UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: Feasibility and acceptability of a behavioral intervention for depression among Latino/as living with HIV.

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This is a research study to evaluate the overall feasibility and acceptability of an individualized approach to selecting treatments for symptoms of depression. Our goal is to determine if this treatment should be studied further and if you think it is appropriate.

STUDY SUMMARY

Introduction: We are asking you to consider taking part in a research study being done by John Sauceda - a faculty member and researcher at UCSF. The research team includes Katerina Christopoulos, MD, and Mallory Johnson, PhD, and professionally trained research staff from the UCSF Department of Medicine. Research studies include only people who choose to take part. If you have any questions, you may ask (us) the researchers or study staff.

The first part of this consent form gives you a summary of this study. We will give you more details about the study later in this form. The study team will also explain the study to you and answer any questions you have.

Purpose of the study: This is a research study to evaluate the overall feasibility and acceptability of an individualized approach to selecting treatments for symptoms of depression. Feasibility is about determining if the treatment is appropriate for further testing, and if the ideas and findings of the study are useful for future research. Acceptability is about how well you tolerate the treatment you may take part in.

You are being asked to participate because you are living with human immunodeficiency virus (HIV), reported a moderate level of depressive symptoms, and receive health care at San Francisco General Hospital Ward 86. You also identified yourself as a Latino(a) or Hispanic.

Study Procedures: If you choose to be in this study, you will attend weekly or biweekly sessions with a therapist to help you with your depression. You will be asked to talk about your depression and record how you are feeling throughout the week. Sometimes, you may be asked to communicate through text-messages.

You will be in this study for up to three months. Each session is 50-60 minutes, and at minimum, we ask you to complete eight sessions. In some cases, you may be asked to participate in up to 13 sessions.

Possible Risks: There are risks to taking part in a research study. Some of the most likely risks of participation in this study include:

- Breaches of confidentiality - Your participation and identity may be disclosed by accident.
- Inconvenience - The time to participate and topics may be uncomfortable for you.
- Discouragement - This study treatment may not work for you.
- Mood changes - You may experience greater depressive symptoms during the course of the study.

There are no known physical risks if you participate in this study

We will tell you more about these risks and other risks of taking part in the study later in this consent form. There may also be risks that we do not know about.

Possible Benefits: There is no expected direct benefit to you from participating in this study.

- Your data could help us learn how to treat and manage depression.
- You may get relief from your depression, but this cannot be guaranteed.

Your Other Options: You do not have to participate in this study. Your other choices may include:

- Getting treatment, such as medications, for depression without being in a study.
- Getting another form of psychotherapy for depression without being in a study.
- Taking part in another study.
- Getting no treatment.

You can talk to your doctor about your choices before agreeing to participate in this study.

The following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

DETAILED STUDY INFORMATION

This part of the consent form gives you more detailed information about what the study involves.

Why is this study being done?
The purpose of this study is to evaluate the feasibility and acceptability of two different behavioral therapies for depression. Each behavioral therapy has shown to be effective for treating moderate depression. However, we are evaluating how well we tailor each therapy to your unique experience as a patient to learn how make these therapies more effective in the future. We also plan to evaluate how easy/hard it is to use cell phones to send/receive text messages in combination with these therapies.

The information collected will help us identify how realistic it is to use a similar approach to treat depression among a larger group of Latino patients living with HIV. The ultimate goal of this research is to develop improved tools to treat depression among all people living with HIV.

Who is paying for this study?
This study is being sponsored by the National Institutes of Health.

How many people will take part in this study?
About 45 Latino(a)/Hispanic patients will take part in this portion of the study at UCSF.

What will happen if I take part in this research study?
The study will take place in two stages. We are starting everyone with one of two therapies:
1) Brief Behavioral Activation Therapy (BAT) - a plan to be more active and social to improve how you feel and think; OR
2) BAT and text-message support - a plan to be more active and social to improve how you feel and think and text-message communication and reminders.

You will start with one of these two. Your assignment to one of these two is completely random - it is a 50/50 chance. We are not choosing which one you are starting with for any reason, your starting point was picked completely by chance - like a heads or tails in a coin flip. We can explain in more detail how this works if you would like.

If you agree to participate, the following will happen:

<u>Stage 1</u>:
- During the first stage, you will be assigned a bilingual behavioral therapist (such as Dr. Sauceda) or therapist in training who is fluent in both English and Spanish.
- You will be asked to complete five sessions of either BAT or BAT and text-
- message support.
- These sessions will happen bi-weekly over the course of 5 weeks.
- You may be asked to use your cellphone as part of the first stage of your therapy. If this is the case, you will use your cellphone to receive text messages such as appointment reminders, and to send response text-messages to “check-in” with your behavioral therapist throughout the week.

After 5 weeks, or after five of the eight sessions, we will thoroughly assess your severity

of depression to see how you are responding to the behavioral therapy. This involves asking you questions about sadness, sleep, concentration, and suicide ideation.

Stage 2:

- Depending on how you respond to the first stage of the behavioral therapy, you may be asked to try a second type of therapy or continue with the first type of therapy. Just like at the start of the study, your assignment to a second type of therapy or continuation with the same therapy is completely random - it is a 50/50 chance.
- During the second stage of the study, you will be asked to complete one of the following:
  - 1 - Stay the course with your current assignment, which means finishing three more sessions, which makes the overall total of eight sessions;
  - 2- Switch to a longer therapy, which includes six sessions of a therapy called cognitive-behavioral therapy (CBT). CBT is a plan that teaches you about negative self-thinking and how to change when you have negative thoughts. Also, it is longer because you would have completed five sessions, and will try eight new sessions, bringing the total to 13 sessions.
  - 3- Receive one booster session of the same program you are on, which brings the session total to nine sessions.
- You may additionally be asked to send and receive text messages on your cellphone as part of the second stage therapy to communicate with your therapist.

Content and Process:
The sessions are designed to learn about you, your daily life, and issues that affect your mood. Over the course of the sessions, we will work with you to teach you about the therapies and the skills involved in managing depression. Over the course of each session, you will be asked about the social activities you do, your daily schedule, the causes of stress and sadness, and then we will work together to make a plan to try new strategies to help you feel better.

You will work with your behavioral therapist to keep a daily log of the activities you are doing, and be asked to give us a score on how your mood is at certain periods of time. You will also be asked to write down other thoughts about how you are thinking and feeling, and share these with your behavioral therapist.

After completing all treatment sessions, you will be asked to complete a post-treatment session. This is an information interview to collect information about your experience with your therapy sessions. Our questions will include what you thought about it, what you found difficult or easy to do, how you thought we did in conducting the study, and what we can do better in the future. We will also ask you to complete a brief survey.

During the treatment sessions, you will be asked to share personal information about your life with your therapist. Outside of the treatment sessions with your behavioral therapist, we will write a letter to your HIV care provider at Ward 86 to let them know

that you are in a study about depression and that they should treat you as they see fit. We will not tell them any other aspects of your participation.

How long will I be in the study?
If you agree to participate in the study, you will be asked to complete from 8 to 13 therapy sessions. The total study period is three months. Each session will last about 60 minutes.

Can I stop being in the study?
Yes, your participation is entirely voluntary, and you can decide to stop at any time. Just tell us right away if you wish to stop being in the study.

We may also stop you from taking part in this study at any time if we believe 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?
(1) Confidentiality: Participation in research could involve a loss of privacy. While we will work to the best of our abilities to keep your identity and research records confidential, we cannot guarantee total privacy. There is the potential risk of having others (e.g., family, friends, co-workers) find out about your participation in the study.

To protect your privacy, all treatments will take place in a private room at San Francisco General Hospital or through secure internet video conference platforms. We will help set you up with that option if you would like to use video conferencing. All records of your participation in the study, including your name and contact information, will be kept in a locked file cabinet or on secure UCSF servers. Only the study staff will have access to your confidential information. At no time will any public reports about the study mention your name or the names of other participants. Any audio recorded throughout the treatment sessions are only done to make sure each behavioral therapist is following the program, and it will be destroyed at the end of the study. Audio recordings are not used for research purposes. Your name will not appear anywhere in any transcripts.

The use of text-messages to communicate with the study could lead to the disclosure of your personal sensitive information, such as HIV status or issues with depression. Our team will take special measures to ensure that your personal information is not revealed to others without your permission. All study phones used by our research team will meet minimum UCSF security standards. All text-messages used to communicate with you will be sent through a private encrypted network. Text-messages sent will never include potentially identifying information or stigmatizing words. We will also review with you how to make sure your text-message and phone settings are set to private if you prefer.

(2) There is a risk that the treatments may not work for you or your depression gets worse. You may not have significant improvement in your depression, which may make you feel discouraged, upset, or hopeless about your ongoing issues with depression. Again, we can provide any referrals to your HIV care provider or social work staff at Ward 86 for any emergencies or other options you are interested in.

(3) Inconvenience: Some of the topics or themes described during the treatment sessions might make you uncomfortable; talking about your personal life, mental health, and/or experiences living with HIV may make you feel embarrassed, angry or uneasy in some way.

Some of the discussions we have may make you feel uncomfortable or upset, but you are free to decline to answer any questions you do not wish to answer or choose not to take part the study at any time.

Are there benefits to taking part in the study?
There is no direct benefit expected to you from taking part in the study. Your participation could help health professionals better learn more about HIV care and treatment for depression. You may also receive some relief from your depression given you will be taught skills to learn how to self-manage it. This benefit is not guaranteed but can occur if you complete the program.

What other choices do I have if I do not take part in this study?
You are free to choose not to participate in the study. If you decide not to take part in this study, there will be no penalty to you. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

As a patient of Ward 86, you can always seek psychiatric, medical and social services elsewhere. If you have interest in those programs, we are more than willing to make those referrals for you.

You can always choose other therapies and pharmacological treatments are complementary to our program - taking anti-depressant does not mean you cannot be in our study.

Will information about me be kept private?
Your personal information may be given if we identify reports of child abuse and neglect, or harm to yourself or others. However, we will do our best to make sure that the personal information gathered for this study is kept private. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used. However, we cannot guarantee total privacy.

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

- The University of California
- The National Institutes of Health (NIH) and other government agencies involved in keeping research safe for people.

Certificate of Confidentiality
We will do everything we can to keep others from learning about your participation in the research. To further help us protect your privacy, the investigators are given a

Confidentiality Certificate from the Department of Health and Human Services.

The investigators can use this certificate to refuse to disclose information (for example if there were a court subpoena) that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

Disclosure will be necessary, however, upon request of DHHS for the purpose of audit or evaluation.

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. Note however, that if an insurer or employer, learns about your participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy. Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others. The Certificate of Confidentiality will not be used to prevent disclosure to local authorities of child abuse and neglect, or harm to yourself or others. A Certificate of Confidentiality does not represent an endorsement of the research study by the Department of Health and Human Services or the National Institutes of Health.

What are the costs of taking part in this study?
You will not be charged for any of the study treatments or procedures.

Will I be paid for taking part in this study?
In return for your time, effort, travel expenses, and use of text-messages, you will be paid $30 per each session completed with the study. You will be asked to participate in 8-to-13 treatment sessions, and a post-treatment session. Not everyone will get the same amount, as this depends on the type of treatment that you got by chance, and how many sessions you completed. Some people will get a total of $240, whereas others may get up to $390 for completing all study sessions. However, this is based on the 50/50 chance of what treatment you received, and how many sessions you completed.

How will my information be used?
Researchers will use your information to conduct this study. Information gathered during this research study will only be used for this study. They will not be shared with other researchers.

What are my rights if I take part in this study?
PARTICIPATION IN RESEARCH IS VOLUNTARY. 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 you decide, there will be no penalty to you in any way. You will not lose any of your regular benefits, and you can still get your care from our institution the way you usually do.

Who can answer my questions about the study?
You can talk to us about any questions, concerns, or complaints you have about this study. My name is John A. Sauceda and my number is 650-761-0642.

If you have any questions, comments, or concerns about taking part in this study, please feel free to ask us at any time. If for any reason, you do not wish to do this, or you still have concerns after doing so, you may contact the office of the Institutional Review Board at UCSF (a group of people who review the research to protect your rights – Phone - 415-476-1814 or email – IRB@ucsf.edu).

CONSENT

You have been given a copy of this consent form 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 be in this study, or to withdraw from it at any point 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