

Official Title: Evaluating an Online Adjunctive Support following Intensive Services (OASIS) Strategy for Youth with Selective Mutism

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PARENTAL CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Evaluating Remote Treatment Options for Youth with Selective Mutism

SUMMARY INFORMATION

Things you should know about this study:

- **Purpose:** The purpose of the study is to learn about how best to treat children with selective mutism. We want to know if remote treatment options help children with selective mutism.
- **Procedures:** If you agree to be in the study, you, your child, and your child's teachers will complete study assessments. Your family will also receive treatment for selective mutism. You will participate in videoconferencing-based group parent training sessions. Your family will also be given the option to participate in a videoconferencing-based intensive group behavioral treatment program.
- **Duration:** This will take about 9 months.
- **Risks:** The main risk or discomfort from this research is feeling emotional during study procedures.
- **Benefits:** The main benefit to your child from this research is possibly experiencing less anxiety or distress.
- **Alternatives:** Other treatments may be available to your family through the Florida International Center for Children and Families or other local mental health providers.
- **Participation:** Taking part in this research project is voluntary.

Please carefully read the entire document before agreeing to participate.

PURPOSE OF THE STUDY

The purpose of this study is to learn about how best to treat children with selective mutism. We want to know if remote treatment options help children with selective mutism. Your family is being asked to be in this study because your child is between the ages of 4 and 10 years and he or she may have selective mutism.

NUMBER OF STUDY PARTICIPANTS

If you agree to be in this study, your family will be one of 20 families in this research study.

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DURATION OF THE STUDY

Your family will be in this research study for up to 9 months. In March or April 2020, you will complete a 2-hour assessment by phone. You will also complete a 1-hour set of questions online. This assessment will determine whether your family is eligible for the study. In June 2020, you will complete another 1-hour assessment by phone. You will also complete a 1-hour set of questions online. Your family will participate in the videoconferencing-based group parent training sessions between June 26-July 12, 2020 and, if your family opts in, the videoconferencing-based intensive group behavioral treatment (remote IGBT) program July 20-24, 2020. In August, you will complete another 1-hour assessment by phone. You will also complete a 1-hour set of questions online. Regardless of whether your family participates in the remote IGBT, you will complete a final 1-hour assessment by phone in November 2020. You will also complete a 1-hour set of questions online. In total, your family's participation in this study should include no more than 40-50 hours across 9 months.

PROCEDURES

If your family agrees to be in this study, we will ask you to do the following things:

1. **Intake:** To find out whether your family is eligible to be in the study, you will be asked to complete a 2-hour assessment by phone with one of our study therapists in March or April 2020. You will also be asked to complete a 1-hour set of questions online. You will also be asked to give our research team your child's 2019-2020 school year teacher's email address. We will then ask your child's teacher to complete a 10-minute set of questions online. Your child's teacher will receive a \$15 electronic gift card for completing these questions.
 - a. You will be asked to make sure your child does not start or change medications between June and November 2020.
2. **Baseline:** If your family is eligible to be in the study, you will be asked to complete another 1-hour assessment by phone with one of our study therapists in June. You will also be asked to complete another 1-hour set of questions online.
3. **Parent Training:** You and your child's other caregivers will attend 3 videoconferencing-based group parent training sessions, totaling 5 hours, offered between June 26-July 12, 2020.
4. **Lead-In Sessions:** If your family opts in to participating in the remote IGBT, you will present for individual videoconferencing-based sessions between July 13-July 19, 2020. This is to make sure your child can talk to at least 1 study therapist before the remote IGBT begins.
 - a. If your child cannot talk to at least 1 study therapist during individual sessions, your family will not be eligible to participate in the remote IGBT.
5. **Remote IGBT Program:** If your family opts in and is eligible, you will attend the remote IGBT program July 20-24, 2020.
 - a. Your child will attend the remote IGBT for approximately 2-3 hours per day (depending on your child's age/developmental level) and will be in an online classroom with other children. Your child will be paired with an individual study therapist each day.
 - i. Your child will also participate in a 10-minute assessment at the beginning and end of each remote IGBT session.

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- b. You and your child's other caregivers will participate in at least 1 videoconferencing-based, "live" parent coaching session, during which a study therapist will guide you through use of treatment-related strategies with your child.
6. Post-Treatment: Regardless of whether your family opts in to participating in the remote IGBT, you will also be asked to complete another 1-hour assessment by phone with one of our study therapists in August 2020. You will also be asked to complete another 1-hour set of questions online. You will receive a \$50 electronic gift card for completing these assessments. You will also receive a report including your child's symptoms, your family's participation, and our recommendations.
7. Follow-Up: In November 2020, you will be asked to complete a final assessment by phone with one of our study therapists. You will also be asked to complete a final 1-hour set of questions online. You will receive a \$50 electronic gift card for completing these assessments. You will also be asked to provide our research team with your child's 2020-2021 school year teacher's email address. We will then ask your child's teacher to complete a 10-minute set of questions online. Your child's teacher will receive a \$15 electronic gift card for completing these questions.
8. In total, your family's participation in this study should include no more than 40-50 hours across 9 months.
9. Your participation is completely voluntary, and you are free to withdraw from the study at any time. If you decide to withdraw from the study, you will still be invited to participate in study assessments.
10. Your family's assessments with study staff may be recorded on digital audio and/or video. The recordings will only be viewed by research staff involved in the study. These recordings will be saved as password-protected files on password-protected computers at Florida International University. Only the research team will have access to these files. These recordings will be stored for seven years after the study ends. Then, they will be destroyed.
 - a. You or your child can request that recordings are destroyed at any time. However, recording is required for the study, so this would mean your family could no longer participate in the study.

RISKS AND/OR DISCOMFORTS

The study has the following possible risks: First, you or your child may feel emotional or uncomfortable when answering questions for the study. You and your child do not have to answer any questions that make you feel uncomfortable and you can take a break or stop answering questions at any time. Second, you or your child may feel discomfort during treatment sessions. This is because part of the treatment includes having your child face his or her fears. Third, allowing us to use and store your family's information comes with the risk of a potential loss of privacy. We will protect your family's privacy by labeling your information with a code and keeping the key to the code in a password-protected file on a password-protected computer at Florida International University.

BENEFITS

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Your family may or may not benefit from being in this study. The study has the following possible benefits to your family: First, your child may experience less anxiety or distress after being in the study. Second, you may experience less parenting stress after participating in the study. Third, others may benefit in the future from information learned from this study. Finally, your family will receive a report that documents your child's symptoms, your family's participation in the treatment program, and our clinical recommendations.

ALTERNATIVES

Your family does not have to take part in this research study. Other treatments may be available to your family through the Florida International Center for Children and Families or other local mental health providers. Any significant new findings developed during the course of the research which may relate to your child's willingness to continue participation will be provided to you. If you are not interested in the research aspects of the program, you may still participate in the same fee-for-service treatment options.

CONFIDENTIALITY

The records of this study will be kept private and will be protected to the fullest extent provided by law. In any sort of report we might publish, we will not include any information that will make it possible to identify your child. Research records will be stored securely and only the research team will have access to the records. However, your child's records may be inspected by authorized University or other agents who will also keep the information confidential.

We will keep study records confidential in the following ways:

1. Your family's information will be de-identified by using a code, so that no identifying information is directly connected to your study records, except for on one master key. This key will be the only link between the code and your family's information and will be kept in a password-protected file on a password-protected computer at Florida International University that can only be accessed by the research team.
2. All study data will be stored on password-protected files on password-protected computers at Florida International University that can only be accessed by the research team.
3. All hard copy data will be stored in a locked filing cabinet in a locked office at Florida International University that can only be accessed by the research team.
4. Your family's study data will not be shared with individuals outside of Florida International University, but it is possible that your family's records could be reviewed for audit purposes by authorized University or other agents who will also keep the information confidential.
5. Only first names will be used in study assessments and treatment sessions.
6. All of your family's study materials will be shredded and destroyed in seven years.

If we learn about serious harm to you or someone else, we will take steps to protect the person endangered even if it requires telling the authorities without your permission. If we have reason

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to believe that your child is being abused, we will report this to the Florida Abuse hotline. In these instances, we would only disclose information to the extent necessary to prevent harm.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by US Law. This web site will not include information that can identify your child. At most, the web site will include a summary of the results. You can search this website at any time.

USE OF YOUR CHILD’S INFORMATION

- Identifiers about your child might be removed from the identifiable private information and, after such removal, the information could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

COMPENSATION & COSTS

Your child’s teacher will receive a \$15 electronic gift card for completing online questions prior to your family participating in remote treatment services. Your family will receive a \$50 electronic gift card for completing the Post-Treatment program assessments. Your family will receive a \$50 electronic gift card for completing Follow-Up assessments. Your child’s teacher will receive a \$15 electronic gift card for completing online questions during the Follow-Up assessments. The remote treatment options under study are being offered as part of an ongoing fee-for-service treatment program, thus, you are expected to pay for treatment. The cost of your family’s treatment will be based on a sliding scale that takes into account your family’s income and number of dependents and ranges from \$150-\$1,750 based on which components your family agrees to participate in. There are no additional costs to your family for participating in the research aspects of this program.

RIGHT TO DECLINE OR WITHDRAW

Your child’s participation in this study is voluntary. Your child is free to participate in the study or withdraw his/her consent at any time during the study. Your child will not lose any benefits if he/she decides not to participate or if your child quits the study early. The investigator reserves the right to remove your child from the study without your consent at such time that he/she feels it is in the best interest.

RESEARCHER CONTACT INFORMATION

If you have any questions about the purpose, procedures, or any other issues relating to this research study you may contact Dr. Jonathan Comer, Ph.D. at the Center for Children and Families at Florida International University by phone at 305-348-7580 or email at jocomer@fiu.edu.

IRB CONTACT INFORMATION

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If you would like to talk with someone about your child's rights of being a subject in this research study or about ethical issues with this research study, you may contact the FIU Office of Research Integrity by phone at 305-348-2494 or by email at ori@fiu.edu.

AUTHORIZATION TO USE OR DISCLOSE HEALTH INFORMATION

If you sign this document, you give permission to the health care providers at Florida International University (FIU) Center for Children and Families and the study researchers to use or disclose (release) your child's health information that identifies your child in this research study.

What information may be used and given to others?

The health information that may be used or given to others includes your child's personal and medical information. For example:

- Past and present medical records
- Research records
- Records about your child's study visits

Who will use or receive my child's health information?

The health information listed above will be given to the study researchers. The information may also be given to the study sponsor, the Institutional Review Board (IRB) that reviewed this research, authorized FIU agents, and other federal or state agencies as necessary.

Why will this information be used and/or given to others?

To do the research, to study the results, and to make sure that the research was done right.

Is my child's health information protected after it has been given to others?

Those persons who receive your child's health information may not be required by Federal privacy laws to protect it and may share your child's information with others without your permission, if permitted by laws governing them.

What if I decide not to give permission to use and give out my child's health information?

You do not have to sign this document, but if you do not, your child will not be able to be in this research study. If you do not sign this document, your child's right to other medical treatment will not be affected.

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May I withdraw or revoke (cancel) my permission?

You may change your mind and withdraw or take back your permission at any time. When you withdraw your permission, no new health information identifying your child will be gathered after that date. Information that has already been gathered may still be used and given to others. To withdraw your permission, you must write to: Dr. Jonathan Comer, Ph.D. at the Florida International University Center for Children and Families, 11200 S.W. 8th St., AHC-1-140, Miami, FL 33199.

Does my permission have an expiration date?

This permission does not have an expiration date.

PARTICIPANT AGREEMENT

I have read the information in this consent form and agree to participate in the portions of the study marked with my initials (select one):

_____ By entering my initials here, I agree that my family will participate in the remote parent training sessions and all study assessments.

_____ By entering my initials here, I agree that my family will participate in the remote parent training sessions, the remote IGBT program, and all study assessments.

I have had a chance to ask any questions I have about this study, and they have been answered for me. I understand that I will be given a copy of this form for my records.

Signature of Parent/Guardian

Date

Printed Name of Parent/ Guardian

Printed Name of Child Participant

Signature of Person Obtaining Consent

Date