Parental Permission

TITLE OF PROJECT: Treating anxiety and oppositional problems
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1. PURPOSE OF PROJECT:
Your child invited to participate in a study that will determine how effective and feasible a 12 week treatment is for children who have generalized anxiety disorder (GAD) and oppositional defiant disorder (ODD). Generalized anxiety is characterized by a wide range of worries that are difficult to control, including worries about school, friends, health of self or others, and world events. Behaviors associated with these worries can include avoidance, reassurance seeking, physical symptoms, and can be interfering. Oppositional defiance is marked by inappropriate levels negative, defiant, disobedient, and hostile behaviors toward authority figures. Behaviors associated include temper outbursts, persistent stubbornness, unwillingness to compromise, a persistent testing of limits and even verbal and minor physical aggression. Children who experience both GAD and ODD can be particularly susceptible to difficulties regulating emotions and controlling their behaviors. This project will compare symptoms of GAD and OCD before treatment, after treatment, and again at a 1 month follow up. The treatment involves 12 weekly sessions. The treatment is designed to assess the efficacy and feasibility of an emotion focused cognitive behavioral therapy and collaborative problem solving (CPS) for the family. Children will learn to identify and cope with a variety of emotions. Together, the family will learn CPS to solve problems together, in order to reduce negative behaviors.

2. PROCEDURES:
To accomplish the goals of this project, your child will first be randomly (by chance) assigned to a waitlist that lasts between 2 to 4 weeks. It is necessary for us to have a brief waitlist condition so that we can determine if any change in your child’s behaviors occurs simply due to the passage of time and that your family participated in the assessment. After the specified time on the waitlist, the treatment will begin. Treatment sessions will be approximately 90 minutes long for 12 weeks. This will be a cumulative 18 hours of therapy, over the span of 12 weeks. The treatment itself consists of approximately 45 minutes of emotion focused cognitive behavioral therapy for your child and 45 minutes of family collaborative problem solving, in each session. The child portion will focus on identifying emotions (e.g., happy, sad, angry, worried) in the self and others and coping strategies for these emotions include relaxation, self-talk, and challenging negative thoughts. The family collaborative problem solving will emphasize looking for unsolved problems in the family which lead to negative behaviors in the child. The family will be taught to work together, taking everyone’s concerns into account, in order to reach viable solutions to implement in the home. Each week you will be asked to record how your child is doing. Additionally, after treatment, we will ask you to return to the clinic for an assessment approximately one week and one month after completion, so we can assess how things are going.

In order to determine whether the treatment is effective, your child will be asked a variety of questions and administered a semi-structured diagnostic interview about your child, prior to the beginning of the experimental treatment (3 hours), following treatment (2 hours), and at a 1 month follow up (2.5 hours). The total amount of assessment time will be approximately 7.5 hours, over the span of many months. These questions will be focused on your child’s level of worry, disruptive behaviors and other problems
your child may be experiencing, and what currently happens when your child experiences these behaviors. All sessions you and your child attend at the clinic will be videotaped. Videotaping is done for the purpose of reliability, to document that our interviewers and therapists carefully followed the research protocol.

3. RISKS:
There may be some risks from your participation in the study. It is possible that your child may feel uncomfortable answering some of the questions asked. Your child does not have to answer any questions or discuss any topics that make your child feel uneasy nor will your child ever be asked to do anything he/she is not prepared to do. Of course, your child may stop participating in the project at anytime if he/she feels too uncomfortable. However, to minimize this discomfort and to help your child manage the discomfort should it occur, all project staff are highly trained. The therapists and graduate student clinicians working on the project have experience working with children and families, and are being supervised by Dr. Ollendick, a licensed clinical psychologist with over 35 years of experience working with children.

4. BENEFITS:
Results of this study may help us determine whether this treatment is effective for youth with GAD and ODD and whether the format is feasible for children and their families. Such a development would allow us to share this information with other mental health professionals and to assist them in working with other children and adolescents. Although no guarantee of treatment outcome can be provided to you, it is anticipated that this experimental treatment will benefit your child.

5. EXTENT OF ANONYMITY AND CONFIDENTIALITY:
Results of this study will be kept strictly confidential. At no time will we release your results to anyone without your written consent unless you have indicated that you will hurt yourself or someone else, or that your child has indicated that someone is hurting him/her, or that he/she has or intends to hurt himself/herself or someone else. In that situation, by law it would be necessary for us to report that information to the Department of Social Services and/or the police immediately. If a child is identified as suicidal or homicidal, the child will be referred to another mental health agency (e.g., inpatient hospitalization), or to the Emergency Room, as deemed appropriate. Such interventions would be necessary in order to ensure the safety of the child and/or others. Additionally, therapists and assessors are at times subpoenaed to provide testimony and requested by court order to provide information and/or records, and in such cases information would have to be shared by law. In all other cases, the information you provide will have your name removed and only a subject number will identify you during analyses and any write-up of the research.

The treatment sessions will be conducted by graduate clinicians enrolled in the doctoral program in clinical psychology at Virginia Tech. All clinicians will be supervised by Dr. Ollendick. As noted above, all sessions will be videotaped. The videotapes will be reviewed by research assistants (undergraduate and graduate students in the Psychology Department at Virginia Tech) and evaluated to ensure that the treatments are being implemented appropriately. The videotapes will be erased at the end of the study.

6. COMPENSATION:
The experimental treatment will be offered to you free of charge. No direct compensation will be offered for your participation. However, if as a result of the project, it is determined that you or members of your family should seek counseling, a list of local services will be provided. Additional counseling would be at your own expense.
7. FREEDOM TO WITHDRAW:
You are free to withdraw from participation in this study at any time without penalty. Should you choose to withdraw there will not be any penalty regardless of the reason for your decision to do so. You are also free to not answer any questions that you choose without penalty.

8. USE OF RESEARCH DATA:
The information from this research may be used for scientific or educational purposes. It may be presented at scientific meetings and/or published and reproduced in professional journals or books, or used for purposes that Virginia Tech’s Department of Psychology considers proper in the interest of education, knowledge, or research. Only persons directly affiliated with the project, such as the Principal Investigator, Faculty Advisor, graduate students in psychology affiliated with the project, or trained undergraduate research assistants will have access to confidential participant information.

9. SUBJECT’S RESPONSIBILITIES:
I voluntarily give permission for my child to participate in this study. My child has the following responsibilities:
• Completing and returning questionnaires
• Participating in therapy sessions
• Participation in interviews and assessments

10. SUBJECT’S PERMISSION:
I have read the above description of the study. I have had an opportunity to ask questions and have them answered. I hereby acknowledge the above and give my voluntary consent for my child’s participation in this study.

I further understand that if my child participates s/he may withdraw at any time without penalty.
I understand that should I have any questions regarding this research and its conduct, I should contact any of the persons named below.

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CHILD’S NAME: __________________________________________________________

PARENT/GUARDIAN’S NAME:_________________________________________Date: ___________

PARENT/GUARDIAN’S SIGNATURE: _______________________________________Date: ___________

WITNESS:_______________________________________________________Date: ___________