Official Title: **Depression Prevention Initiative - A Study of Interpersonal Psychotherapy-Adolescent Skills Training (IPT-AST) in School Settings**

NCT #: **NCT01201382**

Version Date: **April 11, 2011**

DEPRESSION PREVENTION INITIATIVE
Parent Consent Form

Purpose of Study
You and your child are being asked to participate in a research study that is being conducted by Dr. Jami Young, who is a professor in the Graduate School of Applied and Professional Psychology at Rutgers University. The purpose of this study is to determine if different programs can help prevent depression in teenagers. You are being asked to participate in this study because your child reported having some symptoms of depression on the surveys/he completed in class. We do not know whether you child will develop more serious depression. These interventions are an attempt to prevent your child's symptoms from getting worse.

Study Procedures
This study provides counseling for teenagers with at least 2 symptoms of depression, but not enough symptoms to receive a diagnosis. This study involves being randomly assigned, that is by chance (like by flipping a coin), to receive a group intervention that focuses on improving relationships (Teen Talk) or a different group intervention that will be chosen by the school counselor (group counseling). All interventions will take place at the school.

Teen Talk will be led by research personnel who have been trained in this particular intervention. The Teen Talk program consists of2 40-minute pre-group individual sessions with the group leader before the group starts and then weekly (SO-minute) or twice weekly (40-minute) group sessions for approximately 8 weeks. Mid-way though the group, teenagers will attend an individual session with one of the group leaders. Parents will be invited to participate in this mid-group session. Following the group program, each teenager will meet with one of the group leaders for 4 individual booster sessions (lasting 40 minutes each), spaced out over a period of 6 months.

The remaining teenagers will participate in group counseling with a school counselor. The focus of the group will be determined by the counselor leading the group. Teenagers in group counseling will be seen individually for a 40-minute pre-group session and then will participate in weekly or twice weekly group sessions for approximately 8 weeks. Mid-way though the group, teenagers will attend an individual session with the school counselor. Parents will be invited to participate in this mid-group session. At the end of group counseling, each of the adolescents will meet with the school counselor for 4 individual booster sessions (40 minutes each) which will be spaced out over 6 months.

If you allow your child to participate in the study, we will ask you to fill out some basic information about him/her and about yourself. This assessment will take 1 hour. Next, your child will have an evaluation meeting of approximately 90 minutes in length to see ifs/he is eligible for the project. This evaluation will ask questions about depression and other emotional problems that teenagers may experience. Your child will be eligible to participate in the study ifs/he has at least 2 symptoms of depression, but not enough symptoms to receive a diagnosis. The information from this evaluation will be shared with the school counselor. This information will not be shared with other school personnel unless there is an indication of risk to your child, either because of suicidal ideation or behavior and/or reported child abuse.

Your child will not be eligible to participate in the study ifs/he does not have at least 2 symptoms of depression or is s/he has a depressive illness. If your child has a depressive illness, we will give him/her a referral to an outside agency for treatment. If your child has another emotional problem, we will let you know whether s/he is eligible to participate in the study and we will refer your child to an outside agency for treatment. We will consult with you and the school counselor about these treatment decisions.

Eligible teenagers will participate in an additional evaluation meeting of approximately I hour in length before starting the intervention. During this evaluation, your child will answer questions about feelings, relationships, and functioning. Mid-way through the group, your child will participate in another I hour evaluation to see how he/she is doing. Your child will complete evaluations again at the end of group and 6 months, I year, 18 months, and 24 months after group. Each of these evaluations will last about 90 minutes and will include questions about your child's feelings, relationships, and functioning.

If your child begins to feel worse during the project, s/he will be evaluated and referred for more intensive treatment if necessary, either with the school counselor or in the community. We will consult with you and the school counselor about these treatment decisions. If at any time during the project, an evaluation indicates a serious problem that requires immediate care, such as suicidal ideation or suspected abuse, we will work with you and the school counselor to determine the appropriate course of action. In the case of suicidal ideation or behavior, an adolescent will be considered at imminent risk ifs/he indicates intent to hurt self with a specified plan. If an adolescent is considered at imminent risk, we will inform you and the appropriate school personnel and we will work with the school to immediately link your child to emergency mental health services in accordance with the schools' usual crisis procedures. If your child does not have Medicaid or other health insurance, you will have to pay for the follow-up treatment that occurs in the community.

As part of your child's participation in the project, we will contact you by phone in the middle of the group, at the end of the program, and 6 months, 1 year, 18 months, and 24 months after the program to have you answer questions about yourself and your relations with your child. In addition, the project staff will track how your child is doing in school over the next 2.5 years. By signing this consent form, you give project staff permission to review your child's school records to help us understand if participation in groups helps school performance, such as school attendance, grade point average, and any disciplinary actions. You will also be asked to sign a release form inviting your child's teacher to provide information about how your child is doing at school.

Alternative to Study Participation

Many teenagers who have some symptoms of depression receive no treatment. Some teenagers get better over time and others get worse. The alternatives to participation in this study are for your child to not receive treatment, to receive treatment elsewhere, or to see the school counselor without participating in the study.

Participant's initials _

Audiotaping and Videotaping
You child's evaluations will be audiotaped as a requirement for participation in the study. We will also record sessions in both group programs, either using video or audio recording. These recordings will help the research team understand how the group interventions work. All recordings (CDs/DVDs) will be stored for five years after the study is completed, after which they will be destroyed. Like all research information, these recordings will be stored in a secure location and will be kept confidential.

Risks
The evaluations are time consuming and are about personal matters. It is possible that you or your child will feel upset, tired, or anxious. If this happens, you or your child can choose not to answer specific questions or ask to have the evaluation stopped at any time. Some teenagers may experience mild distress when they talk about their problems in the group intervention programs. This will be monitored and addressed throughout the project and, if needed, your child will be referred for additional treatment. If your child discloses thats/he intends to harm him/herself or intends to harm someone else, both you and the appropriate authorities will be notified. If your child discloses potential child abuse, this·information will be reported to the appropriate authorities.

Benefits
Possible benefits of participating in the study include a decrease in depressive symptoms and improved functioning. These interventions may also help prevent your child from developing a depressive disorder later on. In addition, this research may help scientists learn more about the prevention of depression in teenagers. However, your child may or may not receive any direct benefit from taking part in this study.

Compensation
Your child will receive a $20 gift certificate for each ofthe following assessments s/he completes: eligibility, baseline, mid-intervention, post-intervention, 6-months, 12-months, 18-months, and 24-months post-intervention resulting in a possible total of$160 over approximately· 2.5 years. You will receive a $10 gift certificate for each assessment you complete: baseline, mid-intervention, post-intervention and follow-up assessments, with a possible total of $70 over 2.5 years. The gift certificates are to pay for time spent completing the evaluations. If you, or your child, do not complete an assessment, you will not be paid for that assessment. Your child will receive a gift certificate following each assessments/he completes. Since most of your assessments will take place over the phone, your gift certificates will be mailed to you following completion of the assessment. If you and your child complete the first evaluation and are not eligible for the study, your child will receive a $20 gift certificate and you will receive a $10 gift certificate. You will not receive further compensation.

Confidentiality
All records will be coded and regular access will be restricted to members of the research team. Records will be kept at Rutgers University. Electronically stored data will be coded and password protected in a secure database. The research team and the Institutional Review Board (a committee that reviews research studies in order to protect research participants) at Rutgers University are the only parties that will be allowed to see the data, except as may be required by

law. If a report of this study is published, or the results are presented at a professional conference, only group results will be stated. All study data will be kept for 5 years after the study has been closed.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, crimin,al, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects 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 or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances: suspected or known neglect or sexual or physical abuse of a child, or threatened violence to self or others. Such information will be reported to the appropriate authorities.

If during the evaluation or intervention, your child reports a serious problem that may jeopardize his/her safety or health, then the researchers will contact you and appropriate school personnel, unless there is a very good reason not to. Research staff may not be able to discuss this with your child first. In the group programs, other students in the group will hear his/her thoughts and feelings. We ask that everyone respect the confidentiality of other group members, but there is a risk that confidentiality will not be maintained.

Research Standards and Rights

Your participation and your child's participation are voluntary. You can refuse to participate or discontinue participation at any time, without any penalty. A decision not to participate will not affect the services your child receives at school and will not affect his/her grades. In addition, you and your child may choose not to answer any questions with which you are not comfortable.

You and your child will be notified of any significant new findings that may relate to your willingness to continue to participate in this study. Rutgers University does not provide compensation or payment for treatment of research related injuries.

The investigators will answer to the best of our ability any questions that you may have now or in the future about the procedures described above. If you are concerned about any aspect of the project, please do not hesitate to contact Dr. Jami Young (the Principal Investigator) at:

Graduate School of Applied and Professional Psychology
Rutgers University
152 Frelinghuysen Road
Piscataway, NJ 08854-8085
Tel: 848-445-3934
Email: jfyoung@rci.rutgers.edu

The Rutgers University Institutional Review Board has reviewed this study. If you have any questions about your rights as a research participant, you may contact the IRB Administrator at Rutgers University at:

Rutgers University Institutional Review Board for the Protection of Human Subjects
Office of Research and Sponsored Programs
3 Rutgers Plaza
New Brunswick, NJ 08901-8559
Tel: 732-932-0150 x 2104
Email: humansubjects@orsp.rutgers.edu

Statement of Consent

Your child will also be asked ifs/he wishes to participate in this study. Sign below if you agree to participate and agree to allow your child to participate in this research study. You will be given a copy of this consent form for your records.

Name of Child (Print)_____

Name of Parent/Legal Guardian (Print)_____

Parent/Legal Guardian's Signature_____ Date_____

Name of Study Staff Witness (Print) _____

Study Staff Witness' Signature_____ Date _____

APPROVED
Date: 5/4/11

EXPIRES

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Approved
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Videotaping and Audiotaping Consent

Your child's evaluations will be audiotaped as a requirement for participation in the study. We will also record group sessions in both interventions to better understand the techniques that are being used in the groups, using either audio or video recording. In addition, the recordings of the Teen Talk sessions will be used to ensure adherence to particular techniques and strategies, to assist in supervision, and for training Teen Talk group leaders. These recordings (CDs/DVDs) will be stored for five years after the study is completed, and then will be destroyed. Like all research information, the recordings will be stored in a secure location and will be kept confidential.

Your signature on this form grants the investigator named above permission to record your child as described above during participation in the above-referenced study. The investigator will not use the recordings for any other reason than that/those stated in the consent form without you and your child's written permission.

Name of Child (Print)_____

Name of Parent/Legal Guardian (Print)_____

Parent/Legal Guardian's Signature_____ Date_____

Name of Study Staff Witness (Print)_____

Study Staff Witness' Signature_____ Date _____

EXPIRES

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