Cover page

Psilocybin-assisted Group Therapy for Demoralization in Long-term AIDS Survivors

NCT02950467

Informed Consent Form

20 February 2019

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title:
Psilocybin-assisted Therapy for Demoralization in Long-term AIDS Survivors

Consent Form for Participants

Introduction

We are asking you to consider taking part in a research study being done by Dr. Brian Anderson, MD, MSc and Dr. Josh Woolley, MD, PhD at UCSF. The study team will also explain the study to you and answer any questions you have.

Research studies include only people who choose to take part. It is your choice whether or not you want to take part in this study. Please take your time to make a decision about participating. You can discuss your decision with your family, friends and health care team.

You are being asked to take part in this study because you have HIV, are at least 50-years old, and suffer from psychological demoralization, which is defined as a sense of hopelessness, helplessness and a loss of meaning and purpose in life. Demoralization is common among patients suffering from chronic disease.

Why is this study being done?

The purpose of this study is to test the safety and feasibility of combining group therapy sessions with one individual psilocybin treatment session as a treatment for demoralization. We want to find out what effects, good and bad, this can have on your mental and physical health. Psilocybin is a psychedelic (or hallucinogenic) drug and the active ingredient in "magic mushrooms." It has been shown that at moderate-to-high doses, pure psilocybin administered in a clinical setting can result in a transcendent-type experience characterized by significant changes in your mood, your thinking, and your perception of time, your body and your surroundings. Research participants have reported experiencing immersive "visions" when the eyes are closed as well as perceptual illusions and hallucinations when the eyes are open. This state of mind can feel like having an intense dream while you are awake. Some participants have reported having experiences that are very blissful, challenging, or sometimes both at the same time. Recent studies have shown that combining individual psychotherapy with a single moderate-to-high dose psilocybin drug session is safe in cancer patients and can improve their levels of depression and anxiety, including when the psilocybin experience is at times rather challenging or distressing. We believe that combining group therapy and such a transcendent-type experience could lead long-term AIDS survivors to experience improvements in demoralization.

The study investigators are all UCSF faculty or physicians and they will not receive any compensation beyond their usual salaries to conduct this study. Other study costs will be covered by donations from non-profit organizations, including the Heffter Research Institute, the River Styx Foundation, the Stupski Foundation and the Usona Institute. Dr. Anderson and Dr. Woolley received travel reimbursement from the Usona Institute in 2016. The study drug, psilocybin, will

be provided, at cost, by researchers at Johns Hopkins University or the Usona Institute. No patents pending are related to this study in any way.

How many people will take part in this study?

Up to 36 participants will take part in this study. The study will consist of between three and six therapy groups of six participants each. Each participant will have the option of inviting one of their primary caregivers or important others in their life to participate in the study, but the person they invite will neither receive psilocybin nor group therapy, instead they will answer questions about the participant before and after the participant completes the treatment.

What will happen if I take part in this research study?

All study procedures will be done at the UCSF Langley Porter Psychiatric Institute (401 Parnassus Ave, San Francisco, CA) or the UCSF Alliance Health Project (1930 Market St, San Francisco, CA).

Before you begin the main part of the study…
You will need to have the following exams, tests or procedures to find out if you can be in the main part of the study. Some of these exams, tests or procedures are part of regular mental health care and may be done even if you do not join the study. If you have had some of these tests recently (within the last month), they may not need to be repeated. This will be up to your study doctor.

- Psychological tests to check for some psychiatric conditions that you or some of your family members may have had in your/their lifetime
- Psychological tests to assess your current mental health
- Physical exam
- Electrocardiogram (a.k.a., an "EKG"): stickers will be placed on your body for a few seconds to detect the electric activity in your heart
- Blood drawing (venipuncture): a blood sample will be drawn by inserting a needle into a vein in your arm. A total of about ten tablespoons will be drawn for the whole study. Blood tests will include, among other tests, HIV viral load, CD4 and CD8 count, and a test for syphilis.
- Urine tests, including a urine drug screen for recent illicit drug use

During the main part of the study...
If the exams, tests and procedures show that you can be in the main part of the study, and you choose to take part, then you will need the following tests and procedures that are being done to see how the study is affecting your mental and physical health.

- Ten group therapy sessions
- One individual therapy session before starting the group therapy
- Psychological assessments before the first group therapy session and after the last group therapy session
- Brief psychological assessments on the days of the group therapy sessions

- One individual (without the other group members) psilocybin treatment session during which your heart rate and blood pressure will be repeatedly monitored. Study therapists will be with you the entire time of the session. On the morning of your psilocybin session, you will complete a blood draw and given a urine sample before the psilocybin session starts.
- ***Before the psilocybin treatment session, you must make arrangements to be brought home by someone (such as a caregiver) because the treatment may impair your ability to travel home on your own after the session. For the remainder of that day, you must agree not to operate any motor vehicles.***
- The day after the psilocybin treatment session you will return to the study site to have an individual therapy session with the study clinicians, complete some psychological tests, and complete another blood draw.

When you are finished receiving the last group therapy session...

Two weeks after the last group therapy session, you will be invited to participate in (see Study Plan below):

- A focus group (with the participants and other caregivers/important others from the therapy group) to reflect on your experiences in the study and to give formal feedback to the researchers

Three months after the last group therapy session you will be asked to complete (see Study Plan below):

- Psychological tests to assess your mental health. You will be emailed a link to an online survey or, if you prefer, you can be mailed these tests and you will then mail them back to the researchers.

In between the focus group and the 3-month follow-up, you may also be asked to participate in: A brief (1 hour) video-recorded interview with study staff about your mental health and your thoughts on how the study has affected you

Please note: During your enrollment in the trial the study clinicians will continue to remind you of what medications are contraindicated for this study. If you wish to make any changes to your medication regimen after you complete the final group therapy session, you will need to discuss these changes with your prescribing medical provider. ***Study clinicians will not advise you on medication changes after you complete the study intervention.***

Study Timeline

Audio-video recording

You will be audio- and video-recorded at all in-person study sessions, and transcriptions will be made from the audio files. These recordings will be used to study your behavior during the study. The confidentiality of the recordings and transcriptions will be protected by limiting access to them only to study staff and researchers who are training in how to provide the model of psychotherapy that is being tested in this study. The recordings and transcriptions will be stored on encrypted computers and backed-up onto encrypted hard drives kept in locked rooms at UCSF and will be kept in perpetuity by the UCSF Department of Psychiatry. Some audio files will be transcribed using HIPAA-compliant speech-to-text software through the IBM web-based software Watson, immediately after which the audio file will automatically be deleted from the IBM website.

How long will I be in the study?

The total study length will be about 5 months. Before the first group therapy session, you will participate in 1 individual therapy session that will last about 1 hour; and you will complete a baseline evaluation session that will last about 1 hour. You will then be asked to participate in 10 group therapy sessions over a 2-month period; each group therapy session will last about 1.5 hours. During this 2-month period you will have one individual psilocybin treatment session, which will last about 8 hours. The day after your psilocybin session, you will have one on-site follow-up visit that will last about 1.5 hours. At the end of the 2-month period you will complete an endpoint assessment that will last about 1 hour. Two weeks after completing the 2-month treatment period, the study doctor will ask you to return for one follow-up focus group that will last about 2 hours. We would like to keep track of your medical and mental health condition for another 3 months after the focus group. Before you complete the study, you will be asked to complete a follow-up evaluation (either an online or a paper-and-pen questionnaire) that should take you about 1 hour. You may also be asked to participate in a follow-up interview of about 1 hour's length.

Can I stop being in the study?

Yes. You can decide to stop at any time, *with the exception of during the drug treatment session* (see below). Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop your participation safely.

It is important to note that while you are under the effects of the study drug (which last about 5-6 hours), if you tell the study doctor that you wish to stop being in the study, you will still be required to remain at the study site until the study doctor has determined that the drug effects have worn off and it is safe for you to leave. At the beginning of the treatment day you will hand over your shoes, keys, wallet and phone to the study therapists for safe keeping, and these will only be returned to you at the end of the session. **When you leave the study site you must be accompanied by a friend or family member who will help you get home.**

It is important to tell the study doctor if you are thinking about stopping so any risks from the psilocybin-assisted psychotherapy can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?

You may have side effects while in the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects from psilocybin go away soon after the psilocybin session ends. In some cases, side effects can be serious, long lasting, or may never go away.

You should talk to your study doctor about any side effects you experience while taking part in the study.

One notable risk that you will take on by participating in this study is the loss of confidentiality. Because this is a group therapy study, the other members of the group will learn about your medical history based on what you share in the group. There is a risk that group members will not keep your personal information confidential and could share it with others outside of the study. The audio/video recordings made in the study also put you at risk of losing confidentiality.

Medical risks and side effects related to psilocybin include those which are:

Likely

- Mild-to-moderate elevations in heart rate or blood pressure
- Anxiety, fear, paranoia or confusion that resolve when the psilocybin session ends
- Headache that resolves within 24 hours
- Impairment in coordination and being unsteady on your feet
- Nausea during or soon after the psilocybin session

Less Likely

- Vomiting during the psilocybin session
- Fatigue or insomnia soon after the psilocybin session
- Loss of control of bowels and/or bladder
- Feeling very restlessness or agitated
- Decreases in heart rate or blood pressure
- Physical discomfort or pain

Rare but serious

- Severe elevations in blood pressure that require medications (such as sublingual nitroglycerine) to bring it back to normal
- Anxiety, depression, mania, psychosis, or distressing perceptual disturbances that last for >24 hours after ingesting the psilocybin
- Severe anxiety, mania or psychosis that require medications (such as oral or intramuscular lorazepam or olanzapine) during the medication session to maintain your safety and/or the safety of study staff
- Thoughts of wanting to die or suicide
- Elevated body temperature, muscle stiffness and confusion caused by the serotonin syndrome

- **Blood drawing (venipuncture) risks:** Drawing blood may cause temporary discomfort from the needle stick, bruising, infection, and fainting.

- **Unknown Risks:** The experimental treatments may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

- For more information about risks and side effects, ask your study doctor.

Are there benefits to taking part in the study?

Taking part in this study may or may not make your health better. While doctors hope psilocybin-assisted psychotherapy will be helpful in treating your mental health, there is no proof of this. We do know that the information from this study will help doctors learn more about psilocybin-assisted psychotherapy as a treatment for demoralization and other mental health conditions in people living with HIV. This information could help future patients living with HIV and other palliative care patients.

What other choices do I have if I do not take part in this study?

Your other choices may include:

- Getting treatment or care for your mental health without being in a study.
- Taking part in another study.
- Getting no treatment.

- Palliative care is care that helps reduce pain, tiredness, appetite problems and other problems caused by incurable diseases like HIV. It does not treat the HIV directly, but instead tries to improve how you feel. Palliative care tries to keep you as active and comfortable as possible for as long as you live.

Please talk to your doctor about your choices before deciding if you will take part in this study.

How will information about me be kept confidential?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. Some information from your medical records will be collected and used for this study. If you do not have a UCSF medical record, one will be created for you. Your signed consent form and some of your research tests will be added to your UCSF medical record. Therefore, people involved with your future care and insurance may become aware of your participation and of any information added to your medical record as a result of your participation. Study tests that are performed by research labs, and information gathered directly from you by the researchers will be part of your research records but will not be added to your medical record. One exemption is that you will be tested for the sexually transmitted infection syphilis and new cases of syphilis are required to be reported to the Department of Public Health. Another important exemption is if the study staff are concerned that you are suicidal. Study staff will regularly assess you for thoughts of suicide. If you are suicidal, you will be evaluated by a study physician for imminent risk of harming yourself, and you may need to be hospitalized and removed from the study. Also, your personal information may be given out if required by law. Finally, if information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Organizations that may look at and/or copy your medical records for research, quality assurance, and data analysis include:

- The University of California
- Government agencies (e.g., the Food and Drug Administration (FDA)) involved in keeping research safe for people.

We intend to invite participant feedback on the scientific publications that are produced from this work. There may be the opportunity for participants from the different therapy groups to meet and provide feedback together. If you choose to participate in a meeting like this, then other study participants beyond those in your therapy group will know that you participated in the study.

What are the costs of taking part in this study?

You will not be charged for any of the study activities.

Will I be paid for taking part in this study?

In return for your time, effort and travel expenses, you will be paid $200 if you complete the entire study. For completing the Enrollment Assessment, you will receive $50 cash at the end of the visit, and then to cover your transport costs you will receive $10 cash as the end of every visit after that. If on the day of your psilocybin treatment session your ride home requires parking near the study site, we will reimburse you for that as well.

What happens if I am injured because I took part in this study?

It is important that you tell your study doctors, Dr. Brian Anderson, MD, MSc and Dr. Josh Woolley, MD, PhD, if you feel that you have been injured because of taking part in this study. You can tell the doctors in person or call them at, respectively, 415.476.7432 and 415.221.4810 x24117.

> **Treatment and Compensation for Injury:** If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California, depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415- 476-1814.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions, concerns, or complaints you have about this study. Contact your study doctor(s) Dr. Brian Anderson at 415.476.7432 or Dr. Josh Woolley at 415.221.4810_x24117.

If you wish to ask questions about the study or your rights as a research participant to someone other than the researchers or if you wish to voice any problems or concerns you may have about the study, please call the office of the Institutional Review Board at 415-476-1814.

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.

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CONSENT

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

Date	Participant's Signature for Consent
Date	Person Obtaining Consent

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

EXPERIMENTAL SUBJECT'S

BILL OF RIGHTS

The rights below are the rights of every person who is asked to be in a research study. As an experimental subject I have the following rights:

1) To be told what the study is trying to find out,
2) To be told what will happen to me and whether any of the procedures, drugs, or devices is different from what would be used in standard practice,
3) To be told about the frequent and/or important risks, side effects, or discomforts of the things that will happen to me for research purposes,
4) To be told if I can expect any benefit from participating, and, if so, what the benefit might be,
5) To be told of the other choices I have and how they may be better or worse than being in the study,
6) To be allowed to ask any questions concerning the study both before agreeing to be involved and during the course of the study,
7) To be told what sort of medical treatment is available if any complications arise,
8) To refuse to participate at all or to change my mind about participation after the study is started. This decision will not affect my right to receive the care I would receive if I were not in the study,
9) To receive a copy of the signed and dated consent form,
10) To be free of pressure when considering whether I wish to agree to be in the study.

If I have other questions I should ask the researcher or the research assistant. In addition, I may contact the Committee on Human Research, which is concerned with protection of volunteers in research projects. I may reach the committee office by calling: (415) 476-1814 from 8:00 AM to 5:00 PM, Monday to Friday, or by writing to the UCSF Human Research Protection Program, Box 0962, 3333 California St., Ste. 315, San Francisco, CA 94143.

Call 476-1814 for information on translations.

English - 8/16

NOTES TO PERSON PREPARING CONSENT FORM

1. Consent Document Identification Required by the IRB

Version date and short identifier: Every consent document (consent forms, assent forms, information sheets) must include a version date (month, day, year) in a lower corner of each page. This date should be hard coded -- in other words, the date should not update automatically each time you open the document. The version date should only be changed when the document is modified. If multiple consent documents are used for the study, include a short identifier in the footer on each page to distinguish between the various consent documents. **Any changes in the consent documents require IRB review.**

Page numbering: The pages of every consent document should be numbered, preferably in a format like "1 of 2," "2 of 2," in the footer of the document.

Approval stamp: Approved consent documents in iRIS will receive an approval stamp. To accommodate the stamp, each consent document should have at least a 1.25" top margin and the upper left-hand corner should be blank. Learn more about IRB approval documentation.

2. "Treatment and Compensation for Injury" Statement

VAMC Studies with Sponsor: The VA has specific wording that must be used, which can be found on the IRB website.

Additional Notes Regarding the UCSF "Treatment and Compensation for Injury" Wording: Sponsoring companies often request that their own wording be used for the treatment and compensation for injury policy statement or that minor changes be made in the UC statement. Such requests cannot be honored.

Industry sponsors have three, *and only three*, options regarding the discussion of treatment and compensation for injury in the consent form. First, the sponsor may include its name in the UCSF statement as written in this sample consent form. Second, the sponsor may remain silent on this point, in which case all reference to the sponsor should be omitted from the standard statement. Third, a brief paragraph (one or two sentences) may be added *below and separate from* the UCSF statement to explain the sponsor's policy. However, any description of the sponsor's policy must state what the sponsor *will* cover, not what it will not cover. As a further limitation, the sponsor's statement may not make reference to third party carriers, government programs, or lost wages. *No other changes may be made to the UCSF statement*, as described on the IRB website.

3. Handling Health Information and Complying with HIPAA

HIPAA has specific and strict requirements for use of identifiable information from medical records (which HIPAA calls *protected health information or PHI)*. HIPAA uses different terminology from other human subject protection regulations. Under HIPAA, research subjects must give *authorization* (consent) for use of their PHI. For almost all studies, UCSF requires using separate

forms for research consent and for HIPAA-specific authorization for research access to health information. See HIPAA guidance.

Under HIPAA, any disclosure of PHI that is not specifically included in an individual's *authorization* is prohibited and is subject to penalties. Neither the type of information that will be shared, the use that will be made of the information, nor the persons with whom information will be shared can be changed unless the subject signs a new authorization. This means that if the researchers want to share PHI with any person, company, or institution not already included in the authorization form, the IRB Application and authorization form (and sometimes the consent form) must be modified *and each person about whom information would be shared must be asked to sign the new form(s)*.