A Single Case Experimental Design Investigating CISBAR Intervention for Improving Social Communication after ABI

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EVERYDAY COMMUNICATION PARTNER (ECP)

Consent for Research Participation

Title: A Single Case Experimental Design Investigating CISBAR Intervention for Improving Social Communication after ABI

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You are being asked to participate in a research study. The box below highlights key information about this research for you to consider when making a decision whether or not to participate. Carefully consider this information and the more detailed information provided below the box. Please ask questions about any of the information you do not understand before you decide whether to participate.

Key Information for You to Consider

- **Voluntary Consent**. You are being asked to volunteer for a research study. It is up to you whether you choose to participate or not. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or discontinue participation.
- **Screening**. Please note that this initial intake includes some screening procedures, which are to determine whether you qualify for the study or not.
- **Purpose**. The purpose of this research is to investigate the efficacy of a behavioral treatment program for improving social communication problems after brain injury.
- **Duration.** It is expected that your participation will last between 4-6 weeks, plus one session to be scheduled one month after completion of the rest of the study. The total number of sessions, including the initial intake session and final one-month follow-up session, is expected to number between 13-19, and the total participation time including all sessions will be approximately 9-13 hours.
- **Procedures and Activities.** You will be asked to take part in an initial intake session, complete some questionnaires, and participate as a conversation partner in baseline sessions, treatment sessions, and a follow-up session.
- **Risks.** There may be risks of stress, emotional distress, inconvenience and possible loss of privacy and confidentiality associated with participating in a research study.
- **Benefits**. Your partner will benefit by receiving the study intervention free of charge, which may result in some improvement in social communication.
- **Alternatives.** Participation is voluntary, and the only alternative is not to participate.

Why is this research being done?

The purpose of the research is to investigate the efficacy of a behavioral treatment program, Collaborative Interpersonal Strategy Building with Audio Reflection (CISBAR), for improving social

communication problems after brain injury. You are being asked to participate because you are person who frequently communicates with a person who has had a brain injury. About 8 people (4 who have had a brain injury, each with an everyday conversation partner) will take part in this research.

How long will I be in this research?

The total duration of participation is expected to last between 4-6 weeks, plus one session one month after completion. Please see the table below for an estimate of how long each session will take. Please note that baseline and intervention sessions will be scheduled about three times a week, at times that are convenient for you.

Initial Intake	1 session, 55 minutes
Baseline	5-8 sessions, 15 minutes each
Intervention	5-8 sessions, 55 minutes each
Post-intervention data collection	1 session, 55 minutes
1-month follow up	1 session, 55 minutes
TOTAL	13-19 sessions, 9-13 hours

What happens if I agree to participate in this research?

If you agree to be in this research, you will accompany your partner (the person who has had a brain injury) to all study sessions, and complete some questionnaires, surveys, and rating scales about their communication. This research will be done remotely, via a secure videoconference platform and document sharing system (not in-person). The sessions will be videorecorded. For all surveys, questionnaires, and interviews, you may skip any question that makes you uncomfortable, and you may stop at any time. The questions asked will focus on the social communication skills of your partner (who has had a brain injury).

If you agree to be in this research, your participation will include:

1.) **An intake session.** First we will conduct a screening interview and give your partner a brief questionnaire to make sure that you and your partner are a good fit for this study. If so, you will each complete questionnaires about the social communication of the person who has a brain injury. Next, I will talk with you and your partner so that together we can identify important social communication challenges, and determine a social communication goal to work toward in our sessions together. During this discussion, please do share your perspective on your partner's communication challenges, and let us know any important information you think we should consider when planning a treatment program for social communication for them.

   Your partner will also complete a survey containing some conversation topics that are likely to bring out any problematic social communication behaviors. After they have had a chance to complete the survey, please do also share any additional input you have regarding these possible

topics so that together we can select suitable conversation topics for you and your partner to use in this study.

I will give you a one-page handout, "Conversation Partner Guidelines". These guidelines are provided in order to promote successful communication and minimize risk of unpleasantness and conflict when addressing challenging topics. I will briefly review the guidelines with you, and answer any questions. Please read these guidelines and try to follow them during the study sessions. Please let me know if you have any questions or concerns.

Based on the conversation topics we agreed upon in the intake session, I will create a pool of possible topics, which will be used in the Baseline and Treatment sessions.

2.) Baseline Sessions

Each baseline session will take less than 15 minutes. I will ask you and your partner to talk for about 6 minutes about one of the topics that we agreed upon in the intake session.

3.) Intervention Sessions

Each intervention session will be 55 minutes or less. I will provide some training to your partner on strategies they can use to improve the problematic conversation behavior we discussed in the intake session. Your role will be to act as their conversation partner in two 6-minute conversations, during which they will be practicing these strategies to improve their communication. After the first conversation, we will have a discussion about how it went. In this discussion, you will have the chance to provide some feedback to them, and to rate how well you think they did using a conversation rating scale. Then, you will re-enact your role in the conversation using the same topic so that they can have another opportunity to practice the trained strategies successfully.

4.) Post-Intervention Data Collection

After the last intervention session, we will ask you to fill out some questionnaires again.

5.) Follow-Up Session

We will schedule an additional session with the two of you approximately one month after the last session. During this session, we will ask you about your partner's progress on their goal. You and your partner will each fill out the same social communication questionnaires you filled out before. Also, the two of you will participate in one final 6-minute conversation using a topic that has not been previously used, and each of you will indicate how you think the conversation went using a conversation rating scale.

What happens to the information collected for this research?

The initial intake includes some screening procedures, which are to determine whether you qualify for the study or not. Even if you don't qualify for the study, if you sign this consent form, your signed consent form will be retained in Qualtrics, a secure program for collecting information, along with the signed consent forms of the other participants, for recordkeeping purposes. In future written descriptions and presentations about the study, I may disclose the number of total participants who consented and/or the number of participants who were screened out, along with a summary of general reasons why some candidates were not eligible for the study, but will not disclose any personally identifiable information about these participants.

If you are eligible for the study and choose to participate, recordings of the conversation samples collected in this study will be viewed by a research assistant who will not know which conversation samples were taken after the intervention was introduced. The research assistant will collect data on social communication behaviors occurring in the conversation samples. This data will be analyzed by the research team. We may publish and present the results of this research. However, we will keep your name and other identifying information confidential.

Your responses to the surveys and questionnaires collected as part of this research will be stored in a secure document storage system, and the resulting data will be de-identified and analyzed using statistical methods for the purpose of the research.

How will my privacy and data confidentiality be protected?

We will take measures to protect your privacy. Despite taking steps to protect your privacy, we can never fully guarantee your privacy will be protected. Measures we will take include:

- We will email you blank copies of consent forms, surveys, and questionnaires for your reference, and will have you complete them electronically using Qualtrics, a secure program for collecting information.
- We will use a secure system for videoconferencing with you during study sessions, and will be in a private setting away from the hearing of others. If an unexpected situation/emergency results in someone being in hearing range of our session, I will immediately tell you so that we may put the session on a brief hold and resume when the person is gone.
- We will take measures to protect the security of all your personal information including de-identifying your information and not retaining any paper copies of your information, since your signature on the consent, as well as answers to all surveys and questionnaires, will be stored securely via Qualtrics.
- When analyzing the results and writing up the study for my dissertation and any future publications and presentations, care will be taken to ensure that you would not be personally identified.

Despite these precautions to protect the confidentiality of your information, we can never fully guarantee confidentiality of all study information. Please note that identifiers might be removed from identifiable private information, and that 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.

Individuals and organization that conduct or monitor this research may be permitted access to and inspect the research records. This may include access to your private information and study data or recordings. These individuals and organizations include the Institutional Review Board (IRB) that reviewed this research and government regulatory agencies.

In accordance with the requirements of the 2018 Revised Common Rule of the U.S. Health and Human Services (HHS), please note that I will post a brief description of this study and an unsigned copy of this consent form on ClinicalTrials.gov, a database of clinical studies. This information will not include your name or any personally identifiable information about you.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy. You should understand that the researcher is not prevented from taking steps, including reporting to authorities, to prevent serious harm of yourself or others.

The research team includes individuals who are mandatory reporters. If the research team has reasonable cause to suspect abuse or neglect of a child or adult, a report may be required under Oregon State Law. In such a case, the research team may be obligated to breach confidentiality and may be required to disclose personal information.

What are the risks if I participate in this research?

There may be risks of stress, emotional distress, inconvenience and possible loss of privacy and confidentiality associated with participating in a research study. One foreseeable potential discomfort is due to the need to discuss topics which may generate strong feelings in order to work on communication challenges in your everyday lives. Although there is some risk that the 6-minute study conversations between you and your partner may turn unpleasant, this risk will be minimized by first eliminating any topics you and your partner do not wish to discuss using the Conversation Topic survey, and also reading and following the Conversation Partner Guidelines.

What are the benefits of participating in this research?

You and your partner may directly benefit from this study by receiving the study intervention free of charge, which may result in an improvement in social communication behaviors for your partner.

The research will contribute to the field by investigating the effectiveness of an intervention for social communication after brain injury delivered by teletherapy. The research will be written up in my dissertation and presented in oral presentations and/or journal articles, thereby sharing information that may help other researchers and clinicians replicate the results, which may thus indirectly benefit the population of survivors of brain injury with social communication challenges who may receive a similar intervention in the future.

What if I want to stop participating in this research?

Taking part in this research study is your decision. Your participation in this study is voluntary. You do not have to take part in this study, but if you do, you can stop at any time. You have the right to choose not to participate in any study activity or completely withdraw from continued participation at any point in this study without penalty or loss of benefits to which you are otherwise entitled. Your decision whether or not to participate will not affect your relationship with the researchers or the University of Oregon.

If you decide to leave this research, please contact the principal investigator, Heidi Iwashita (heidii@uoregon.edu, (360) 742-9010) so that I will know you will no longer be participating. If you have already completed some study activities, you can tell me whether you request that your information (e.g. any conversation samples that have already been recorded) be withdrawn from the study, or whether they can still be used.

Please note that if you leave the study, your partner will be withdrawn from the study as well. Please feel free to ask any questions you may have about withdrawing from the study.

The investigators may stop you from taking part in this study. Reasons for withdrawal might include:

- You or your partner are unable to keep your scheduled appointments
- You or your partner cannot follow instructions given by the research team
- Your partner stops participation in the study

Will I be paid for participating in this research?

For taking part in this research, you will be paid a gift card worth up to a total of $100 at Fred Meyer or Bi-Mart (your choice). If you stop study participation after completing five study sessions but before all study sessions, you will receive a gift card worth a total of $50. Please be aware, compensation for participation in research studies may be considered taxable income.

Who can answer my questions about this research?

If you have questions, concerns, or have experienced a research related injury, contact the research team using the information below:

Heidi Iwashita, M.S., CCC-SLP (principal investigator)
(360) 742-9010
heidii@uoregon.edu

An Institutional Review Board ("IRB") is overseeing this research. An IRB is a group of people who perform independent review of research studies to ensure the rights and welfare of participants are protected. UO Research Compliance Services is the office that supports the IRB. If you have questions about your rights or wish to speak with someone other than the research team, you may contact:

Research Compliance Services
5237 University of Oregon

Eugene, OR 97403-5237
(541) 346-2510

STATEMENT OF CONSENT

I have had the opportunity to read and consider the information in this form. I have asked any questions necessary to make a decision about my participation. I understand that I can ask additional questions throughout my participation.

I understand that by signing below, I volunteer to participate in this research. I understand that I am not waiving any legal rights. I have been provided with a copy of this consent form. I understand that if my ability to consent or assent for myself changes, either I or my legal representative may be asked to re-consent prior to my continued participation in this study.

I consent to participate in this study.

Name of Adult Participant	Signature of Adult Participant	Date

As described above, you will be audio/video recorded while performing the activities described above. Recordings will be used for data analysis only, unless you also agree to possible future use in conference presentations or educational purposes (not required).

Initial the space below if you consent to the use of audio/video recordings for data analysis

____ I agree to the use of audio/video recordings for data analysis

____ I agree to the use of audio/video recordings for possible future use in conference presentations (optional)

____ I agree to the use of audio/video recordings for possible future use for educational purposes (optional)

Researcher Signature (to be completed at time of informed consent)

I have explained the research to the participant and answered all of his/her questions. I believe that he/she understands the information described in this consent form and freely consents to participate.

Name of Research Team Member	Signature of Research Team Member	Date