutes (x 2 total)
STARS Program Exit Interview by Zoom (STARS group only) - $25	60-90 minutes
Post-intervention assessment (in-person or by Zoom) - $50	60-80 minutes
4-month follow up assessment (in-person or by Zoom) - $50	60 minutes
6-month follow up assessment (in-person or by Zoom) - $50	60 minutes
Total Estimated Time	**Up to 12 hours**

7) *Project STARS Exit Interview* – If you are assigned to the Project STARS intervention, we will invite you to complete an exit interview (lasting 60-90 minutes) after the completion of your program. This exit-interview will be conducted online with a trained researcher and will focus on your experience in the study, feasibility and acceptability of the intervention, areas for further adaptation, etc.

8) *Safety Assessments* – In addition to the standardized questions that we will ask you during each of the four assessments, we will also conduct routine safety monitoring.

This involves administering a brief safety assessment at the start of every assessment.

During the study, you may also be asked to speak with the study on-call clinician to assess your safety and discuss a safety planning if you disclose suicidal thoughts, suicide attempts, abuse or neglect, or life-threatening events.

9) Upon completion of the final follow up assessment at 6-months, your involvement in the study will be complete. However, we may contact you after enrollment has ended to briefly follow up on any missing information or to clarify a research question. If this happens, the conversation would be brief (< 5 minutes) and would be presented to you as optional.

- TIME INVOLVED: The study will take approximately 10 to 12 hours of your time over the course of six months.

- COMPENSATION: You will receive $50 for completing each of the research assessments (baseline, post-intervention, 4-months follow up and 6-months follow up), so up to $200 in total for assessments. Additionally, you will receive a bonus payment of $25 if you complete all four assessments (Total payment for all four assessments = $225).

  Participants randomly selected to receive the STARS Program will also receive an additional $25 if they take part in the Exit Interview.

  If you choose to complete any of your assessments in person, we will provide you with a transportation voucher to accommodate your travel to and from the research site (if applicable); or alternatively we are able to pay for Lyft service to transport you to and from our office if you live within the local RI / MA region.

  Payment for participating in this study will be made using either an Amazon gift e-card or using ClinCard, a pre-paid Mastercard that works like a debit card. It will be your choice how you get paid.

  If you opt to use the ClinCard, 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 uses ClinCard. You will also get information about how to use this card and whom to call if you have any questions. Money will be added to your card based on the study's payment schedule – typically within 2 days of each

assessment/survey. You may use this card online or at any store that accepts Mastercard.

If your card is lost or stolen, please call or email the study contact for a free replacement card.

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.

- RISKS: Some of the topics and questions discussed throughout the study may cause you emotional distress and/or make you uncomfortable. You do not have to engage in any conversations or answer any questions that you find distressing. You can discontinue participation in the study at any time. Additionally, though the intervention sessions will be conducted one-on-one with a study peer counselor, we will be audio taping interviews and intervention sessions. This introduces a potential risk to confidentiality and loss of privacy. To minimize this risk, all data that is collected will be deidentified and available to only select study staff. Lastly, if a violent intimate partner becomes aware of your participation in this study, it may lead to an increased risk for harm outside the study. We will minimize this risk by taking extra precautions to ensure that all study-related communications do not reveal any specific personal or study information, and prioritize your safety prior to, during and after all study-related procedures. We will also give you a resource guide that contains a list of local health and social services for members of the transgender community, and we can facilitate a visit with appropriate health professionals upon your request.

- BENEFITS: You may not directly benefit from being in this research study. However, you may find the information provided over the course of the study helpful and applicable to your life. Strategies discussed and practiced as a part of this intervention may result in increased capacity and empowerment and increased knowledge in navigating appropriate and affirming health care. Additionally, your participation will be helping other transgender women who have experienced IPV by providing information that has the potential to improve HIV and IPV prevention interventions for this population.

- CONFIDENTIALITY: To maintain confidentiality we will take the following precautions: (1) all staff will be trained in procedures for maintaining confidentiality of participant information; (2) electronic data collection forms will be identified by a unique identification number; (3) the identifier key will be stored separately from the

data collection forms and accessible by the investigative team; and (4) digital audio recordings will be delivered via a secure method to transcribers and each recording will be labelled with a code to ensure name confidentiality. Data will be stored on password protected computers at Brown University School of Public Health and backed up to an encrypted secure server. Access to this encrypted secure server is password protected and only known to the investigative team and project staff and backed up daily.

If you participate in online counseling sessions via the Internet, we will schedule the sessions at a time and location to ensure privacy. We will also instruct you to close the internet browser when the study counseling procedures are complete.

Brown University staff 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.

Any reports (i.e., manuscript publications, conference presentations, etc.) from this study will be anonymized. We do not report your identity or test results to any of our community health partner organizations unless you request our help in accessing resources or would like us to connect you with a health care provided in your community.

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 cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluating federally 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, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

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.

There are limits of confidentiality; most notably, the disclosure of suicidal thoughts, suicide attempts, or abuse or neglect. No mention of the study site or the participation in this particular research protocol will be disclosed.

- VOLUNTARY: 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.

- CONTACT INFORMATION: If you have any questions about your participation in this study, please email stars@brown.edu. If you would like to contact the study principal investigators directly please contact:

  Shufang Sun, Brown School of Public Health at shufang_sun@brown.edu; or
  Dawn Johnson, University of Akron at johnsod@uakron.edu.

- YOUR RIGHTS: If you have questions about your rights as a research participant, you can contact Brown University's Human Research Protection Program at 401-863-3050 or email them at IRB@Brown.edu.

- 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