

Engaging Siblings of Adults with Autism in Future Planning

NCT03374072

9/09/2020 – Informed Consent Form



Consent Form

Protocol Title: Engaging Siblings in Future Planning
Principal Investigators: Gael Orsmond & Kristin Long
Description of Subject Population: Adult siblings interested in family future planning
Version Date: August 31, 2020

Introduction

Please read this carefully. We want to provide you with important information about taking part in a research study. If any of the statements or words in this form are unclear, please let us know. We would be happy to answer any questions.

If you have any questions about the research, please ask us. Taking part in this research study is up to you.

The people in charge of this study are Gael Orsmond and Kristin Long. Dr. Gael Orsmond can be reached at 617-353-2703 or gorsmond@bu.edu. Dr. Kristin Long can be reached at 617-358-4296 or KALong@bu.edu. We will refer to these people as the “researchers.”

Why is this study being done?

The purpose of this study is help adult siblings become involved in family future planning with their brother/sister and parents. We are developing a program to help siblings with family communication around difficult topics, increasing siblings’ knowledge of and confidence in accessing service systems, and problem-solving skills. We will be enrolling adult siblings and their brother or sister.

We are asking you to take part in this study because your sibling is interested in learning more about family communication, accessing service systems, and problem-solving skills. About 45 families will take part in this research study. Siblings will be asked to complete several questionnaires at three time points. Some of the siblings (approximately 20 siblings) will review online information about future planning and services, while others will participate in the Siblings FORWARD program, a 6- or 7-session online program with a facilitator. You will be asked to complete questionnaires at three time points, and some will be asked to participate in

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two sessions of the Siblings FORWARD program with their brother or sister who is participating in this research study.

The National Institute of Mental Health (NIMH) is paying for this research to be done.

How long will I take part in this research study?

We expect that you will be in this research study for approximately 7 months. This includes completion of measures at the start of the study, 3-4 months later (after you have reviewed the information or participated in the online program), and 6-7 months later.

What will happen if I take part in this research study?

If you agree to take part in this study, we will ask you to indicate your willingness to continue on to the measures. After you complete this first set of questionnaires, you will be randomly assigned to one of two groups: some siblings will receive a link to online information and others will be asked to participate in the Siblings FORWARD program, which includes 6- or 7-sessions online with a facilitator. All participants will be asked to complete questionnaires. You will be asked to complete questionnaires via the internet or over the phone with a Boston University researcher at each of the time points below. You may also request a paper-and-pencil copy be mailed to you for completion.

Time 1 Measures

Completing the measures will take between 15 and 40 minutes. If you want to complete the measures with someone, you can ask someone to help you, or we or someone at the Arc can help you do it over the telephone. You will be asked to do the following:

- Ask and answer any questions about this research and give your permission to participate.
- Complete questionnaires about how you see your life, what types of services or supports you receive and need, and how you view your family relationships.
- Learn whether or not your sibling was assigned to participate in online program

We will assign your family by chance (like a coin toss) to one of two study groups. In one group, your brother or sister will review some information online. In the other group, your brother or sister will participate in 6 or 7 online sessions. Neither your family nor the researcher can choose your study group. Your family will have an equal chance of being assigned to either study group.

Meeting with Sibling (online program participants only)

If your brother or sister participates in the online program, you will be asked to participate in two of the program meetings. During these meetings, you will be asked what you want in the future and how you want your brother or sister to be involved. These meetings are expected to last about one hour. You can choose where to participate in these meetings (e.g., at the Arc or at the same location as your brother/sister such as their home, office, etc.).

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Time 2 Measures (all adults)

Approximately 4 months after the meetings with your sibling, we will ask you to complete questionnaires. This will take about 10-40 minutes to complete. You can do this online, over the telephone, or in person at the Arc with a Boston University researcher. We will ask you to complete questionnaires about how you see your life, what types of services or supports you receive and need, and how you view your family relationships.

Time 3 Measures (all adults)

Approximately 3 months later, we will ask you to complete the same measures again. This will take about 10-40 minutes. You can do this online, over the telephone or in person at the Arc with a Boston University researcher.

Video Recording

We would like to video-record the online program sessions. We will store these digital video-recordings on a secure network drive at Boston University, and only approved study staff will have access to these recordings. We will label each program session digital file with a code instead of a name. The researchers will keep a list of the participants in a locked file in their office and/or in a separate password-protected computer file. These digital files will be kept for up to 10 years and then deleted.

If you are assigned to the online program, do you agree to let us video-record you during this study?

_____ YES _____ NO _____ INITIALS

Storing Study Information for Future Use

We would like to store your study information for future research related to sibling relationships, adult future planning for individuals with disabilities, and family programs. We will label all your study information with a code instead of your name. The key to the code connects your name to your study information. The researcher will keep the code in a password-protected computer/locked file.

Do you agree to let us store your study information for future research related to sibling relationships, adult future planning for individuals with disabilities, and family programs?

_____ YES _____ NO _____ INITIALS

How Will You Keep My Study Records Confidential?

We will keep the records of this study confidential by identifying your information with a code instead of your name. The key to the code that connects your name to the information that you provide to us (i.e., the data) will be kept in a password-protected computer file. We will keep all

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of your data in a locked cabinet and/or in a password-protected file on our secure server that can only be accessed by members of our research team. We will keep your identifying information (e.g., your name) in a separate locked cabinet.

We will make every effort to keep your records confidential. However, there are times when federal or state law requires the disclosure of your records. Here are some reasons why we might need to disclose your records:

If, during your participation of this study, we have reason to believe that you are at risk for being suicidal or otherwise harming yourself, we are required to take the necessary actions. This may include notifying your doctor, your therapist, or other individuals. If this were to occur, we would not be able to assure confidentiality.

In the course of the study, it is possible that the research team will receive a report of abuse to a child, an elder, or a disabled person. If, during your participation in this study, we have reasonable cause to believe that abuse is occurring, the research team must report this to authorities as required by law; specifically, abuse of a disabled person will be reported to the MA Disabled Persons Protection Commission (DPPC).

The researchers will make every reasonable effort to protect the confidentiality of your research information. However, it might be possible that a civil or criminal court might demand the release of identifiable research information.

The following people or groups may review your study records for purposes such as quality control or safety:

- The Researcher and any member of the research team
- The Institutional Review Board at Boston University. The Institutional Review Board is a group of people who review human research studies for safety and protection of people who take part in the studies.
- The sponsor or funding agency for this study
- Federal and state agencies that oversee or review research

The results of this research study may be published or used for teaching. We will not include identifiable information on data that are used for these purposes.

Data from this study may be submitted to the National Institute of Mental Health Data Archive (NDA). The NDA is a data repository run by the National Institute of Mental Health (NIMH) that allows researchers studying mental health and substance use to collect and share deidentified information with each other. A data repository is a large database where information from many studies is stored and managed. Deidentified information means that all personal information about research participants such as name, address, and phone number is removed and replaced with a code number. With an easier way to share, researchers hope to learn new and important things about mental illnesses more quickly than before.

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During and after the study, the researchers will send deidentified information about your health and behavior to NDA. Other researchers nationwide can then file an application with the NIMH to obtain access to your deidentified study data for research purposes. Experts at the NIMH who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

You may not benefit directly from allowing your information to be shared with NDA. The information provided to NDA may help researchers find better treatments. NIMH will also report to Congress and on its web site about the different studies that researchers are conducting using NDA data. However, you will not be contacted directly about the data you contributed to NDA.

You may decide now or later that you do not want to share your information using NDA. If so, contact the researchers who conducted this study, and they will tell NDA, which can stop sharing the research information. However, NDA cannot take back information that was shared before you changed your mind. If you would like more information about NDA, this is available online at <http://data-archive.nimh.gov>.

In addition, for participants who are randomly assigned to a condition, a description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Study Participation and Early Withdrawal

Taking part in this study is your choice. You are free not to take part or to withdraw at any time for any reason. No matter what you decide, there will be no penalty or loss of benefit to which you are entitled. If you decide to withdraw from this study, the information that you have already provided will be kept confidential.

Future Contact

We may like to contact you in the future either to follow-up to this study or to see if you are interested in other studies taking place at Boston University.

Do you agree to let us contact you in the future?

_____ YES _____ NO _____ INITIALS

What are the risks of taking part in this research study?

Thinking about the future may be challenging at times. You may be uncomfortable with some of the questions and topics we will ask about. You do not have to answer any questions or participate in any sessions that make you feel uncomfortable.

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The main risk of allowing us to use and store your information for research is a potential loss of privacy. We will protect your privacy by labeling your information with a code and keeping the key to the code in a password-protected computer.

Are there any benefits from being in this research study?

Siblings and their family members who participate in the online meeting may perceive direct benefits, such as skill development, knowledge, and a greater sense of their desired future involvement. Others may benefit in the future from the information that is learned in this study. The information you share with us may help identify the need for services and supports for other adults and their families.

What alternatives are available?

You may choose not to take part in this research study.

Can I still get services for myself or my family member(s) if I choose not to participate in this research study?

Yes, you may still get services for you or your family member(s) if you choose not to take part in this study. Your decision will not change the care you receive now or in the future. Taking part in this research is your choice. If you decide to take part in this study, you may leave/stop the study at any time. There will be no penalty to you and your services will not be affected. If you would like to stop taking part in this research you should let us know.

Will I get paid for taking part in this research study?

You will receive \$25 for completing the Time 1 and Time 2 measures and another \$25 for completing the Time 3 measures. There is no compensation specifically for reviewing online materials or attending the Siblings FORWARD online sessions.

What will it cost me to take part in this research study?

There are no costs to you for taking part in this research study.

If I have any questions or concerns about this research study, whom can I talk to?

You can call us with any concerns or questions. Our telephone numbers are listed below:

Gael Orsmond, Ph.D.
Associate Professor, Department of Occupational Therapy
617-353-2703

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Kristin Long, Ph.D.
Assistant Professor, Department of Psychological and Brain Sciences
617-358-4296

If you have questions about your rights as a research participant or want to speak with someone independent of the research team, you may contact the Boston University IRB directly at 617-358-6115.

Statement of Consent: I have read this information have been given the chance to contact the researchers to ask questions. I agree to participate in the study.

☐

(check box and continue to start survey)

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