Refining and Pilot Testing a Decision Support Intervention to Facilitate Adoption of Evidence-Based Programs to Improve Parent and Child Mental Health

NCT 1171-0623

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Informed Consent for Participation in Research
Phase 2

Project Title:	Refining and Pilot Testing a Decision Support Intervention to Facilitate Adoption of Evidence-Based Programs to Improve Parent and Child Mental Health (NIMH Grant no. K01MH128761)
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Why is Lighthouse Institute doing this study?
This study is a part of a larger research study to learn more about how decision-makers select interventions. We will use this information to help support the use of effective interventions and practices in child welfare.

What will happen?
You will be asked to do three things:

1) Use ORCA (Optimizing Responses for Collaborative Action), a tool to help you consider which interventions might be the best fit for your jurisdiction based on your expertise and preferences. Specifically, you will be asked to use ORCA to consider interventions that might be newly implemented or continue to be implemented as part of your jurisdiction's Family First Prevention Services Act (FFPSA) prevention plan.
- We expect it will take you about 20-30 minutes to complete the tool.

2) Participate in one of two methods for reviewing ORCA's results with your peers, including individuals with whom you already make decisions. All participants in your jurisdiction will participate in the same method.

Method 1: "Live ORCA"- uses a "live" facilitator from our research team.
Expected to take 90-120 minutes over two sessions, but can be flexible to your jurisdiction's preferences

- Occurs over video-conferencing software or in-person, depending on your jurisdiction's preference.
- Discussion will be audio and video recorded.

Method 2: "automated ORCA" or, self-guided.

- The time required is up to your group, though we recommend at least 60-90 minutes.
- We will ask that your group record with a video-conferencing tool that we provide (e.g., Zoom account or similar)

3) Complete web-based surveys at three time points: (1) before using ORCA (Activity 1), (2) immediately after the final live or automated session (Activity 2), and (3) one-year after the final session in Activity 2. These surveys will ask questions about your experiences with group decision making, your thoughts on the interventions that are considered for implementation, your thoughts on the ORCA tool, and some demographic information.

How is this study organized?
Your jurisdiction, along with three other jurisdictions, have agreed to take part in this study. Each jurisdiction is randomly assigned one of two methods for making decisions with ORCA. Participants in each jurisdiction will complete the ORCA tool to rate interventions based on their expertise, decision

priorities, and evidence. ORCA will show how each participant's intervention ratings compared to ratings by other participants in their jurisdiction. Next, each jurisdiction will participate in either: Method 1) Live ORCA, group discussions facilitated by the study team, or Method 2) Automated ORCA — suggested processes for groups to make decisions with the ORCA tool. The processes are designed to be integrated into your jurisdiction's existing decision-making format (i.e., meetings). The study aims to recruit all individuals who typically help make these decisions and/or provide important input into these decisions. All participants will complete the same surveys.

Compensation
You can receive $40 gift cards for completing ORCA on your own and for each completed survey. If you cannot receive gift cards due to your professional position, you can choose to have the $40 donated to your organization or a non-profit organization. In total, you can receive up to $160 in gift cards or donations for completing ORCA and all three surveys. For your participation in decision meetings using ORCA as part of the study, as described above, a donation will be made to your organization, or a non-profit organization of your choice. You may also decline compensation.

How will my information be used for research?
Sessions will be audio and video recorded for research purposes only. The recordings will be transcribed and coded to improve the usability and acceptability of ORCA, ORCA Live, and ORCA Automated. Videos files will be deleted after the transcriptions are verified. Audio files will be deleted three years after the study is complete.

How will information about me be shared with others?
Your information will only be used for research, monitoring, and safety purposes. Any written reports shared with the public will only talk about groups of people and not individuals.

This research is funded by the National Institutes of Health (NIH). NIH requires that we share de-identified data through secure databases so that others can also learn from this research (see https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html). Therefore, your survey answers may be shared with other researchers through a data file. Your name and other information that could identify you, such as where you work, will be taken out of your data file before it is given to anyone else for research. These data files will only have an ID number attached. Your personal information will not be made public. Any information that can identify you will be kept separate from data files. Only the Principal Investigator and study staff who need to contact you will have access to your name and contact information. This information will be kept in a secure file.

NIH might also look at our records as part of an audit or evaluation. They are required to keep your information confidential and secure. We also have a **Certificate of Confidentiality** from NIH. This means we cannot be "forced" to give out any information to anyone that tells them you are in this study. However, we would share information about you with the appropriate individuals if you tell us you are going to hurt yourself or others. We also would share your information with the appropriate authorities if you tell us about a time when you have or might hurt an older person, or if we have concerns about the well-being of a child for whom you provide care. Given the nature of the proposed research activities, we do not anticipate that you will disclose such details.

The ORCA Live and Automated decision-making session(s) (#2 listed above in the "What Will Happen" section) may take place during regularly scheduled meetings within your jurisdiction. There may be policies, regulations, or laws which require these meetings to be public. In such cases, it may not be possible to ensure the confidentiality of your participation in this research. However, your responses to ORCA and the surveys (#1 and #3 listed above in the "What will happen" section) will remain confidential without your express consent to make this information public.

We understand that you may hold a position subject to policies, regulations, or laws regarding public disclosure of activities related to your position. Upon your request and with your consent, your information (Name, Organizational Affiliation) and ORCA Responses can be made publicly available. Your information and ORCA Responses will remain confidential without your express consent and request to make public this information.

Consent to Be Recorded
If you participate in the study, the ORCA Live and Automated decision-making session(s) will be recorded so that members of the study team can transcribe. This means that they will create a written copy of what you said aloud. They will use the transcripts to look for common patterns to better understand group decision-making processes. If you have something very private to say, you have the right to tell the staff to turn off the recorder. If you do not want to be video recorded, you can turn off your camera (if the session is virtual) or sit outside of the video frame (if held in-person) and we will only record audio. If your jurisdiction requires that these sessions not be recorded, we will not record them.

What risks am I taking?
There is a chance that some information about you could be found out. This is not usually a problem. All recordings and identifiable information are kept in locked files or on secure servers. Staff who work on these studies have been trained in protection of your information and are required to follow federal laws, which protect your information. They must follow the rules in the **Certificate of Confidentiality.** There is also a chance that you might feel uncomfortable with some of the questions asked. You are free to refuse to answer any question you are uncomfortable with.

What if I want to quit the study or change what I have consented to?
You may remove yourself from the study at any time by informing Dr. Cruden (Principal Investigator) or Dr. Kelly (Project Manager). This can be during the session or between sessions by contacting Dr. Cruden (gcruden@chestnut.org; 843-513-9928) or Dr. Kelly (tskelly@chestnut.org 309-451-7917). When you stay in this study, you are helping us understand how to support decision making for evidence-based practices. I understand that if I wish to change my responses to any of the following statements (numbered 1-5 below), I can contact Dr. Cruden or Dr. Kelly.

Please read the following statements carefully, then indicate whether you agree or decline to participate in the study.

I agree to take part in the study:

The study has been explained to me. I had a chance to ask questions. I understand that I can choose not to answer any question and that I can take myself out of this study at any time. No one has made any promises about how the study will turn out. My personal information related to the study will be protected and kept private according to federal law. When my information is looked at for a required review or to protect my safety, my records will be protected by federal laws.

I understand that if I have questions or concerns, I can contact the main person in charge of the study. The person in charge is Dr. Gracelyn Cruden (Phone: 843-513-9928, Email: gcruden@chestnut.org). I understand that if I wish to change my responses to any of the following statements (numbered 1-5 below), I can contact Dr. Cruden or Dr. Kelly. If I have questions about my rights as a person in this research study, I can contact the person in charge of protecting my rights, Dr. Ralph Weisheit, at 309-451-7855. I understand that Dr. Weisheit is not a member of the study team.

Consent to Participate:

1 I hereby ___ agree / ____ do not agree (check **one**) to take part in the study that is described in this consent form. I have been given a copy of the consent form.

2 _____ I confirm that I have read this consent, my questions have been answered, and that the signature is mine.

Please review the following statements and check one response for each. Your responses do not impact your eligibility to participate. You can change your responses at any time.

Compensation:

3 I hereby___accept /____decline (check **one**) direct compensation/donation of compensation for my participation in this study.

Making my organization's name public:

4 ___ I hereby **agree** to have my **organization's** name associated with this project in public-facing activities and research products, such as presentations, reports, and manuscripts. I understand that my name will remain confidential, and neither my name, nor my organization's name, will be associated with any specific data or outcomes (such as quotes) in publicly available information.

___ I hereby **do not agree** to have my **organization's** name associated with this project in public-facing activities and research products, such as presentations, reports, and manuscripts.

Making my name and responses public:

5 ____I hereby consent to have my information (Name, Organizational Affiliation) and ORCA responses made publicly available upon request.

___I do not want my information (Name, Organizational Affiliation) and ORCA responses made publicly available.

Participant Name (please print)

_____

Participant Signature (please type, insert electronic signature, or print out and sign)

_____

Date

_____

This consent expires 6 years from the date it is signed.