COVER PAGE

Official Study Title: Cognitive Adaption Training-Effectiveness in Real-world Settings and Mechanism of Action (CAT-EM)

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Henderson Behavioral Health

CONSENT TO PARTICIPATE IN RESEARCH

TITLE OF STUDY: **Effectiveness and Mechanisms of Action for Cognitive Adaptation Training (CAT) in Community Settings (EM-CAT)**

INVESTIGATOR: **Elise Ward**
Sponsor: **National Institute of Mental Health (NIMH)**

Introduction

You are being asked to join a research study. The purpose of a research study is to answer specific questions.

This consent form will explain:

- the purpose of the study
- what you will be asked to do
- the potential risks and benefits

It will also explain that you do not have to be in this study to receive medical care. You should ask questions before you decide if you want to participate. You can also ask questions at any time during the study.

Important Information

This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

Why is this research study being done?	The purpose of this research study is to determine if supports designed to help a person with remembering, organizing, planning, and paying attention improves outcomes for individuals with schizophrenia or schizoaffective disorder.
What will happen to me during the study?	We will collect information about the treatments you receive and how you are doing during the the 12 months of the study. The information will be collected during in-person visits and via video conference. You will also participate in visits at your home that are designed to support you in remembering, organizing, planning, and paying attention.
How long will I participate?	Your participation in the study will be 12 months (one year). You can witdraw consent at any time if you change your mind.

Will taking part expose me to risks?	This research is considered no more than minimal risk, which means that there is no more expected risk to you than what you might experience during a typical day or during a routine physical exam.
How will my data be protected?	Study records that identify you will be kept private. You will not be identified in study records or publications disclosed outside of your treatment center and below agencies involved in this study: • Study sponsor, NIMH, • Coordinating Center of this study - UT Health San Antonio, • Clinical Research Organization (CRO) – Vanguard Research Group, • Clinical staff not involved in the study who may be involved in the participant's treatment, health insurers or payers. The following reviewers may access your study and medical records to make sure that this study is being done properly: • Representatives from federal and state government oversight agencies, • Representatives from the North Shore-LIJ Health System Institutional Review Board (IRB - the committee that reviews research at this institution) We will do our best to protect the privacy of your records but it is possible that once information is shared with people listed on this form, it will be released to others. In the future, we may publish results of this study in scientific journals and may present it at scientific meetings. If we do we will not identify you. If the researchers learn about potential serious harm to you or someone else or other public health concerns, it will be shared with the appropriate authorities.

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research.

Why is this research study being done?

The purpose of this research study is to determine if Cognitive Adaptation Training (CAT) improves outcomes for individuals with schizophrenia or schizoaffective disorder. CAT is a treatment that helps set up customized supports in a person's home or work environment. Supports could include things like signs, alarms, pill containers, checklists, apps and text messages, and the organization of belongings. These supports are designed to help a person with remembering, organizing, planning, and paying attention. They are also designed to get around problems in being motivated. You are being

asked to participate in this study because you have been diagnosed with schizophrenia or schizoaffective disorder and are receiving case management services.

How many people will take part in this study?
Approximately 504 people will enter this study at 8 different clinics across the US.

How long will you be in this study?
Your participation in the study will be 12 months (one year). The study will last for approximately 5 years since it is expected to take up to 3 ½ years to recruit all 504 participants.

What will happen in this research study?
If you qualify for the study based upon the interview and are willing, you will become part of the study. This means that you will allow us to collect information about the treatments you receive and how you are doing during the time you are in the study, that is, over the next 12 months.

The visits that take place in the study will be both in person, here in the clinic with one of the clinic staff and using video conference. We call this "Telemedicine." This means that you will be here in the clinic and the mental health interviewer is at another location, in a private office. You and the interviewer will be able to talk with each other using video equipment, just like you are in the same room.

At the baseline, month 6 and month 12 visit:

- You will take a computerized test that assesses skills such as memory, attention and problem solving
- You will take a computerized test that involves rapid button pressing
- You will complete a telemedicine interview about your symptoms, everyday activities, social functioning, and your thoughts about taking medication
- You will be asked about any recent hospitalizations or visits to the ER
- This visit will take approximately 2 hours

Recording (Optional)
With your consent, some of the visits in your home may be audio recorded for training and/or quality control purposes, meaning other mental health evaluators may listen to the audio recordings in order to assess how CAT is being provided, and/or provide feedback for training purposes. If you choose not to allow your visit to be audio recorded, you can still participate in this study. This component of the study is optional.

_____I **agree** to allow the visits to be audio recorded.

_____I do **not agree** to be audio recorded.

Picture collection (Optional)
With your consent, some pictures may be taken in your home for training and/or quality control purposes, meaning other mental health evaluators may view the pictures in order to assess how CAT is being provided, and/or provide feedback for training purposes. The pictures taken will not include you

or identify you in anyway. If you choose not to allow pictures in your home, you can still participate in this study. This component of the study is optional.

_____I **agree** to allow pictures to be taken.

_____I do **not agree** to allow pictures to be taken.

In addition to the procedures above, you agree to receive Cognitive Adaptation Training in your home over the next year. A case manager from Henderson Behavioral Health will visit with you in your home weekly for 6 months, every other week for 3 months, and then once a month for 3 months.

What are the risks of the research study? What could go wrong?
During the clinical interviews or neurocognitive tests you may become tired or upset about the questions or tests. If this happens, you should tell the interviewer/study personnel and he/she will stop the examination. Depending upon how you feel, you may then 1) take a rest period and resume later, 2) reschedule the appointment or 3) decide not to finish the exam/session.

What are the benefits of this research study?

This research will not benefit you directly; however, the potential information we learn from you may help benefit future patients by informing the development of Cognitive Adaptation Training and facilitate the access to and engagement in needed psychiatric care.

If you do not want to take part in this research study, what are your other choices?
You can choose not to participate in the study.

If you do not want to be part of this research project or decide later on that you don't want to be part of the project, nothing will change for you, your doctor or your treatment. You will get the same treatment at this clinic no matter what you decide to do.

Are there any costs for being in this research study?
This research study is funded by the National Institute of Mental Health. You will not have any added costs from being in this study. All study related visits and procedures will be given to you at no cost. Neither you nor your insurance company will be billed for your participation in this research. Costs associated with your standard of care will be billed to you and your insurance company in the usual way.

Will you receive any payments for participating in this research study?
You will be paid for your time being in the study. You will receive $40 for completing each visit. If you complete all visits in the study you will be reimbursed a total of $120. You have the opportunity to win an additional $10 at each visit while completing one of the assessments that is called the "Effort Expenditure for Rewards Task (EFFrT)" (total of an additional $30 if you win $10 at each visit").
If you do not complete the entire study, you will be paid for the number of visits that you did complete. You will also be reimbursed for your travel expenses for each study visit at the clinic.

It is possible that the payment you receive on this study will be reported to the IRS. If this occurs, you will be issued a 1099 form and be required to provide your social security number at that time for reporting purposes. You will also be responsible for reporting this income while filing your tax return

What happens if you are injured while participating in this study?
If you are hurt from being in the study, you will receive medical care and treatment as needed fromHenderson Behavioral Health. However, you will be responsible for the costs of such medical treatment, directly or through your medical insurance and/or other forms of medical coverage. No money will be given to you.

What are your rights as a research participant?
Your participation in this project is voluntary. If you do not join the study you will not be penalized or lose benefits to which you are entitled. If you join the study you may withdraw at any time without prejudice to your future care at Henderson Behavioral Health. Follow-up examinations may be needed to assure your well being.

Could you be taken off the study before it is over?
It is also possible that your participation in this study may end without your consent. This decision may be made by a researcher, study sponsor or the Institutional Review Board (IRB- the committee that oversees research at this institution).

Reasons for withdrawal may include:

- failure to follow instructions,
- failure to show up for study visits,
- it is not in your best interest to continue on this study, or
- the study is stopped.

If you withdraw from this study or if you are withdrawn from the study, any data already collected will continue to be used. However, no new data will be collected.

What happens if new information is learned?
You will be told of any new findings that may change your decision to continue to participate. Your consent to continue to take part in this study may be obtained again.

What information will be collected and used for this study?
If you agree to be in this study, we will collect health information that identifies you. We may collect the results of tests, questionnaires and interviews. We may also collect information from your medical record. We will only collect information that is needed for the research. This information has been described in this consent form. If you sign this consent form, you are giving us permission to collect, use and share your health information. This permission is called **authorization.**

Study records that identify you will be kept private. You will not be identified in study records or publications disclosed outside the Henderson Behavioral Health, except as detailed below.

Investigators will share information collected from this research study with:

- Study sponsor, NIMH,
- Coordinating Center of this study - UT Health San Antonio,
- Clinical Research Organization (CRO) – Vanguard Research Group,
- Clinical staff not involved in the study who may be involved in the participant's treatment, health insurers or payers.

The following reviewers may access your study and medical records to make sure that this study is being done properly:

- Representatives from federal and state government oversight agencies,
- Representatives from the North Shore-LIJ Health System Institutional Review Board (IRB - the committee that reviews research at this institution)

If you agree to audio recordings and pictures, these recordings and pictures may be viewed by staff at UT Health San Antonio.

We will do our best to protect the privacy of your records but it is possible that once information is shared with people listed on this form, it will be released to others.
In the future, we may publish results of this study in scientific journals and may present it at scientific meetings. If we do we will not identify you.

If the researchers learn about potential serious harm to you or someone else or other public health concerns, it will be shared with the appropriate authorities.

Will you be able to access your records?
If your research records are used for decisions related to your clinical care, then you have the right to review this information and request changes. This is limited to information about your treatment, and does not include information related to procedures or tests that are for research purposes only. You may access this information only after the study analysis is complete. You have the right to know who has and who will see your records. To request this information, or for any questions related to your health information, you may contact the Research Privacy Officer at **954-486-4005 ext. 1612**

How long will your health information be kept?
There is no limit on the length of time we will keep your information for this research because it may be analyzed for many years. We will keep it as long as it is useful, unless you decide you no longer want to take part or we close the study. You are allowing access to this information indefinitely.

Can you change your mind?
If you change your mind about being in the study, you may withdraw at any time. If you want us to stop collecting your health information, you need to send a letter to the researcher at the following address:

Elise Ward
4700 N. State Rd. 7
Lauderdale Lakes, FL 33319

Your letter needs to say that you have changed your mind and do not want the researcher to collect and share your health information. You may also need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

Will information about this study be available to the public?
A description of this clinical trial will be available on http://www.Clinical Trials.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 website at any time.

Does the investigator of this study receive money if you take part?
Funding for this research study is provided by The National Institute of Mental Health. The funding is used to support the activities of the Research Division and to pay back the Division for the costs of the study personnel. Compensation is not based upon the number of people enrolled in the study. If your doctor is an investigator for this study, he or she is interested in both your healthcare and the conduct of this research. You do not have to take part in a research study conducted by your doctor.

Who can answer your questions about this study?
If you have any questions about the study, you may call Elise Ward at 954-730-7284 extension 2813. If you have questions about side effects or injury caused by research you should call Elise Ward at 954-730-7284 extension 2813. If you need emergency care you may call Elise Ward, go to the Emergency Department or dial 911. If you have questions about your rights as a research subject, or concerns about being in the study, you may contact the Office of the Institutional Review Board (the committee that oversees research at this institution) at (516) 465 1910. A signed copy of this consent form will be given to you.

STUDY INFORMATION REVIEW

For Potential Subjects Only to Complete

DIRECTIONS: Below are questions that people frequently have about the study. Each question is followed by 2 answers. One answer is correct and the other answer is wrong (or false). Please put a check mark next to the correct answer.

Question 1. *Do I have to be in the study to get treatment?*

- □ a) To get treatment, I must be in the study.

  OR

- □ b) To get treatment, I do not have to be in the study.

Question 2. *If I start in the study, can I leave before it is over?*

- □ a) If I decide to be in the study, I must stay until it is over.

  OR

- □ b) If I decide to be in the study, I can leave any time that I wish.

Question 3. *Does the study involve interviews using telemedicine?*

- □ a) The study does involve interviews using telemedicine.

  OR

- □ b) The study does not involve interviews using telemedicine.

Question 6. The study involves 3 visits*?*

- □ a) Yes the study includes 3 visits.

  OR

- □ b) No the study does not include 3 visits.

Summation/Signature

You have read the above description of the research study. You have been told of the risks and benefits involved and all your questions have been answered to your satisfaction. A member of the research team will answer any future questions you may have. You voluntarily agree to join this study and know that you can withdraw from the study at any time without penalty. By signing this form, you have not given up any of your legal rights.

_____	_____	_____
Subject's signature	Subject's printed name	Date

_____	_____	_____
Witness's Printed Name	Witness's Signature	Date

(Preferably someone not connected with the research project)

Investigator's Statement

In addition to advising the above participant of other forms of treatment and therapy which are appropriate, I have offered an opportunity for further explanation of the risks and discomforts which are, or may be associated with this study and to answer any further questions relating to it.

_____	_____
Investigator's signature	Date

_____

Investigator's printed name