INDIANA UNIVERSITY INFORMED CONSENT STATEMENT FOR

Intervention to Change Attributions that are Negative (ICAN): a New Approach to Reducing Anger and Aggression after Brain Injury

About this research

You are invited to participate in a research study. Scientists do research to answer important questions which might help change or improve the way we do things in the future.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study. When reading this form, please note that the words "you" and "your" refer to the person in the study that had a traumatic brain injury and not a parent, guardian, or legally authorized representative who may sign this form on behalf of the person in the study."

Taking part in this research study is voluntary

You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with The Rehabilitation Hospital of Indiana (RHI), IU Health, or Indiana University.

WHY IS THIS RESEARCH BEING DONE?

After a traumatic brain injury (TBI), problems with anger and aggression are common. Past studies show that anger can sometimes be the result of the way a person thinks about other people's behaviors. We developed a group therapy program (ICAN) to teach people with TBI to think differently about other people's behaviors. We want to see if the program can change the way people with TBI think about others' behaviors, and if this helps reduce anger. We also want to see how people with TBI like the program. This is a pilot study, which means the treatment we developed is at the very beginning phase of testing and we do not know how well people will respond to it. Also, if you agree, we would like input from a family member or caregiver of yours to see if they notice any difference in your behavior. Therefore, we will ask you for information about a family member or caregiver whom we may contact. However, a family member or caregiver is not required to participate in this study.

You were selected as a possible participant because you have had a brain injury.

The study is being conducted by Drs. Dawn Neumann and Flora Hammond, who are employed by Indiana University Medical School in the Department of Physical Medicine and Rehabilitation. This study is funded by the National Institutes of Health (NIH).

HOW MANY PEOPLE WILL TAKE PART?

Our goal is to identify 40 participants through screening who are eligible to be enrolled into the study. Although we cannot anticipate exactly how many participants will need to be screened to identify 40 eligible participants, we anticipate we will need to screen approximately 120 subjects. Therefore, if you agree to participate, you will be one of approximately 120 people with a TBI who will have been screened for the study, and if you are eligible, you will be one of forty participants to be enrolled.

WHAT WILL HAPPEN DURING THE STUDY?

If you agree to be in the study, your involvement will first include a Screening visit to determine your eligibility. If you are eligible, you will also be asked to participate in two to three Assessment visits and a six-week group therapy program. Some participants will start group therapy approximately one week after their first Assessment Visit (Assessment Visit 1); this is considered the "early group". Others will start therapy approximately two months after Assessment Visit 1; this is referred to as the "later" group. Assignment to the "early" or "later" group is determined by chance, meaning that you have an equal likelihood of being assigned to either group. Starting from the time of Assessment Visit 1, your involvement may last 8 weeks (those assigned to the "early group") or 15 weeks (if assigned to the "later group"). Below is a description of what will occur at each assessment visit and during treatment. Because the dates of visits will depend on many factors, it is important to remember that timeline of events are just our best estimates and may vary. Each assessment visit may be split up over multiple sessions at RHI, over the phone, and/or video conference call.

1. **Screening Visit:** This session is expected to last around 3 hours and will help us determine if you are eligible for the study. Screening may be discontinued at any point in the visit if ineligibility is determined before the visit is over. Below describes some of the things that will occur during this visit.
    - General information and medical history survey: This will include questions such as your age, race/ethnicity, education, employment, the severity of your TBI, and how your TBI occurred.
    - Reading and Listening skills: You will be asked to read a short story and answer questions about it. You will also be asked to listen to a short story and answer questions about it.
    - Mood: We will ask you questions from a few surveys to assess your mood (e.g. anger, sadness).
    - Short Stories and Ratings: You will be presented with some short scenarios either written or verbally that range from 1 sentence to a short paragraph . After each story you will be asked questions about how you would feel if the events in the story happened to you. You will also be asked questions about people in the story and what you thought of their actions. Your responses will be audio-recorded during this part of the session.

- Perspective taking and concern for others: Answer questions about your tendency to think about situations from another person's viewpoint, and your concern for others' feelings.
- Thinking skills: We will give you a few exercises to learn about your thinking skills. Some of your responses will be audio recorded. We will notify you before recording begins.

After the screening, we will review your results and determine if you are eligible to continue the study and proceed to Assessment Visit 1. You will receive a phone call within approximately 3 business days to inform you of the results. Should you not be eligible at this time, there is a possibility we may contact you in the future to rescreen you for the study.

----------(below events for eligible participants only)----------

Participants who meet the enrollment criteria will be asked to return for another study visit (Assessment Visit 1) as soon as we identify approximately 10 eligible study participants.

2. **Assessment Visit 1**: Because we do not know how long it will take to find 10 eligible study participants, we do not know how much time will pass in between your screening visit and Assessment Visit 1. This visit is expected to last about two hours and include the following:
    - Updates regarding your current medications and therapy participation
    - Surveys about your emotions: These surveys will ask you about your feelings and behaviors related to your emotions (e.g. anger).
    - Inference skills activity: you will watch videos and be asked to interpret peoples' emotions, thoughts, and intentions.

You will be asked to identify a caregiver that will provide information and complete surveys during your study procedures. You do not have to have a caregiver in order to participate, and their participation is voluntary.

Group Assignment: After Assessment Visit 1, we will find out which group you have been randomly (by chance) assigned to ("early" vs "late" group). If you are in the "early group", we hope to start the group therapy approximately a week after Assessment visit 1; however it is important to note that the timing of when the group will start may vary depending different factors. If you are in the "late" group, therapy will start approximately 2 months later. See below for a description of the group therapy.

3. **Assessment Visit 2** (~7 weeks after Assessment 1 visit): All eligible participants will return for a second assessment visit. This session will last approximately three hours and involve the following activities (already described above):

- medication and therapy updates
- short story ratings
- mood surveys
- perspective taking and concern for others
- inference skills activity
- If you identify a family member or caregiver, we will contact this person to find out if they have noticed a change in you since you started the study. The caregiver will participate by completing a survey.

4. **Assessment Visit 3** (~14 weeks after Assessment 1 visit): Only participants assigned to the "later group" will return for a third Assessment visit. This session will last approximately three hours and involve the same activities as Assessment Visit 2. If you identify a family member or caregiver, we will contact this person to find out if they have noticed a change in you since you started the study. The caregivers will do this by completing a survey.

- **Group Intervention Description**: 6 sessions lasting approximately two hours once a week for 6 weeks alongside approximately 4 other participants. Participants will be asked to watch videos and share personal situations that will be followed by thinking and role-playing exercises, as well as discussions about your thoughts and feelings. After you complete the treatment, you will be asked to complete some surveys to find out how you felt about the therapy.

WHAT ARE THE RISKS OF TAKING PART IN THE STUDY?

Study risks may include:

• Feeling bothered, uneasy, discomfort, or embarrassed about some questions on the surveys or taking part in the group intervention exercises.

To reduce this risk, please tell the researcher if you do not want to answer a question or if you feel uncomfortable.

• The possible loss of privacy or confidentiality.

Please see section on Confidentiality below to find out how this risk is being reduced.

• Feeling tired due to the length of the session.

To reduce this risk, we will take short breaks. Please tell the researcher if you want more time to rest between surveys.

• Any suggestion of suicide or thoughts of suicide will result in a referral to a psychologist and/or counseling, social, or medical services. Extreme situations may lead to hospitalization.

WHAT ARE THE POTENTIAL BENEFITS OF TAKING PART IN THE STUDY?

Although this study does provide treatment, we do not yet know if this treatment will provide any therapeutic benefits. If you are eligible and undergo treatment, there is the potential that treatment may reduce your anger and aggression. Additionally, what we learn from this study may advance our

understanding and ability to treat emotional problems after TBI. Thus, this study may also help people with TBI in the future.

WHAT ARE THE OTHER TREATMENT OPTIONS?

You do not have to participate in this research. Other options to treat negative attribution bias are available through cognitive behavioral therapy.

WILL I RECEIVE MY RESULTS?

We may learn things about you from the study activities which could be important to your health or to your treatment. If this happens, this information will be provided to you. You may need to meet with professionals with expertise to help you learn more about your research results. The study team/study will not cover the costs of any follow-up consultations or actions.

HOW WILL MY INFORMATION BE PROTECTED?

Efforts will be made to keep your personal records private. However, we cannot guarantee absolute privacy. If required by law, we may need to disclose your personal information. Your identity will be held in confidence in reports in which the study may be published and databases in which results may be stored. Video conference calls for study visits will use a private and secure service through Zoom Health. Video will not be recorded if this happens.

Organizations that may inspect and/or copy your research records for quality assurance and data analysis include groups such as the study investigator and his/her research associates, the Indiana University Institutional Review Board or its designees, and (as allowed by law) state or federal agencies, specifically the Office for Human Research Protections (OHRP), or the National Institutes of Health who may need to access your medical and/or research records.

A description of this clinical trial will be available on **ClinicalTrials.gov**, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

For the protection of your privacy, this research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers may not disclose or use any information, documents, or specimens that could identify you in any civil, criminal, administrative, legislative, or other legal proceeding, unless you consent to it. Information, documents, or specimens protected by this Certificate may be disclosed to someone who is not connected with the research:

(1) If there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases);
(2) if you consent to the disclosure, including for your medical treatment;
(3) if it is used for other scientific research in a way that is allowed by the federal regulations that protect research subjects

(4) for the purpose of auditing or program evaluation by the government or funding agency

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

WILL MY INFORMATION BE USED FOR RESEARCH IN THE FUTURE?

Information for this research may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information is shared. Since identifying information will be removed, we cannot ask for your additional consent.

WILL I BE PAID TO PARTICIPATE?

Participants will receive stipends to compensate for their participation time. Stipends for the full screening visit is $50, and $25 if the visit is ended early due to ineligibility. If the screening visit starts over the phone, participants will receive $25 if ineligibility is determined before coming in person to finish screening, or $50 if participants complete more testing in person. Stipends for remaining visits are also $50 per Assessment visit. During participation in the treatment portion of the study, participants may receive up to three $25 gas cards (e.g., one gas card after Session 2; one gas card after Session 4, and one gas card after Session 6). If a participant withdraws without receiving treatment, he or she will not be eligible to receive any gas cards.

Participants who will be rescreened (within 8 weeks of first screening) and only complete measures not administered at the first screening will be provided a stipend of $10 to compensate for their time.

Additional transportation costs may be covered on a case by case basis for those who need further assistance at the discretion of the Principal Investigator. Participants will be provided additional gas cards as necessary.

WILL IT COST ME ANYTHING TO PARTICIPATE?

There is no cost to you or your insurance company to take part in this study.

WHO SHOULD I CALL WITH QUESTIONS OR PROBLEMS?

For questions about the study or injuries related to this study, call the researcher Dr. Dawn Neumann at (317) 329-2188. After business hours or in the event of an emergency, you may call our 24-hour emergency number: (317)-329-2000 and ask for the on-call physician.

For questions about your rights as a research participant or to discuss problems, complaints or concerns about a research study, or to obtain information, or offer input, contact the IU Human Subjects Office at (317) 278-3458 or (800) 696-2949.

WILL I BE CONTACTED ABOUT RESEARCH IN THE FUTURE?

If you agree, we may contact you after your participation is over to request additional information. Please initial one of the following options:

_____ Yes, I agree to be contacted for the purpose of collecting additional health information.

_____ I do NOT agree to be contacted for the purpose of collecting additional health information.

CAN I WITHDRAW FROM THE STUDY?

You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with The Rehabilitation Hospital of Indiana, IU Health, or Indiana University.

If you decide to participate in this study, you can change your mind and decide to leave the study at any time in the future. The study team will help you withdraw from the study safely. If you decide to withdraw, please inform a member of the study team or call Dr. Neumann or Co-Investigator, Dr. Flora Hammond at 317-329-2000.

Your participation may be stopped by the investigator even if you don't agree if: (1) a bad effect makes it necessary, or (2) the investigator feels it is in your best interest.

You will be told about new information that may affect your health, welfare, or willingness to stay in the study. This study may be stopped by the investigator if (1) a significant, unexpected and unacceptable risk to subjects is discovered, (2) enrollment of subjects is at an unacceptable rate, (3) the study rules are not followed well enough, or (4) study objectives are completed.

PARTICIPANT'S CONSENT

In consideration of all of the above, I give my consent to participate in this research study. I will be given a copy of this informed consent document to keep for my records. I agree to take part in this study.

Participant's Printed Name:_____

Participant's Signature:_____**Date**:_____
(must be dated by the subject)

Participant's Printed Name: _____

Printed Name of Legally Authorized Representative (LAR): _____

Signature of LAR: _____ **Date:** _____

Relationship to Participant: _____

Printed Name of Person Obtaining Consent: _____

Signature of Person Obtaining Consent: _____**Date:** _____