Project #191314

UNIVERSITY OF CALIFORNIA, SAN DIEGO

The BRIDGES Project

CONSENT TO PARTICIPATE IN RESEARCH STUDY

You are invited to join a research study led by Dr. Jamila K. Stockman in the Division of Infectious Diseases and Global Public Health, Department of Medicine at the University of California, San Diego. This study is funded by a four-year grant from the California HIV/AIDS Research Program (CHRP), in collaboration with the UC San Diego Center for AIDS Research HIV Disparities Core. The purpose of this study is to test a program for women living with HIV that could help them stay in HIV treatment and find support services for difficult life experiences, such as violence, trauma, substance use, and/or mental health issues.

PURPOSE OF THE STUDY:

The BRIDGES Project is a program designed to improve your ability to access and stay in HIV care. You can be a part of this study because you are a woman living with HIV/AIDS who has faced barriers to HIV care.

To help test The BRIDGES Project, we will enroll 100 women living with HIV who have faced barriers to care. Women will receive either: (1) standard Ryan White HIV care, or (2) additional sessions on learning to overcome barriers to HIV care. Women enrolled in the study will be randomly put into one of these groups. The next section describes all of the things you will be asked to do if you choose to take part in this research study.

PROCEDURES:

Your study activities will be held at the AntiViral Research Center (AVRC), located at 220 Dickinson St, Suite A, San Diego, California 92103.

Intervention Design

You will be randomly put into either: (1) a standard Ryan White HIV care group (Standard Care Group); or (2) a group that receives additional sessions (Extra Sessions Group). You will be put into one of these groups by random chance. As a result, about 50% of women will be put into the Standard Care Group, and about 50% of women will be put into the Extra Sessions Group. This process is similar to flipping a coin.

You will be put into either:

> **Standard Care Group**. If you are randomly put into the standard care group, you will be connected with treatment in San Diego County through the Ryan White HIV/AIDS Program (i.e., referrals to physical, dental and mental health services; medical case management; and support services [e.g., alcohol/substance use

recovery, family support]). If you are already receiving standard Ryan White care somewhere, you may continue to receive services there. If you are not already receiving services and do not know where to receive services we will refer you to Neighborhood House Association (NHA) Coordinated HIV Services (CHIVS) program. NHA will help you to decide what services you need and how to access them. If you prefer, you can access case management services via Ryan White HIV/AIDS Program elsewhere in San Diego County.

If you accept services through NHA, you will be connected to a Case Worker. They will help you to assess your needs (e.g., updates on insurance, housing, referrals needed, behavioral assessment [e.g., depression, sexual assault]). If you need additional support, and don't know where or how to access services, you can ask for case management services via Ryan White HIV/AIDS Program in San Diego County. If you ask for Case Management, you will meet with a Case Manager (who can provide more support than a Case Worker). Together you will talk about your needs. With your Case Manager, you can set goals for your care plan, including medical care, housing, financial, and other resources, as needed. Referrals will be made to appropriate services. If you need help with your medical care, your Case Manager will help you to get care. Your Case Manager will reach out to you at least once a month to talk about your needs and goals, until you are comfortable managing you care by yourself. Your study involvement will last 6 months.

OR:

Extra Sessions Group. If you are randomly put into The BRIDGES Project group with extra sessions, we will connect you with Ryan White HIV/AIDS Program services (see above as described under Standard Care Group). If you are already receiving standard Ryan White care somewhere, you may continue to receive services there. Also, you will be matched with a Peer Navigator, who is another woman living with HIV. Your Peer Navigator will talk with you one-on-one in-person, over the phone or through text messages, and during 6 in-person group sessions. Group sessions will be with other women living with HIV, and will cover topics about how to manage your HIV care and barriers to care. Your study involvement will last 6 months.

Study Activities: All Participants

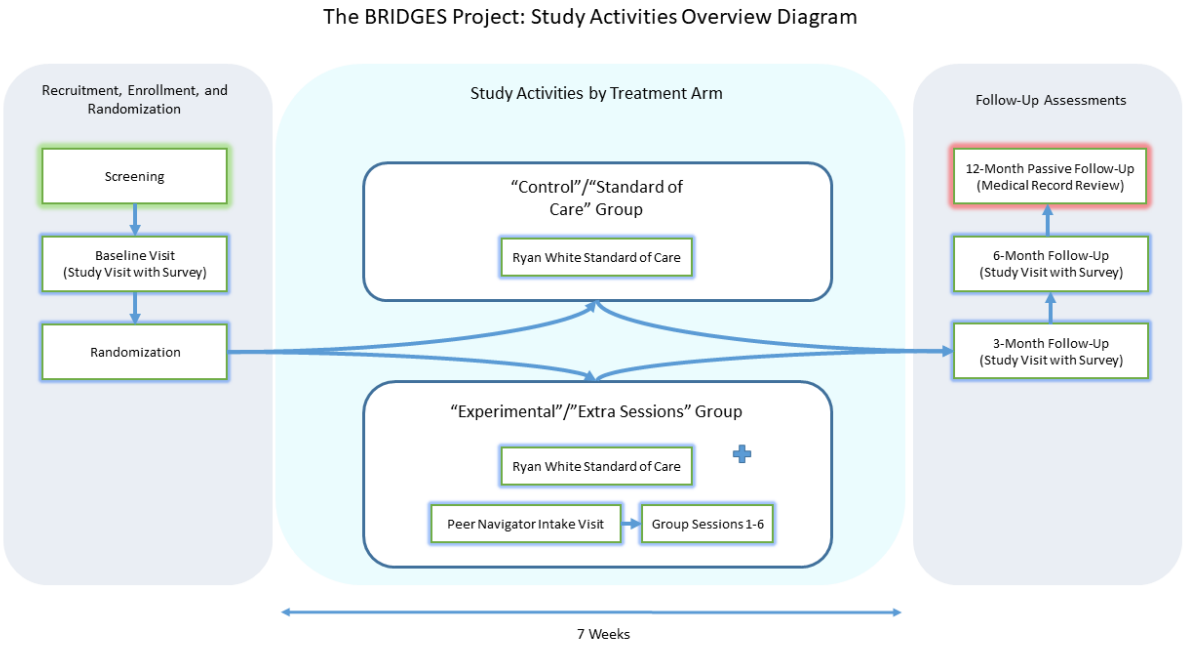
Your study involvement will last 6 months. During this time, you will be asked to do the following, *no matter which group you are in*:

Informed Consent. After screening for The BRIDGES Project, meeting the requirements to be in the study, and agreeing to be in the study, you will be asked to provide written consent (permission) to continue with the study activities. You will also be asked to sign a HIPAA Authorization form. Finally, you will be asked to tell us about all providers and clinics that you receive HIV care from. This will occur for all study participants.

Baseline Survey (Month 0). During your first visit, you will be asked to answer survey questions asked by a study staff member. Questions will be about you, your life experiences, mental health, physical health, history of HIV care and treatment, social support, health care interactions, and thoughts on medical care. This survey will take approximately 1 hour of your time. This will occur for all study participants.

Randomization. Following the baseline visit, you will be randomly put into either: (1) a standard care group or (2) an extra sessions group. This will occur for all study participants.

The BRIDGES Project Study Activities Overview



Follow-up Assessments: All Participants

Survey Data (3 months and 6 months post-baseline). You will be asked to come into the AVRC office and answer survey questions at both 3 months and 6 months after your first visit. The surveys will include all topics covered in the first survey, as well as information on HIV care and support care usage, and ART use. This will occur for all study participants.

Release of Information (ROI) Forms. At each follow-up visit, study staff will ask you to sign Release of Information (ROI) forms for each provider or clinic that you receive HIV care from. This form allows us to request information about your HIV care visits and viral load. At each follow-up visit, you will also be asked if you have received additional HIV care from any new providers or clinics, so that we can get an ROI Form for the new providers or clinics. This will occur for all study participants.

Study Passive Follow-up Period. During the first and follow-up visits, you will be asked to sign two kinds of forms: (1) Release of Information (ROI) forms and (2) HIPAA Authorization forms. These will provide the research team with your permission to request some of your medical information. If you give us permission, we will request medical information from your local HIV care providers. We will collect information on clinic visits, HIV viral load, and CD4 values. This will occur 7 to 12 months after your first study visit. This will occur for all study participants.

Study Activities: Extra Sessions Group ONLY

The BRIDGES Project One-on-One Sessions. If you are put into the extra sessions group, then you will be connected with a Peer Navigator (PN) and she will schedule a first in-person one-on-one meeting with you. At the first meeting, your PN will talk with you about your needs and connect you to the care and services you need. These areas may include domestic violence, mental health care, medical case management, substance use, assistance with other health conditions, and immigration issues. Your PN will give you support and connect you with HIV medical care and support services as needed. Together, you will come up with a treatment plan for your needs. If you are not currently receiving services, you will be asked to attend your first HIV medical care visit within 30 days of your first meeting with your PN.

Your PN will reach out to you at least 6 times in the first two months and after that as needed. Your PN will also connect with you through phone calls and text messages in preparation for HIV care and support service visits and following visits. This will occur only for the Extra Sessions Group.

The BRIDGES Project Group Sessions. If you are randomly put into the extra sessions group, you will be asked to go to The BRIDGES Project Group Sessions. Sessions will start one to two weeks after your first study visit, and will happen every week for 6 weeks.

The 6 group sessions will include the following topics:

Class 1: Emotional Awareness
Class 2: Emotional Regulation
Class 3: Emotionally Engaged Living
Class 4: Identifying and Changing Relationship Patterns
Class 5: Increasing Assertive Communication and Behavior
Class 6: Flexibility in Relationships

The group sessions will be in English and last 2 hours. You will be in the sessions with 6-10 women, and you will be with the same women for all of the sessions.
Your PN and their partner PN will run the sessions. Your PN will check-in with you after each class in-person or by phone. This will occur only for the Extra Sessions Group.

Follow-up Assessments: Extra Sessions Group ONLY

Group Session Exit Survey. If you are randomly put into the Extra Sessions Group, after each group session (Weeks 1-6) you will be asked to answer a few questions through an "exit survey". These surveys will take about five minutes each. This will occur only for the Extra Sessions Group.

Intervention Evaluation. If you are randomly put into the Extra Sessions Group, after all 6 group sessions are done, you will be sent a link to an optional digital survey with questions about the group sessions and sessions with your Peer Navigator. This will occur only for the Extra Sessions Group.

POTENTIAL RISKS AND DISCOMFORTS:
Your being in this study may have some risks. It is possible that you may feel uncomfortable with some of the questions asked or topics raised during your study visits or group sessions. Participation in this study may involve some emotional distress. If any questions make you feel uncomfortable or upset, you do not need to answer them. If you are in need of mental health services, your Peer Navigator will refer you to counseling agencies with low fee services, so that you may talk to someone about your problems. However, you will be responsible for the cost of these services. If you feel

that you need to speak with someone right away, we can arrange for you to speak with someone.

This study is confidential and voluntary. No identifying information such as your name will be included in any published reports. All of these steps will be taken to ensure that the information you give us will be kept private; however, there is a slight possibility that someone could find out about your information. Because this is a research study, there may also be some unknown risks that are currently don't know about. You will be informed of any new information that may affect your decision to participate in this study.

Being in this study is voluntary and you can choose not to answer any question, without it affecting your participation in this study. We will do everything possible to protect your confidentiality and research records will be kept confidential to the extent provided by law.

ANTICIPATED BENEFITS FOR THE PARTICIPANT:
There may be no benefit to participating in this research. However, it is possible that participating in this study may help you increase your knowledge on some issues, including barriers to HIV services, coping skills, and support services for women living with HIV. Also, you may benefit from knowledge and/or referrals for additional medical evaluation and care, including mental health, substance abuse and domestic violence hotlines/services.

ANTICIPATED BENEFITS TO SOCIETY:
Your participation in this study will help the researchers to learn about ways support can be more responsive to the health care and personal needs of HIV-positive women. In addition, what we learn help us to understanding how it might better support the needs of similar HIV-affected communities.

ALTERNATIVES TO PARTICIPATION:
Instead of being in this study, you can choose not to participate. If you do not want to participate in this project, resources will be made available to you. You may choose to contact local service providers that offer support groups for women with HIV.

PAYMENT FOR PARTICIPATION:
You will receive payment for your participation in this study.

If you are in the STANDARD CARE GROUP, you will receive payment after each of the following:

- Baseline Study Visit ($35)
- Follow-Up 1 Study Visit (3 months post-Baseline) ($35)
- Follow-Up 2 Study Visit (6 months post-Baseline) ($35)

- Completion of all 3 Study Visits ($10)

If you are in the STANDARD OF CARE GROUP and complete all visits, the total amount of payment will be $115.

If you are in the EXTRA SESSIONS GROUP, you will receive payment after each of the following:

- Baseline Study Visit ($35)
- Peer Navigator Intake Session ($10)
- Group Session 1 ($10)
- Group Session 2 ($10)
- Group Session 3 ($10)
- Group Session 4 ($10)
- Group Session 5 ($10)
- Group Session 6 ($10)
- Follow-Up 1 Study Visit (3 months post-Baseline) ($35)
- Follow-Up 2 Study Visit (6 months post-Baseline) ($35)
- Completion of all 3 Study Visits ($10)

If you are in the EXTRA SESSIONS GROUP and completed all visits and sessions, the total amount of payment will be $185.

Also, this study will cover transportation costs via a public transportation day pass that can be used on local buses and light rail trains throughout San Diego. If you do not have access to public transportation, we may be able to set up transportation to and from study visits via Lyft Concierge.

FINANCIAL OBLIGATION:
Neither you nor anyone else will be billed for your participation in this research.

EMERGENCY CARE AND COMPENSATION FOR INJURY:
You may call Dr. Jamila K. Stockman at 858-822-4652 if you think you are injured or ill because of this study. If you are injured as a direct result of participation in this research, the University of California will provide any medical care you need to treat those injuries. The University will not provide any other form of compensation to you if you are injured. You may call the Human Research Protections Program Office at (858) 246-4777 for more information about this, to inquire about your rights as a research subject or to report research-related problems.

PRIVACY AND CONFIDENTIALITY:
Every reasonable effort will be made to keep your records confidential. We will adhere to all regulatory guidelines and local laws and regulations for confidentiality and safety monitoring and protection. As a result of participating in this study, it is possible that you

may be identified by others, including law enforcement or healthcare personnel, as being a woman who is living with HIV.

The study will take the following actions to keep participant data confidential: (1) we will hold study visits in private locations (i.e. UCSD Clinic Offices); (2) physical papers with your information on them will be stored in a locked cabinet; (3) a number will be assigned to your data and samples, and all data will be labeled with that number, not your name; and (4) only specific research study members will have access to your electronic data records.

Research records may be reviewed by the UCSD Institutional Review Board, collaborating investigators, doctors and staff. There is also a slight risk that confidentiality may be breached in the management of data, although multiple safeguards will be implemented to avoid this risk. All direct identifying information such as name and medical record number will be destroyed at the end of the study.

Under certain circumstances we may release identifying information if we feel it is the best interest of you or others. For example, we may disclose medical information in cases of medical necessity. We may also take steps (including notifying authorities) to protect you or someone else from serious harm, including child abuse. Because funding for this research comes through California HIV/AIDS Research Program, staff from that and other Department of Health and Human Services (DHHS) agencies may review records for audit or program evaluation. They, too, will protect your privacy.

All study staff and personnel have been trained to protect your confidentiality. However, this 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 or employer learns about your participation and obtains your consent to receive research information, the researchers and study staff may withhold information regarding your involvement in the study. This means that you and your family must also actively protect your own privacy.

Additionally, we ask that you protect the confidentiality of yourself and other participants in this study. Anything you say during a group session could be repeated by another participant outside of the group session. While we ask that you and other participants do not share what is said in group sessions with others outside of the study, you should also avoid saying anything during a group session that you do not want shared. We also ask that you and other participants do not disclose the names of others in the study.

The researchers and staff from this study reserve the right to disclose voluntarily identifying information if you need medical help. We may also disclose identifiable information about you in other cases, which are explained below.

Under California law, we must report information about known or reasonably suspected incidents of abuse or neglect of a child, dependent adult or elder including physical, sexual, emotional, and financial abuse or neglect. If any researcher has or is given such information, he or she may be required to report such information to the appropriate authorities. We may need to report information about known or reasonably suspected incidents of abuse or neglect of a child, dependent adult or elder including physical, sexual, emotional, and financial abuse or neglect. If any researcher has or is given such information, he or she may report such information to the appropriate authorities.

The researchers may not be able to keep confidential any thoughts you may have of harming yourself or others. If you disclose that you are thinking about or have plans to harm yourself or others, we will disclose this information to law enforcement and/or medical personnel.

If the study results are published or presented, you will not be identified.

PARTICIPATION AND CONSEQUENCES OF WITHDRAWAL:
Your participation in this research is VOLUNTARY. You will be told if any important new information is found during the course of this study that may affect your wanting to continue. If you choose not to participate, that will not affect your relationship with UCSD or any future services that will receive from UCSD or any other San Diego service organization If you decide to participate, you are free to withdraw from the study at any time without penalty.

WITHDRAWAL OF PARTICIPATION BY THE INVESTIGATOR:
The Principal Investigator may take you out of the study, even if you wish to continue with the study. If you're upset and prevented from continuing to be in the study, you may have to drop out. Dr. Jamila K. Stockman will make the decision whether you can carry on with the study. This decision may be made either to protect your health and safety, or because the Principal Investigator believes you are not appropriate for the study. If you must drop out because the Principal Investigator asks you to (rather than because you have decided on your own to drop-out), you will still be paid.

IDENTIFICATION OF INVESTIGATOR:
If you have any questions about the research, please feel free to contact:

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9500 Gilman Drive, MC 0507
La Jolla, CA 92093-0507

Tel: (858) 822-4652
Fax: (858) 534-7566
Email: jstockman@ucsd.edu

RIGHTS OF RESEARCH SUBJECTS:
You may withdraw from this study (your consent) at any time without penalty. You are not waiving any legal claims, rights or remedies because of your participation in this research study. If you have questions regarding your rights as a research subject, you may contact the Human Research Protections Program (HRPP):

Phone:
858-246-HRPP (858-246-4777)
Fax:
858-246-3FAX (858-246-3329)

External Mail:
Attn: Human Research Protections Program (HRPP)
University of California, San Diego
9500 Gilman Drive, Mail Code 0052
La Jolla, California 92093-0052

Additional Study Notification

We may learn about other studies you could participate in. If we do, we would like to tell you about them. You do not have to take part in any other study.

Do you agree to be told about other research studies?

□ Yes □ No

Initials_____

YOUR SIGNATURE AND CONSENT

You have received a copy of this consent document and a copy of the "Experimental Subject's Bill of Rights" to keep.

You agree to participate.

_____	_____
Signature of participant	Date
_____	_____
Signature of the person conducting the informed consent discussion	Date