A Culturally Tailored Web-Based Cognitive Behavioral Stress Management for Latino Sexual Minority Men living with HIV and Cancer

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Title of Study: *A Culturally Tailored Web-Based Cognitive Behavioral Stress Management for Latino Sexual Minority Men Living with HIV and Cancer*
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The purpose of this study is to evaluate a new, web-based, culturally-tailored program called SmartManage among Latino sexual minority men living with both HIV and cancer. SmartManage is a program that involves learning skills to aid in managing HIV and cancer, and interactive online group sessions.

How many people will take part in the study?
We expect about 30 men will be in this research study.

What happens if I say yes, I want to be in this research?
If you agree to take part in this study, your involvement will last about 12 weeks. You will be asked to complete an intake questionnaire online which will ask you a series of questions about your life such as quality of life, stress, and mood. We will also ask you questions about your health in general. This questionnaire should take about 30 minutes to complete. When you finish your intake questionnaire, the research staff will get you registered for your group on the SmartManage website. You will complete the SmartManage intervention over 10 weeks. For the intervention, you will review the website modules on your own, which cover: 1) HIV and cancer co-management, 2) communication, 3) partnering with your healthcare providers, and 4) sex and intimacy. The modules should take about 60 minutes to complete.

Each week, you will be part of an online interactive group that will discuss these topics and conduct exercises to build skills and reduce stress. The group session will include 4-6 people and last about 90 minutes. The group sessions will be led by a therapist and delivered via videoconference. All group discussions are confidential, and you are not required to use your name to participate in the group. Group sessions may be video or audio-recorded for the purposes of training and supervision. No recording will be done without your prior knowledge and consent. If you decline video or audio-recording, you will not be penalized in any way.

After you complete the 10-week intervention, you will be asked to take an online exit questionnaire, which will include questions about your quality of life, stress, and mood, as well as other health-related questions. The exit questionnaire will also include questions about your opinions on the SmartManage intervention and website. The exit questionnaire should take about 30 minutes to complete.

You will be invited to participate in a final interview. The interview will be conducted by phone or videoconference and last about 30 minutes. During this interview, you will be asked about any challenges or factors that influenced your participation in the program, the impact of the program on your health, and suggestions for improvement. You may choose to respond or not respond at any point during the discussion. Also, if you wish to stop the interview, you can do so at any time. The interview will be recorded either via videoconferencing software (e.g., Zoom) or audio-recorded and transcribed (written out word-for-word) for later review. If you prefer not to be video or audio-recorded, our staff will only take notes during the interview.

What should I think about before I enroll in this research?
You may want to participate because the intervention may help you build coping and communication skills that may in turn help improve and/or maintain your health and wellbeing. You may not want to participate because participation will take time and effort. You should ask any questions you may have and obtain answers before you decide.

Do I have to be in this research?
No. Your participation in this study is voluntary. You do not have to take part if you do not want to, and you can leave the study at any time. Whatever you decide, you will not be penalized or lose benefits.

Can I be removed from the research without giving my OK?
The person in charge of the research study can remove you from the research study without your approval. Possible reasons for removal include providing fraudulent data, the study team determining from your survey responses that you no longer meet eligibility requirements to participate in the study, the study team's belief that it is in your best interest, and any other reason deemed appropriate by the person in charge of the study.

Is there any way being in this study could be bad for me?
Some questions involve personal or sensitive information. You are always free to not answer a question if you do not want to.

You may be embarrassed or distressed when asked about health-related topics or when participating in the group sessions or individual interviews. You do not have to answer any

questions that you do not want to. The research team will be able to answer any questions you have at any point during the study procedures and refer you to a psychiatrist or clinical psychologist associated with the study to address any extreme acute or persisting distress, if needed.

Group sessions provide a particular challenge to confidentiality because it is possible that participants may repeat comments outside the group at some point in the future. We will ask you and others in the group not to talk to people outside the group about what was said in the group and to keep what was said in the group confidential. We will also ask you to attend the group sessions alone from a quiet, private, confidential room with no background noise.

Although every reasonable effort has been taken, confidentiality during internet communication activities cannot be guaranteed. Your confidentiality will be kept to the degree permitted by the technology being used. The study team will teach you how to set your username and password for this study.

What if I get hurt because of my participation in this study?
Although risks are unlikely, if injury should occur, treatment will in most cases be available. If you have insurance, your insurance company may or may not pay for these costs. If you do not have insurance, or if your insurance company refuses to pay, you will be expected to pay. Funds to compensate for pain, expenses, lost wages and other damages caused by injury are not available.

What are the benefits to being in this study?
By participating in this study, you may learn coping and communication skills, which may aid in improving your health.

What conflict of interest issues may be related to this research?
Dr. Frank Penedo, one of the investigators in this study, has disclosed that he has a personal interest related to this study.

The University of Miami has an interest related to the study.

Please ask any questions to assure yourself that this relationship has not overly influenced the conduct of this research study. If you require further information, please contact the study doctor or HRSO at 305-243-3195 to ask questions or discuss concerns.

If you have any questions regarding disclosure review and the conflict management process at UM, please call 305-243-0877.

What happens to the information collected for the research?
The researchers will keep all study records, including any codes to your data, in a secure location. This location will either be a locked file cabinet in a locked office or a secure server. Research records will be labeled with a code. A master file that links names and codes will be maintained in a separate and secure location. All electronic files containing identifiable information will be password-protected. Only the members of the research staff will have access to the passwords. At the end of this study, the researchers may publish their findings. Information will be presented in summary format and you will not be identified in any publications or presentations.

Your information may be looked at and/or copied for research or regulatory purposes by:

- The sponsor, if any;
- Department of Health and Human Services (DHHS);
- other government agencies;
- other University of Miami employees for audit and/or monitoring purposes; and
- other organizations collaborating in the research

A Certificate of Confidentiality (CoC), issued by the NIH, covers this research. A CoC helps protect your identifiable information. A CoC protects your private information from all legal proceedings. Unless you consent, information from this research study that identifies you will not be shared outside this research except as described above.

- No one can be forced to share your identifiable information for a lawsuit.
- Your information can't be used as evidence even if there is a court subpoena.

The CoC does not prevent some disclosures.

- The researchers can't refuse requests for information from those funding this research. The National Institute on Minority Health and Health Disparities may need information to assess this project.
- You can still share information about yourself. You can also freely discuss your involvement in this research, but this is your choice. The information you share will no longer be protected by the CoC.
- The researchers must disclose things required by law. This includes suspected child abuse and neglect, harm to self or others.

Please remember that while we (the researchers) will keep your information confidential and will remind all participants that what is said in the group should not be repeated outside of the group, we have no control over what happens outside of the group. You are reminded to not share anything you wouldn't want repeated outside of this group.

This trial will be registered and may report results on www.ClinicalTrials.gov, a publicly available registry of clinical trials.

Will the information collected be used in future research?

Information collected about you will be used for this research and may also be used for other research studies here at the University of Miami. We may also share the information with other institutions for research. Before using the information for other research, the study team will remove information that identifies you so the individuals performing the research will not know who the information came from. We will not ask for additional consent from you to use your information for the additional research.

Payment

If you agree to be in this research study, you will receive a $75 electronic payment (e.g., Zelle, digital gift card) for completing the intake questionnaire and $75 for completing the exit questionnaire. The initial payment will only be paid out if you continue to meet the eligibility criteria after the completion of the intake questionnaire. In addition, if you know of another person who is potential eligible (i.e., adult man with HIV and cancer) and would be interested in being in this study, we will offer an extra payment of $20 per referral. If you participate in the final interview, you will receive an extra payment of $25.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 305-243-3021.

This research has been reviewed and approved by an Institutional Review Board ("IRB").

The Human Subject Research Office (HSRO) provides administrative support to the University of Miami's IRBs. Please call the HSRO at 305-243-3195 if you are a participant in any research being conducted by UM, and:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

PARTICIPANT'S STATEMENT/SIGNATURE

- *I have read this form and the research study has been explained to me.*
- *I certify that the personal information I have given is true and accurate.*
- *I have been given the chance to ask questions, and my questions have been answered. If I have more questions, I have been told who to call.*
- *I agree to be in the research study described above.*
- *I will receive a copy of this consent form after I sign it.*

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

AUTHORIZATION FOR VIDEO/ AUDIO RECORDING

I hereby authorize the University of Miami, Department of Public Health Sciences, to take video and/or audio recordings of me. I authorize the University to use in any manner said video or audio recordings, in whole or in part for the purpose of training and supervision.

I agree that the University of Miami, its Trustees, officers, employees, faculty and agents will not be responsible for any claims arising in any way out of the taking and use as described above of such recordings. I understand that I will not have an opportunity to inspect and approve such recordings prior to their use.

I agree to be ☐ video and/or ☐ audio recorded for the purposes stated above.

☐ Yes ☐ No

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date

FUTURE STUDIES

We may conduct additional studies related to the study we are describing in this form. If we do conduct these studies, we will contact you at that future time to see if you would like to be part of the future study. Your participation in this study does not depend in any way on your participation on any future study. If we have difficulty finding you, we may call your contact persons to find out where you are.

I agree to be contacted for future studies

□ Yes □ No

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____
Printed Name of Person Obtaining Consent

_____ _____
Signature of Person Obtaining Consent Date