Official Title of the Study: The BRIgHT Program: Building Resilience in HIV Together NCT

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Partners HealthCare System
Research Consent Form

Subject Identification

Certificate of Confidentiality Template
Version Date: August 2016

Protocol Title: The BRIgHT Program: Developing a Resilience Intervention for Older, HIV-Infected Women

Principal Investigator: Christina Psaros, PhD

Site Principal Investigator:

Description of Subject Population: Women age 50 and over living with HIV

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

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.

Why is this research study being done?

We are doing this research to better understand how we can help older women with HIV cope with the demands of living with HIV. We have started to develop a group program that we think will help older women with HIV develop resilience, the ability to cope with long term stress. The program is designed to occur in groups of up to 10 women. There will be 10 weekly 90-minute group sessions, as well as up to 4 one-on-one assessment visits or interviews during the study.

We are asking you to take part in this research study because you are a cisgender woman age 50 or over who is living with HIV, speaks English, and may benefit from learning additional skills

to improve your level of resilience. Up to 60 women will take part in this phase of our research study. This study will be funded by the National Center for Complementary and Integrative Health (NCCIH), a division of the National Institutes of Health (NIH).

How long will I take part in this research study?

It will take you about 6 months to complete the study. During this time, we will ask you to complete an individual assessment before the program starts, then ten weeks of the group program, an individual assessment after the program is finished, and an optional one-on-one interview. Additionally, we will ask you to complete a 3-month individual follow up assessment. In total, the study entails 10 weekly group sessions and 4 one-on-one assessment visits (including the optional one-on-one interview) where you will fill out a series of questionnaires.

What will happen in this research study?

If you agree to participate in this research study, we will ask you to complete an individual assessment before starting the program (the baseline assessment, approximately 45 minutes in length). At this visit, we will also ask you to have two tubes of blood drawn to measure viral load and CD4 count, which can be done at the MGH Clinical Research Center (CRC) in White Building 12 at 55 Fruit Street, Boston, MA 02114. This will require you to register with MGH as a research participant, but does NOT require you to receive your primary care at MGH and will not affect your primary care elsewhere. If you are a patient at a Partners hospital, your medical records may be reviewed for the purposes of this research study. Specifically, we will abstract your viral load and CD4 count from your medical records, if applicable. The purpose of this is to save you an unnecessary blood draw if you have recently had these tests done during a clinical visit. All blood draws are optional; if you wish, you may opt out and still participate in the study.

After the baseline assessment, participants will be randomly assigned to one of two possible treatment conditions. You will either be enrolled to participate in the BRIgHT Program Group or a Supportive Psychotherapy Group. The BRIgHT Program Group participants will take part in an adapted mind-body resiliency intervention (the Relaxation Response Resiliency Program), which aims to increase stress management, coping, and relaxation skills among older women living with HIV. The Supportive Psychotherapy Group participants will take part in weekly support groups that facilitate discussions around stressful or difficult topics that participants have experienced related to aging as a woman living with HIV.

Randomization to each treatment group is decided by chance, like a coin toss. You and the study team cannot choose the study groups. You will have an equal chance of being assigned to each of the two groups. Once we have enough interested women (around 10-12) to form a group, we will schedule the sessions. We will then ask you to attend ten group sessions, lasting 90 minutes each.

When the sessions are over, we will ask you to complete another individual assessment (the post-treatment assessment, approximately 60-90 minutes, and the one-on-one interview). The post-treatment assessment will be very similar to the baseline assessment, but we will also ask you to sit down one-on-one with a member of our study team and tell us your feelings about the program so that we can improve it during the one-one-one interview. At this visit, we will also ask you to have one tube of blood drawn to measure viral load.

Finally, we will ask you to complete a third individual assessment approximately 3 months after your post-treatment assessment. This final assessment will be very similar to the baseline and post-treatment assessments. At this visit, we will also ask you to have one final tube of blood drawn to measure viral load.

All group sessions and one-on-one interviews will be audiotaped so we can further improve the content of our program. We will ask your permission to call you before your appointments, or to email you confirmatory information about your scheduled appointment if you prefer.

Please note, the Partners standard is to send email securely. This requires you to initially set up and activate an account with a password. You can then use the password to access secure emails sent to you from Partners HealthCare. If you prefer, we can send you "unencrypted" email that is not secure and could result in the unauthorized use or disclosure of your information. If you want to receive communications by unencrypted email despite these risks, Partners HealthCare will not be held responsible. Your preference to receive unencrypted email will apply to emails sent from this research group/study only.

During the individual assessments we will ask you questions about many areas, including your background, who in your life supports you, your experience with stigma or discrimination, sexual well-being, and how you manage your HIV. Some of these are sensitive topics, and you can refuse to answer any questions that make you feel uncomfortable.

Since it might be challenging for participants to make group sessions each week due to unforeseen scheduling conflicts or emergencies, we will offer options for making up sessions. For participants who have attended at least one session in person, calling into a maximum of three group sessions is possible. You can also attend up to three in-person make-up sessions if you need to miss a group session for any reason.

The group sessions will teach you skills such as relaxation, how to more effectively solve problems, and how to think about stress differently. **Because living with HIV is a sensitive matter, we will ask all participants to avoid discussing the identity of group members and content of group sessions outside of the sessions.**

What are the risks and possible discomforts from being in this research study?

If you participate in this study, you may feel some psychological discomfort during assessments or group sessions. If this occurs, you may stop participating at any time. You can also ask the group leader or assessor to help you identify a referral to a mental health professional. While we take many steps to protect your confidentiality, it is possible that a breach in confidentiality could occur and someone could learn about your HIV status. Please be careful where you keep this form, as it talks about HIV diagnosis. There may be other risks that are currently unknown.

What are the possible benefits from being in this research study?

You may not benefit from participating in this study. However, you may learn skills to help you cope more effectively with stress. In addition, your participation may help health care providers better care for older women living with HIV.

What other treatments or procedures are available for my condition?

You do not have to participate in this research study to learn stress management skills or to increase resilience. These skills could also be learned in other settings, such as psychotherapy.

Can I still get medical care within Partners if I don't take part in this research study, or if I stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should I do if I want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will I be paid to take part in this research study?

Yes. You may receive up to $268 over the course of the study, including $37 for each of the 4 assessment visits, and $12 for each of the 10 group sessions. A reimbursement schedule is below.

We may be using an approved, outside vendor (Forte Research) make these payments to you via a reloadable credit card-based system, called Forte Payments. This secure system is similar to a gift card or credit card. If you are paid by this system, you will be given a Forte Payments Visa card when you enroll in the study. Once the card is activated, the study team will add a payment after each paid visit you complete. The payment should be available to you within a day. You may use the card anywhere Visa cards are accepted, such as at a grocery store.

We will need to collect your Social Security number in order to make these payments, and it will be shared securely with the company that runs the card-based system. Payments like this are considered taxable income. If you receive more than $600, the payment will be reported to the IRS as income by the hospital. If you provide a receipt for something like travel expenses and we can cover that, that is not considered taxable income. Reimbursement of expenses will not be made using the Forte Payments card.

Visit Type	Visit Compensation
Baseline assessment	$37
Group session #1	$12 (transportation only)
Group session #2	$12 (transportation only)
Group session #3	$12 (transportation only)
Group session #4	$12 (transportation only)
Group session #5	$12 (transportation only)
Group session #6	$12 (transportation only)
Group session #7	$12 (transportation only)
Group session #8	$12 (transportation only)
Group session #9	$12 (transportation only)
Group session #10	$12 (transportation only)
Post-treatment assessment (alone)	$37
Optional one-on-one interview (alone)	$37
Post-treatment assessment and one-on-one interview (paired)	$62
3-month follow-up assessment	$37
Total Maximum Compensation	**$268**

What will I have to pay for if I take part in this research study?

Study funds will pay for certain study-related items and services. We may bill your health insurer for, among other things, routine items and services you would have received even if you did not take part in the research. You will be responsible for payment of any deductibles and co-payments required by your insurer for this routine care or other billed care. If you have any questions about costs to you that may result from taking part in the research, please speak with the study doctors and study staff. If necessary, we will arrange for you to speak with someone in Patient Financial Services about these costs.

What happens if I am injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Christina Psaros, PhD, is the person in charge of this research study. You can call her at 617-699-4433 Monday through Friday, between the hours of 9:00-5:00. You can also call Allison Labbe, PhD at 617-643-0382 Monday through Friday, between the hours of 9:00-5:00 with questions about this research study. If you have questions about the scheduling of appointments, study visits, or other general questions, please call Georgia Goodman at 617-726-3679.

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

If I take part in this research study, how will you protect my privacy?

Federal law requires Partners to protect the privacy of health information that identifies you. In the rest of this section, we refer to this information simply as "health information."

In this study, we may collect health information about you from:

- Past, present, and future medical records
- Research procedures, including research office visits, tests, interviews, and questionnaires

Certificate of Confidentiality for Health Information and Other Identifying Information from the Research

In this research study, we have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). By granting the Certificate, DHHS is not approving the research itself, but is helping us strengthen the privacy protections for your health information and other identifying information from the research. With the Certificate, we cannot be forced (for example by court order or subpoena) to disclose your health information or other identifying information from the research in any Federal, State or local civil, criminal, administrative, legislative, or other proceedings. (Note that information that is not from the research, such as existing hospital or office health records, is protected by general privacy law but does not receive the Certificate's stronger protection. The Certificate also does not prevent you or a member of your family from voluntarily releasing any information about yourself or your involvement in this research study.)

Why Health Information and Other Identifying Information from the Research Might Be Used or Shared, and By/With Whom

Even with these privacy protections, your health information and other identifying information from the research may still be used within Partners by the researchers and the staff involved in this research study, by the Partners ethics board that oversees the research, and by other staff within Partners who need the information to do their jobs (such as for treatment, payment (billing) or health care operations such as overseeing the quality of care or research). Your information may also be shared by these groups with others outside of Partners for certain purposes as follows.

We may use and share your information with:

- The sponsor(s) of the research study, and people or groups it hires to help perform this research study
- Other researchers and medical centers that are part of this research study and their ethics boards
- A group that oversees the data (study information) and safety of this research
- People or groups that we hire to do certain work for us, such as data storage companies, insurers, and lawyers
- Federal and state agencies (such as DHHS and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections), with other U.S. or foreign government bodies, and with organizations that provide independent accreditation and oversight of hospitals and research. For example, disclosure may be necessary upon request of DHHS for an audit, program evaluation, or investigation. Disclosure may also be necessary if required by the federal Food, Drug, and Cosmetic Act or its regulations.
- A public health or public safety authority, or with specific individuals who may be at risk of harm, if we learn information that could mean harm to you or others. When state mandatory reporting statutes would require us to disclose information, including about child or elder abuse, we will voluntarily disclose that information.

What Study Information May Become Part of Your Electronic Medical Record?

Certain information from the research will be put into your medical record and will not be covered by the Certificate of Confidentiality. This includes a record of study enrollment, records of medical tests or procedures done at the hospitals and clinics, and information that treating health care providers may need to care for you. Please ask your study doctor if you have any questions about what information will be included in your medical record.

Some people or groups who get your health information might not have to follow the same privacy rules that we follow and might use or share your health information without your permission in ways that are not described in this form. For example, we understand that the sponsor of this study may use your health information to perform additional research on various products or conditions, to obtain regulatory approval of its products, to propose new products, and to oversee and improve its products' performance. We share your health information only when we must, and we ask anyone who receives it from us to take measures to protect your privacy. The sponsor has agreed that it will not contact you without your permission and will not use or share your information for any mailing or marketing list. However, once your information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information. The protections of the Certificate of Confidentiality and other Partners privacy protections will continue to apply to your health information and other identifying information from the research for as long as our researchers keep the information.

The results of this research may be published in a medical book or journal, or used to teach others. However, your name or other identifying information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your health information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your health information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. The Certificate of Confidentiality and other Partners privacy protections will continue to apply to your health information and other identifying information from the research that our researchers keep.

You have the right to see and get a copy of your health information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my health information to be used and shared as described above.

Subject	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

- I have explained the research to the study subject.
- I have answered all questions about this research study to the best of my ability.

Study Doctor or Person Obtaining Consent	Date	Time (optional)

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