

Title: Examining the Active Ingredients of Consultation to Improve Implementation of a Parent-mediated Intervention for Children With Autism in the Community Mental Health System

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Research Participant Information and Consent Form

Study Title: Examining the active ingredients of consultation to improve implementation of a parent-mediated intervention for children with autism in the community mental health system

Researcher and Title: Diondra Straiton, M.A., Graduate Student & Brooke Ingersoll, Ph.D., Professor

Department and Institution: Michigan State University Department of Psychology

Contact Information: Diondra Straiton, straiton@msu.edu, 203-241-0173

Sponsor: This study is funded by the National Institute of Mental Health under Award Number F31MH127814 (PI: Straiton) and the Autism Science Foundation under Award Number UNDG 22-002 (PI: Greateorex).

BRIEF SUMMARY:

You are being asked to participate in a research study. Researchers are required to provide a consent form to inform you about the research study, to convey that participation is voluntary, to explain risks and benefits of participation including why you might or might not want to participate, and to empower you to make an informed decision. You should feel free to discuss and ask the researchers any questions you may have.

You are being asked to participate in a research study to examine the active ingredients of consultation to improve implementation of Project ImPACT for children with autism in the community mental health system. Your participation in this study will take about 6.5 months in total. This will include a self-directed online tutorial, attendance at weekly consultation sessions, completing weekly online questionnaires, and submitting recorded telehealth sessions and a final questionnaire 8-weeks post-consultation.

PURPOSE OF RESEARCH:

The purpose of this study is to identify the potential active ingredients of a consultation model designed to improve implementation outcomes within a community mental health system. Groups of 3-5 providers will be recruited from four applied behavior analysis (ABA) agencies (~20 providers in total) that contract with the Michigan Medicaid Autism Benefit. To be eligible, you must meet the following criteria:

- At least 18 years of age
- Qualified to bill through the Medicaid Autism Benefit through the community mental health system in Michigan.
- Have at least one caregiver on your caseload who would be appropriate for Project ImPACT who agrees to enroll in the study. Appropriate caregivers must be at least 18 years of age and their child must meet the following criteria:
 - Have a community diagnosis of ASD established using the Autism Diagnostic Observation Schedule OR other validated autism diagnostic tool
 - Receive services through the Medicaid Autism Benefit OR meets household income criteria consistent with families enrolled in Medicaid

- Child age between 18 months and 6 years
- Have at least 1 ABA session per week with you

WHAT YOU WILL BE ASKED TO DO:

You will be asked to complete a 6-hour self-directed online tutorial on Project ImPACT and will have 2 weeks to do this. Next, your agency will be randomly assigned to the length of the baseline period (between 3-6 weeks) and the order in which you will receive consultation components. Either you or the research team will record one parent coaching session per week between you and your enrolled family. You will complete weekly online questionnaires on implementation outcomes (e.g., feasibility of Project ImPACT), with time reserved during consultation sessions to complete them. Consultation will be conducted in 4-week phases. During the feedback phase, you will be asked to select 5-minute clips of session recordings and receive oral feedback by the consultant and peers. During the case support phase, the consultant will lead the group in problem-solving common barriers that providers experience with their cases. During the skill rehearsal phase, the consultant will lead skill rehearsal practices in which you will role play elements of a Project ImPACT session. During the follow-up period, consultation will not occur, and you will continue implementing Project ImPACT with your cases. Eight weeks post-consultation, the research team will record a Project ImPACT session with your enrolled family. You and the caregivers will also complete a final online questionnaire. Finally, we will ask you to participate in three 1-hour interviews regarding your thoughts about the consultation phases and Project ImPACT.

At the end of this consent form, you will be asked if you are willing to give permission to use the video collected during this research study for other purposes. These other purposes are voluntary and are not required to participate in the research study.

POTENTIAL BENEFITS:

You will directly benefit from your participation in this study by receiving training and consultation in Project ImPACT, an evidence-based parent training intervention to improve social communication skills in children with autism spectrum disorder. Consultation will help you by providing you with additional support regarding how to use Project ImPACT with your current clients. Your participation in this study will also help us to better understand which components of consultation are the most helpful in supporting providers to use an intervention (feedback on taped sessions, case support discussions, or skill rehearsal).

POTENTIAL RISKS:

By participating in this study, there are some minimal risks. Because consultation and telehealth sessions will be video and audio recorded, it is possible that these recordings may be viewed by someone who is not meant to see them. This is unlikely because we will either have clinicians use a HIPAA compliant server to upload all research recordings OR session recordings will be auto-recorded on Zoom and saved to the MSU research team's Zoom cloud. By 7:00 pm EST each weekday, the research team will upload all recordings to a secured server housed by Michigan State University and delete all files from the Zoom cloud (if applicable). If you give permission for us to use the video recordings for additional purposes, we will keep copies of those recordings secure in a HIPPA compliant online server. You may also feel minor discomfort in filling out questionnaires. You are free to skip any question that you prefer not to answer.

PRIVACY AND CONFIDENTIALITY:

Consultation sessions will be video and audio recorded so that research staff can verify the components that were utilized in each consultation session (e.g., feedback on taped sessions). Session recordings will be uploaded directly to the encrypted MSU server following each consultation session. Telehealth sessions will be video and audio recorded so that research staff can measure your adherence to the Project ImPACT manual and competence in parent coaching. Telehealth sessions will either be recorded by you and then uploaded to a HIPAA compliant online server OR auto-recorded on Zoom and saved to the MSU research team's Zoom cloud. Recordings will then be uploaded to an encrypted server at MSU by research staff.

Interviews will be audio recorded so that they can be transcribed. Information that identifies you will be removed from the transcripts, and then the recordings will be deleted. The transcripts, which are not linked to you, could be used for future research studies, or distributed to another investigator for future research studies without additional informed consent from you.

You will not be identified in any presentation or written reports about this study unless you give permission below for us to use video recordings for other purposes outside of the research project. If so, the video recordings would include images and audio of you and your child, but no presentations or written reports would include other identifiable information like your names or contact information. These additional video permissions are optional. All survey data will be collected online via Qualtrics, a secure HIPAA compliant web-based database for survey collection. Information from the web-based surveys that you fill out will be identified by numerical ID code only. Your identifying information (e.g., name and contact information) will be kept on a secure university server and will be kept separate from your study data. The de-identified study data will be downloaded from Qualtrics into a separate database on a secure university server.

After 3 years, all audio and video recordings will be destroyed unless you give permission below for us to use video recordings for other purposes outside of the research project. Our research team and the Michigan State University Human Research Protections Program will have access to this study information.

Researchers cannot release or use information, documents, or samples that may identify you unless you say it is okay. However, researchers may release this information if required by law, such as reporting of child or elder abuse and threats to harm yourself or others. You are welcome to discuss your own involvement in the research with others, and you are also welcome to access to your own information.

Agency leaders will only be provided with aggregate data from their agency, meaning that no identifiable data or information will be shared with agency leaders. All shared data will be averaged across all providers at your site. Agency leaders will not be provided with direct quotes from your interviews.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil,

criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

YOUR RIGHTS TO PARTICIPATE, SAY NO, OR WITHDRAW:

Participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. You have the right to say no. You may change your mind at any time and withdraw. You may choose not to answer specific questions or to stop participating at any time. Choosing not to participate or withdrawing from this study will not affect your job performance at your agency.

COSTS AND COMPENSATION FOR BEING IN THE STUDY:

You will be compensated \$45 in total for your time.

RESEARCH RESULTS:

We will share de-identified reports with data averaged across providers at your agency.

FUTURE RESEARCH

If you give permission, the audio and video recordings of your Project ImPACT telehealth sessions may be used for related research about how community providers use Project ImPACT via telehealth.

The interview transcripts could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

CONFLICT OF INTEREST:

Dr. Ingersoll is a co-developer of Project ImPACT. She receives royalties from Guilford Press for the curriculum and fees for training others in the program. Dr. Ingersoll donates profits from this work to support research and continued development of Project ImPACT.

CONTACT INFORMATION:

If you have concerns or questions about this study, such as scientific issues, how to do any part of it, or to report an injury, please contact the researchers:

Brooke Ingersoll, Ph.D., BCBA-D: ingers19@msu.edu, 517-432-8412

Diondra Straiton, M.A.: straiton@msu.edu, 203-241-0173

If you have questions or concerns about your role and rights as a research participant, would like to obtain information or offer input, or would like to register a complaint about this study, you may contact, anonymously if you wish, the Michigan State University's Human Research Protection Program at 517-355-2180, Fax 517-432-4503, or e-mail irb@msu.edu or regular mail at 4000 Collins Rd, Suite 136, Lansing, MI 48910.

ADDITIONAL INFORMATION:

I agree to allow audiotaping/videotaping of the consultation sessions, telehealth sessions, and interviews for research purposes. I understand that this is required for my participation in the study.

Video recordings of consultation sessions and telehealth Project ImPACT sessions will be transferred to the secured university server. These recordings will remain there for 3 years and will then be deleted, unless you give permission for other purposes below. Interview transcripts will be de-identified and audio recordings of interviews will be immediately destroyed upon completion of transcription, which will be completed within 2 years of data collection.

☐ Yes

☐ No

Initials _____

Please initial below to indicate **which additional uses** of video recordings you are willing to consent. Your video will only be used in the ways you consent to below. You may choose to give permission to any number of the uses listed below and you are also able to decline giving permission for the uses listed below.

No identifying information besides images and audio of you would be shared if you were to give permission for the uses listed below.

Uses	Initials
1. The video and still images can be shown during in-person or virtual training for professionals.	_____
2. The video and still images can be shown at scientific meetings and professional talks.	_____
3. The video and still images can be used in a password-protected online tutorial for professionals.	_____
4. The video and still images can be used in a password-protected online tutorial for families.	_____
5. The video and still images can be show to other families as part of coaching/clinical services.	_____
6. The video can be shown to university students for educational purposes.	_____

7. The video can be used in future research through the MSU Autism Lab. _____

Video Consent and Release

Your Contact Information

Name: _____

Email: _____

Phone: _____

Please indicate if we can contact you in the future about additional uses of your video.

- ☐ Yes, you may contact me
- ☐ No, you may NOT contact me.

DOCUMENTATION OF INFORMED CONSENT.

By clicking the arrow below, you are indicating that you voluntarily agree to participate in this research study and that you give permission for the video recordings to be used as indicated above.

Research Participant Information and Consent Form

Study Title: Examining the active ingredients of consultation to improve implementation of a parent-mediated intervention for children with autism in the community mental health system

Researcher and Title: Diondra Straiton, M.A., Graduate Student & Brooke Ingersoll, Ph.D., Professor

Department and Institution: Michigan State University Department of Psychology

Contact Information: Diondra Straiton, straiton@msu.edu, 203-241-0173

Sponsor: This study is funded by the National Institute of Mental Health under Award Number F31MH127814 (PI: Straiton) and the Autism Science Foundation under Award Number UNDG 22-002 (PI: Greatorex).

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You are being asked to participate in a research study. Researchers are required to provide a consent form to inform you about the research study, to convey that participation is voluntary, to explain risks and benefits of participation including why you might or might not want to participate, and to empower you to make an informed decision. You should feel free to discuss and ask the researchers any questions you may have.

You are being asked to participate in a research study to examine the active ingredients of consultation to improve implementation of Project ImPACT for children with autism in the community mental health system. Your participation in this study will take about 6.5 months in total. This will include granting permission for your provider to record one telehealth session per week with you and your child and completing online surveys about your child's social communication at 4 time points.

PURPOSE OF RESEARCH:

The purpose of this study is to identify the potential active ingredients of a consultation model designed to improve implementation outcomes within a community mental health system. Groups of 3-5 providers will be recruited from four applied behavior analysis (ABA) agencies (~20 providers in total) that contract with the Michigan Medicaid Autism Benefit. Approximately 20 families who work with enrolled providers will participate.

To be eligible, you must meet the following criteria:

- Be at least 18 years of age
- Have a child between 18 months and 6 years who has a community diagnosis of ASD established using the Autism Diagnostic Observation Schedule OR other validated autism diagnostic tool
- Receive services through the Medicaid Autism Benefit OR meet household income criteria consistent with families enrolled in Medicaid
- Have at least 1 ABA session per week with your provider

WHAT YOU WILL BE ASKED TO DO:

Your provider or the research team will record one telehealth session per week between your provider and your family. Your provider will receive consultation and support on how to deliver Project ImPACT, an evidence-based parent training intervention to improve social communication in young children with autism spectrum disorder (ASD). You will be asked to give permission to have your child's Project ImPACT telehealth sessions recorded weekly during the time period before, during, and 8-weeks after your provider completes consultation. At 4 different timepoints, you will complete measures of social communication for your child via an online questionnaire. During the follow-up period, your provider will continue implementing Project ImPACT with you. Eight weeks after your provider finishes consultation, your provider or the research team will record one more Project ImPACT session. You and your provider will also complete a final online questionnaire 8 weeks after your provider finishes consultation.

At the end of this consent form, you will be asked if you are willing to give permission to use the video collected during this research study for other purposes. These other purposes are voluntary and are not required to participate in the research study.

POTENTIAL BENEFITS:

You will directly benefit from your participation in this study by receiving Project ImPACT, an evidence-based parent training intervention to improve social communication skills in children with autism spectrum disorder. Your participation in this study will also help us to better understand which components of consultation are the most helpful in supporting providers to use an intervention.

POTENTIAL RISKS:

By participating in this study, there are some minimal risks. Because consultation and telehealth sessions will be video and audio recorded, it is possible that these recordings may be viewed by someone who is not meant to see them. This is unlikely because we will either have clinicians use a HIPAA compliant server to upload all research recordings OR session recordings will be auto-recorded on Zoom and saved to the MSU research team's Zoom cloud. By 7:00 pm EST each weekday, the research team will upload all recordings to a secured server housed by Michigan State University and delete all files from the Zoom cloud (if applicable). If you give permission for us to use the video recordings for additional purposes, we will keep copies of those recordings secure in a HIPAA compliant online server. You may also feel minor discomfort in filling out questionnaires. You are free to skip any question that you prefer not to answer. All survey data will be collected online via Qualtrics, a secure HIPAA compliant web-based database for survey collection. Study staff will have access to study data on a "need to know basis" only. All study staff will receive confidentiality and security training and extensive training on data management and storage.

PRIVACY AND CONFIDENTIALITY:

Consultation sessions will be video and audio recorded so that research staff can verify the components that were utilized in each consultation session (e.g., feedback on taped sessions). Session recordings will be uploaded directly to the encrypted MSU server following each consultation session. Telehealth sessions will be video and audio recorded so that research staff can measure your provider's adherence to the Project ImPACT manual and competence in parent coaching. Telehealth sessions will either be recorded by your clinician and then uploaded to a HIPAA compliant online server OR auto-recorded on Zoom and saved to the MSU research

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Researchers cannot release or use information, documents, or samples that may identify you unless you say it is okay. However, researchers may release this information if required by law, such as reporting of child or elder abuse and threats to harm yourself or others. You are welcome to discuss your own involvement in the research with others, and you are also welcome to access to your own information.

Results from this study will not affect your child's services. The research team will provide ABA agency leaders with trends in data averaged across all families and providers at the agency. No identifiable information about you or your family will be shared with your child's ABA agency.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

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Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons

not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

YOUR RIGHTS TO PARTICIPATE, SAY NO, OR WITHDRAW:

Participation is voluntary. Refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled. You may discontinue participation at any time without penalty or loss of benefits to you or your child which you are otherwise entitled. You have the right to say no. You may change your mind at any time and withdraw. You may choose not to answer specific questions or to stop participating at any time. Choosing not to participate or withdrawing from this study will not affect your job performance at your agency.

COSTS AND COMPENSATION FOR BEING IN THE STUDY:

You will be compensated \$45 in total for your time.

RESEARCH RESULTS:

We will share de-identified reports with data averaged across providers to your child's ABA agency.

FUTURE RESEARCH

If you give permission, the audio and video recordings of your Project ImPACT telehealth sessions may be used for related research about how community providers use Project ImPACT via telehealth.

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Brooke Ingersoll, Ph.D.: ingers19@msu.edu, 517-432-8412

Diondra Straiton, M.A.: straiton@msu.edu, 203-241-0173

If you have questions or concerns about your role and rights as a research participant, would like to obtain information or offer input, or would like to register a complaint about this study, you may contact, anonymously if you wish, the Michigan State University's Human Research Protection Program at 517-355-2180, Fax 517-432-4503, or e-mail irb@msu.edu or regular mail at 4000 Collins Rd, Suite 136, Lansing, MI 48910.

ADDITIONAL INFORMATION:

I agree to allow audiotaping/videotaping of my child's Project ImPACT telehealth sessions for research purposes. I understand that this is required for my participation in the study.

Video recordings of telehealth Project ImPACT sessions will be transferred to the secured university server. These recordings will remain there for 3 years and will then be deleted, unless you give permission for other purposes below.

☐ Yes

☐ No

Initials _____

Please initial below to indicate **which additional uses** of video recordings you are willing to give permission for. Your and/or your child's video will only be used in the ways you consent to below. You may choose to give permission to any number of the uses listed below and you are also able to decline giving permission for the uses listed below.

No identifying information besides images and audio of you and your child would be shared if you were to give permission for the uses listed below.

Uses	Initials
1. The video and still images can be shown during in-person or virtual training for professionals.	_____
2. The video and still images can be shown at scientific meetings and professional talks.	_____
3. The video and still images can be used in a password-protected online tutorial for professionals.	_____
4. The video and still images can be used in a password-protected online tutorial for families.	_____
5. The video and still images can be show to other families as part of coaching/clinical services.	_____
6. The video can be shown to university students for educational purposes.	_____
7. The video can be used in future research through the MSU Autism Lab.	_____

Video Consent and Release

Your Contact Information

Name: _____

Email: _____

Phone: _____

Child(ren)'s Name (if applicable): _____

Please indicate if we can contact you in the future about additional uses of your and/or your child(ren)'s video.

- ☐ Yes, you may contact me
- ☐ No, you may NOT contact me.

DOCUMENTATION OF INFORMED CONSENT.

By clicking the arrow below, you are indicating that you voluntarily agree to participate in this research study and that you give permission for the video recordings to be used as indicated above.