Community Study of Outcome Monitoring for Emotional Disorders in Teens

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Informed Consent Form

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Title of Research Study: Community Study of Outcome Monitoring for Emotional Disorders in Teens (COMET)

Expected Duration of Subject's Participation: Approximately 30 weeks

IRB Number: 20150187

External Sponsor/Funding Entity: National Institute of Mental Health (NIMH)

What Is The Purpose Of This Research Study?

This study is being done to compare three types of talk therapies for youth who struggle with emotional and behavioral problems (e.g., anxiety, sadness, worries) in Community Mental Health Clinics in Connecticut (CT) and Florida (FL). One of the treatments is the usual type of talk therapy used at your clinics, and the other two are treatments that were developed at other clinics, but that have not been used at your clinic. We do not know if one treatment is better than the other and they might work equally well. All therapies will be delivered by trained mental health clinicians in Community Mental Health Clinics to see if they help youth with emotional disorders. There is no medication involved in this study.

Who is Eligible to Participate?

Youth who are 12-18 years old and have problems with depression and/or anxiety will be invited to join the study. At least one parent must agree to participate because some of the questions are for parents to help the clinician get a good picture of how the adolescent is feeling and how treatment is going.

Youth will not be eligible to join the study if they have other mental health problems that require immediate treatment (like feeling or talking about hurting or killing themselves or others), or who are currently already receiving talk therapy for emotional problems. Youth who are not eligible to join this study may still receive treatment through existing options at the clinic.

Why Am I Invited To Participate?

You/your child are being asked to join because you/your child may be having difficulties at home, in school, or with family or friends related to anxiety and/or depression and are interested in seeking treatment at a Community Mental Health Clinic in Miami that is participating in this study. The clinic where you are seeking treatment has reviewed the study and has agreed to participate as one of the study clinic sites.

How Many Other People Do You Think Will Participate?
This study will take place in Community Mental Health Clinics in FL and CT. We expect to enroll at least 222 eligible adolescents aged 12-18 years old.

Is Participation Voluntary?
Participation in this study is voluntary. Before making a decision about whether to participate in this research study, please read this consent form carefully and discuss any questions you have with the researcher. You/your child may also want to talk with family members, your primary care physician or a friend before making a decision. If you/your child do not join this study, your relationship with your clinician, the clinic, or with the University of Miami will not be affected.

How Long Will My Participation In This Study Last?
Participation in this study will be for approximately 30 weeks.

What Are the Costs To Me For Participating In This Study?
Participants will not be responsible for any additional costs (other than what the usual cost for receiving treatment at the clinic would be) for participating in the research.

What Will I Be Asked to Do?
If you agree to participate in this study, we will ask you/your child to do the following things:

- You and your child will complete an evaluation with study staff to see if this study is right for you. The evaluation will take between 2-4 hours and will include completing an interview, questionnaires, and a computer task.
- If the study is right for you or your child, you or your child will be put into one of the three talk therapy groups randomly (by chance, like the flip of a coin). All of the participating clinics will have clinicians trained in each of the three groups.
- You will also complete evaluations with study staff at 8 weeks, 16 weeks, and 28 weeks after treatment has started in order to see how treatment is going.
- The information you/your child's shares about their feelings and behaviors with the study staff during these meetings will be shared with your treating clinician, so that he or she may best be able to help you/your child.
- The therapy sessions will be audio recorded and assessment interviews will be video recorded. Audio recordings and weekly forms will either be picked up by study staff or clinicians may upload the recordings and forms to a secure website (Dropbox or Box.com). These files will then be downloaded to the University of Miami and/or UConn server and password protected so they will only be accessible to study staff. This will be done to be sure that the clinician is delivering the therapy correctly and the interviewer is asking the right questions. The tapes will be reviewed only by members of our study team and no names will be written on the tapes. Nobody in the clinic will see or hear the tapes, only the study staff.
- The project will also access your/your child's clinic records to obtain information about the services you use at the clinic, what happened in your treatment sessions, and results of evaluations conducted by the clinic during your time in the study. Your clinic may ask you to sign an additional form giving the clinic permission to release that information to the project.
- Because this is a research study that uses copyrighted forms and follows standardized procedures including respecting children's confidentiality, no completed or blank copies of study forms will be shared.

What are the risks of participating?
You/your child may feel uncomfortable answering some of the study questions and/or being taped. You may always choose not to answer a question that makes you feel uncomfortable. Some of the computer tasks we ask you/your child to complete might be frustrating or difficult at times. There are no physical risks associated with participating in this study.

What Are the Benefits Of Participating In This Study?
While there is no guarantee of benefits, you/your child may feel better after treatment. Each of the 3 treatments is slightly different but each has its own potential benefit(s).

Will I Be Compensated For Participating In This Study?
Parent and child will be compensated up to $220 in this study. Payments will be delivered in the form of a gift card and will occur at each of the completed assessment points: $20 to the adolescent and $20 to the parent at the first assessment (before treatment starts), $10 to the adolescent and $10 to the parent at 8 weeks (because it is very short), and $40 to the adolescent and $40 to the parent at 16 weeks and 28 weeks.

Child may also receive up to $16 for his/her participation in a computer task that will occur at each of the 4 visits (up to $4 per visit). Payments will be delivered in the form of cash.

What Alternative Procedures or Treatments Are Available To Me?
You do not have to participate or allow your child to be in this research study. If you decide not to join or allow your child to join this study, you or your child can still receive the standard services available at the clinic. You can ask the clinician about other services available that may be of help to you or your child.

If you or your child does not join this study, neither you nor your child's care at the clinic will be affected.

How Will My Personal Information Be Protected?
The following procedures will be used to protect the confidentiality of study data. All research forms will be labeled with a code number (and no names will be used on data forms) to protect your identify. All contents of the research record will be labeled only with that code number.
All electronic files (e.g., databases, spreadsheets, etc.) containing any identifying information will be password protected. Any computer hosting such files will also have password protection to prevent access by un-authorized users. We will protect the confidentiality of your data to the best of our ability, but cannot guarantee 100% protection. However, our study team has a lot of experience handling private information and will all that we can to protect your personal information (e.g., not putting your name on any forms, locking your surveys in file cabinets so that no one can look at them, using secure computers and databases, and not talking to anyone outside of the study about your participation).

At the conclusion of this study the researchers intend to publish an article on their findings. Information will be presented in summary format and you will not be identified in any publications or presentations.

You should know that sometimes people who oversee studies at University of Miami may see your information to confirm that the researchers are adequately protecting your information. The sponsor, the National Institute of Mental Health, the Department of Health and Human Services, University of Miami's Institutional Review Board and the Human Subjects Protection Office may also inspect records. They may inspect records to ensure that the study is being done correctly. Also, if during the course of the study we learn of child abuse or neglect or suicidal/homicidal intent we are required to report it to State officials.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information or documents 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 for this use. Information or documents protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, 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); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects. The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect or suicidal/homicidal intent.

Contact over the Internet

Although contact over the Internet (e.g. information sent by e-mail or communication through programs such as Skype) is not secure and may not remain confidential, many of our participants prefer communicating with us over the Internet. In order to communicate with you via a communication program such as Skype or email, we need your permission. If you would like to take advantage of this option, please initial your choice below:
This is voluntary and will not affect your participation in the research study.

_____ I give staff permission to contact me over the internet.

_____ I do not give staff permission to contact me over the internet.

What If I Decide To Stop Participating In The Study?

- You and/or your child can agree to be in the study now and can change your mind later.
- If you and/or your child wish to stop being in the study, tell the study staff right away.
- Leaving this study early will not stop you or your child from getting regular medical care and will not affect your relationship with the clinic or with University of Miami.

If you decide to withdraw we ask that you let us know by calling Dr. Amanda Jensen-Doss, a Principal Investigator of the study, or by sending a written notice (contact information is on the first page). If you withdraw from the study, data that has already been collected will still be used for the study; no further information will be collected from you after study withdrawal.

Can Someone Else Make Me Stop Participating In This Study?

You and/or your child may be taken out of the study if:

- Staying in the study would be harmful or unsafe.
- The study is cancelled or has ended.
- There may be other reasons that we don't know at this time to take you and/or your child out of the study.

What if I Have Questions?

The Principal Investigator and all study staff are willing to answer any questions you have about the research. You are encouraged to ask questions before deciding whether to take part. You are also encouraged to ask questions during the study. If you have questions, complaints or concerns about the research, you should call one of the Principal Investigators (305-284-8332, 305-284-6476).

If you have questions about your rights as a research subject you may contact a coordinator at the Institution Review Board at (305) 243-3195.

Dr. Jill Ehrenreich-May is the first author of the therapist guide and workbooks for the Unified Protocols for Transdiagnostic Treatment of Emotional Disorders in Children and Adolescents (UP-C and UP-A) and receives royalties from these publications. She also receives payments for UP-C and UP-A clinical trainings, consultation and implementation support services.

You may also call a coordinator at the Institutional Review Board if you want to talk to someone who is not a member of the research team in order to pass along any suggestions, complaints, concerns or compliments about your involvement in the research, or to ask general questions or obtain information about participation in clinical research studies.

Please do not call the IRB number for medical related issues or to schedule or cancel an appointment.

Although you are taking part in a project funded by a grant to University of Miami, the UConn Institutional Review Board has also approved the study, as UConn project staff will be involved in supervision, consultation, and data analysis.

Consent To Participation:

By signing this form you acknowledge that you have read this informed consent document, have talked with research personnel about this study, have been given the opportunity to ask questions and have them satisfactorily answered, and voluntarily consent to participate in this project as described in this form.

By signing this form the individual obtaining consent is confirming that the above information has been explained to the subject and that a copy of this document, **signed and dated by both the person giving consent and the person obtaining consent**, along with a copy of the Research Participant Feedback Form, will be provided to the participant.

By signing this form, participants 18 years or older also grant permission for their parent(s) to take part in the study, and for their personal information to be shared with their parent(s).

Role	Printed Name	Signature	Date	Time
Subject		(if 18 years or older)		
Parent (if child is younger than 18 years old)				
Person obtaining consent				