NCT03709472
Computer Assisted Family Intervention to Treat Self-Harm Disparities in Latinas and Sexual/Gender Minority Youth

Informed Consent date: 2/3/2022

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

Title of Study: Computer Assisted Culturally Informed Family Based Treatment of Adolescents
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Sponsor: National Institute of Minority Health and Health Disparities

Key Information: The following is a short summary of this study to help you decide whether you want to be in this study. More detailed information is given later on in this consent. You and your adolescent are invited to be in a research study. You can choose to take part in the study or not. We want to learn about how to help adolescents and families deal with problems. Within this study, you and your family will get treatment that can help with the types of problems your adolescent may be experiencing.

There are no major risks in being in this study. However, during the interviews or sessions, you could become upset when talking about your experience or other personal information.

No direct benefits are promised to you for being in this study. You and your adolescent may learn skills to better manage your mental health. Your time in this study may help us develop family-based therapies for others experiencing many different forms of stress.

If you do not want to be in this study, we will provide you with a resource sheet which lists other programs that might benefit you. This study is funded by the National Institute of Minority Health and Health Disparities and is part of the University of Miami.

Detailed Information: The rest of the form gives more detailed information about the study.

PURPOSE

The purpose of this study is to learn if a computer-assisted treatment to help adolescents with problems of depression, self-harm, family conflict, substance use, and emotional dysregulation will be successful at reducing these symptoms and improving family relationships. Two kinds of treatments will be compared in this study.

What should I know about this research study?

- Someone will explain this research study to you.
- Participation is voluntary.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the Program Director, Dr. Daniel Santisteban, at (305) 284-9511.

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.

How many people will take part in the study?

We expect about 100 adolescents (ages 11-18) and their families to be in this study.

What happens if I say yes, I want to be in this research?

- You and your family are to answer some questions to see if your family is a good fit for this study. This first set of questions should take about 60 minutes and will be completed either in person or virtually via Zoom.
    - <u>If this is not the right study for you</u>, you will be offered information on programs that can better serve you and your family.

- <u>If this is a good study for you</u>, you and your family will be asked to do another question session either in person or virtually via Zoom that will take about 2 hours. Questions ask

about your adolescent's behavior, emotional stress and difficulties. Some questions ask about how things are going in your family and at your adolescent's school. Your adolescent will also be asked about risky sexual behavior and experiences with physical or sexual abuse. Your answers will not be shared with family members unless the behaviors place the adolescent at risk. Our interviewers speak both English and Spanish. All of the questions are available in English and Spanish.

- You will be asked to do a second question session virtually via zoom that will take 2 hours (1 hour for child and 1 hour for parent). Questions ask about your family, what is important to your family, and other family questions related to gender, sexuality, and self-harm. Your answers will not be shared with family members unless the behaviors place you at risk. If you decide to do this extra question session, each child will be offered a $15 gift card to either Amazon or Target and each parent will also be offered a $15 gift card to either Amazon or Target.

- After the question session, your family will be assigned randomly (like flipping a coin) to one of the two treatments. The two treatments are:
  - **Computer Assisted Culturally Informed and Flexible Family Based Treatment for Adolescents (CA CIFFTA).** CA CIFFTA will be offered at the Institute for Individual and Family Counseling (IIFC) at the University of Miami or virtually via Zoom and includes:
    1. Family therapy sessions
    2. Individual adolescent therapy sessions
    3. Technology-delivered psycho-educational modules
  - **Treatment as Usual (TAU).** TAU will be offered through a treatment agency in the community or virtually via Telehealth and typically consists of:
    1. Traditional treatment with no technology

- Both treatments will last about 16 weeks. There will be an additional 8 weeks of continuing care. If it appears that your adolescent's symptoms are very severe and that they may be helped by medications (such as medications for depression), we will help make a referral to a physician. This is so that you can consider the option of medication for your adolescent.

- At the end of treatment, you and your adolescent will be invited to be in two follow-up question sessions in person or via Zoom. The first follow-up question session will be given after treatment is completed. The second follow-up question session will be given 6 months after treatment is completed. The question sessions allow us to evaluate if our program has helped your family. They will also help us learn whether we need to improve anything about our treatment. Each of the follow-up question sessions will about last 2 hours. We will pay you $75 at the post-treatment question session and $100 at the 6-month post-treatment question session for your time and effort. These questions will be similar to the ones you and your adolescent answered in the initial question session. If you or your adolescent feel uncomfortable answering any particular question or set of questions, you can choose not to answer them. The money will be given to you in person or sent through cash deposits via Zelle.

- We will also ask your permission for your adolescent's school records and any court records that he or she may have. We will ask you to sign a release of information so that we can obtain the information.

- We record all treatment sessions for research purposes. We review our sessions in order to learn how to change and improve treatment. We also do this in order to supervise therapists within the research study. Recordings have only case numbers and not names. Recordings will not be shared with anyone; only project staff will have access to them. Recordings will be destroyed within 5 years unless you provide a separate consent form to have them used for training. In this consent form, you are agreeing that videos will be used only for research purposes and not training purposes. With your permission, we might also use videos to train future family therapists. You can participate in this study even if you do not agree to have videos used in training. If you do agree, you will be asked to complete a separate form for using videos in training.

What happens if I say yes, but I change my mind later?

You can leave the research at any time. It will not be held against you. Remember, your participation in this study is completely voluntary. If you and your family decide to stop participating, you will be offered alternative treatments.

What should I think about before I enroll in this research?

Before you sign this consent form you should think about whether you can commit to attending therapy sessions every week for about 4 months. You should ask any questions you may have and obtain answers before you decide.

Is there any way being in this study could be bad for me? (Detailed Risks)

You and/or your adolescent may get tired or stressed from answering so many questions. Some questions can be personal. You and/or your adolescent may take a break at any time. Also, you do not have to answer any questions that you do not want to answer.

There are some risks in the treatment part of this study. We will not disclose any health information of other problems that you or your adolescent have to your family or friends. However, you or your adolescent may decide to disclose such things during therapy. If you or your adolescent decide to do this, you may feel embarrassed, distressed, sad, or guilty. There also may be times when disagreements come up with your adolescent. These disagreements may be difficult.

We may be required to report any risk to yourself and/or others, child abuse, neglect, or other forms of abuse to outside agencies. This is so we can help protect you.

You and your adolescent have the right to ask questions about the potential hazards of this study at any time. You and your adolescent will be asked to tell the study doctor about any possible discomfort you might have at any time during this study.

What happens to the information collected for the research?

Each person in the study will be given a code number. This code number will be used to identify all of your information. All information will be kept in locked cabinets and in protected electronic systems. Only the study researchers will have access to this information. When we report the results of the study, we will report group results. Your records and results will not be identified as belonging to you without your said permission.

We will limit the use and sharing of your personal information, like research study records, to only people who have a need to review this information. We cannot promise complete confidentiality. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. 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

One possible limitation on confidentiality is if information is revealed about harm to yourself or others, child abuse, neglect, or other forms of abuse. It is required by law to report this information to the appropriate authorities.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented to this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research, except 1) if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings; see below); 2) if you have consented to the disclosure, including for your medical treatment and related administrative activities; or 3) if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institute of Minority Health and Health Disparities which is funding this project, or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a

Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide written consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law such as harm to yourself or others, child abuse, neglect, or other forms of abuse that is required by law to be reported to the appropriate authorities. The Certificate of Confidentiality will not be used to prevent disclosure for any purpose that you have consented to in this informed consent document. Any information disclosed by your authorization may no longer be protected by the Certificate of Confidentiality.

By signing this consent form and the release of information, you give permission to the researchers to access your adolescent's school records. This is for us to know whether treatment is helping your adolescent do well in school or not. Information may be shared with the National Institutes of Health, and people working with the Sponsor to supervise the study. The Department of Health and Human Services (DHHS) may review these research records. Your records may also be reviewed authorized University of Miami employees or other agents (such as the Department of Children and Families) for audits. These authorized people will follow the same guidelines for confidentiality as the researchers.

U.S Law requires a description of this clinical trial to be available on http://www.ClinicalTrials.gov. This Web site will not have information that can identify you. The Web site will include a summary of the results. You can search this Web site at any time.

Can I be removed from the research without my OK?

Your participation in this study may be stopped at any time by the investigator or the sponsor without your permission. Some reasons for this include: 1) your adolescent is at particular risk for self-harm and more intense services are needed or 2) your adolescent is not attending treatment sessions and may be at risk for self-harm and/or other risky behaviors.

What else do I need to know?

Payment: If you agree to be in this study, we will pay you $75 at the post-treatment assessment and $100 at the 6-month post-treatment assessment for your time and effort.

Emergency Contacts: We will ask you for the names of 3 people who will always know how to reach your family. This information is so that we can find you. If we need to contact any of these people, we will only tell them that you are in a study at the University of Miami on families. We will not give them any other information about the study.

Your Alternatives.

1. If you and your adolescent choose to be in this research study, you will be asked to sign this consent form.
2. You and your adolescent can choose to not be in this study. Remember, there is no penalty to you if you decide not to participate in this study.
3. Alternative treatments are available in community agencies.

What if there are new findings?

You will be told about any new information that might change your decision to be in this study.

Benefits

This research is designed to benefit families and adolescents in the future because we can learn how to make our treatment better. You may benefit from the treatment offered to help you with your problems.

Costs

There are no costs to you for your participation in this study.

PARTICIPANT'S STATEMENT/SIGNATURE

- *I have read this form and the research study has been explained to me.*
- *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.*

_____
Adolescent Name (print)

_____ _____
Parent/Guardian Signature Date

_____
Parent/Guardian Name (print)

_____ _____
Signature of Person Obtaining Informed Consent Date

_____

Name of Person Obtaining Consent (print)