Promoting Activity and Cognitive Enrichment in Schizophrenia

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Western Psychiatric Institute and Clinic
of UPMC Presbyterian

Part of
UPMC Health System

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CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: COGNITIVE ENHANCEMENT THERAPY (CET) AND ENRICHED SUPPORTIVE THERAPY (EST) FOR PERSISTENT NEGATIVE SYMPTOMS IN SCHIZOPHRENIA

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Purpose of this Research Study/Project

You are invited to participate in a research study because you are diagnosed with schizophrenia or schizoaffective disorder and are having difficulties with negative symptoms like:

- lack of motivation,
- feeling disconnected from friends and family,
- not fully feeling emotions like happy, sad or upset,
- not being able to express yourself when speaking.

Many individuals with these conditions have difficulty with "cognition" or thinking and understanding social situations. Many also have trouble managing their emotions and getting the support they need. In this research study, we will see if a treatment for improving thinking (Cognitive Enhancement Therapy or CET) is better or more effective than a study treatment designed to give you support and help you manage your emotions (Enriched Supportive Therapy or EST). We will see which of these treatments is better at helping people with schizophrenia think and feel better. EST is what is commonly used in treatment. Some recent research studies have suggested that CET may be an equally effective or better treatment.

There are two parts to this study. In the first part, you will have a screening interview about your symptoms to see if you initially qualify. If you qualify, you will be entered into a queue and seen by a clinician until your psychiatric symptoms are stabilized. During this time, you will complete a battery of assessments at the beginning and every 4 weeks until you are stabilized (this may last from 1 to 6 months). Once stabilized, you will complete videotaped screening interview to see if you qualify to participate in the treatment portion of the study.

After screening, if eligible, you will start treatment in either CET or EST. CET and EST treatments both involve weekly visits over the 18-month course of the study. There will also be testing timepoints throughout the study, at the 6-, 12- and 18-month study time points.

This research study will include only people who choose to take part. This form describes the study in more detail, so you can make an informed decision about participating. The research staff will review the study with you and will answer any questions that you may have. Please take as much time as you need before making your decision. If you choose not to take part in the study, we can provide other professional resources where you may be able to get treated if needed.

What procedures will be performed for research purposes?

If you decide to take part in this research study, you will undergo the following procedures that are not part of your standard medical or psychiatric care at the University of Pittsburgh Medical Center. After the "screening procedures" listed below are complete, and if you qualify, you will be randomized to 1 of 2 experimental treatment groups. Randomized means chosen by chance, like flipping a coin. Neither you nor the study team gets to choose your group. One experimental treatment group will receive CET and the other experimental treatment group will receive EST.

Screening Procedures:

Procedures to determine if you are eligible to take part in a research study are called “screening procedures”. For this research study, the screening procedures include:

1. A 1-3-hour cognitive testing session where you will be asked about the symptoms of your condition and complete an intelligence test and a demographic questionnaire, which includes things like your address, gender, birth date, etc.

2. Release of your recent medical records to the research staff for review.

3. During the time period in the queue for monitoring and stabilization, you will receive 1-2 hours of assessments approximately every 4 weeks to check on your symptoms, how you are functioning and possible side effects to your antipsychotic medication(s).

4. A 1-2-hour videotaped interview where you will be asked about how you function and would react to different situations.

Experimental Procedures:

If you qualify to take part in this research study, you will undergo the experimental procedures listed below. The in-person research-based interviews/assessments, the study screening procedures and the informed consent procedures, will be conducted at Western Psychiatric Hospital satellite research locations, the physical locations of theses satellite research clinics are Sterling Plaza at 201 N. Craig Street and 3501 Forbes Avenue. This research study will involve the recording of current and future identifiable medical information from psychiatric records for the purposes of determining eligibility and medication compliance for this project. The information that will be recorded will be limited to outpatient and inpatient treatment records (specifically: psychiatric evaluations, on-going psychiatric progress notes, medication modifications). Additionally, if you are found eligible, Dr. Eack and the members of his research team may continue to access your medical record indefinitely.

You will be asked to wear a Fitbit device, similar to a watch, which will track your daily activities, such as total number of steps taken, active minutes per day and number of hours you sleep for the duration of your time in the research study. You will also be asked to participate in 3 optional functional Magnetic Resonance Imaging (fMRI) scans. This information is described in detail on the fMRI consent form which will be reviewed with you separately.

1. A 2-3-hour videotaped interview where we will ask you about how you are doing interacting with other people including friends and family. We will ask about how you are doing with everyday tasks of life.

2. A 6-hour cognitive testing session (separated into two 3-hour appointments) where you will take tests to examine your attention, memory, and other thinking abilities.

3. If you are selected to participate in CET, you will attend weekly individual, computer, and group sessions led by a trained professional. We will first provide computer-assisted training in attention, followed by memory and problem-solving abilities training. You do not need to know how to operate a computer to participate. The goal will be to help you improve your thinking abilities. You will also be asked to join a small group of other study participants. The skills learned from the computer exercises will be help with solving problems in a group. These group exercises will focus on;
    - developing skills so you can understand what you read or hear in a conversation;
    - learning how to receive, summarize and send a message;
    - learning how to plan for and maintain a career and satisfying relationships,
    - overcoming possible disabilities or handicaps that result from your condition.

    All group sessions are videotaped to monitor your progress and for review. The video recordings of the group sessions will include the faces of people who are in the group. This treatment will require about 3 hours of your time each week for up to 18 months. If you receive CET, we will track your attendance. In addition, the research staff will document your progress with notes that will be part of your medical record at UPMC.

4. If you are selected to participate in EST, you will attend weekly individual supportive therapy sessions with a trained professional. The goal will be to help you to;
    - learn about your condition,
    - handle possible crises in your life,
    - provide practical assistance with everyday problems,
    - learn about how stress can affect your condition,
    - recognize your early cues to distress and apply healthy coping strategies,
    - aid your family (or close friend) in learning more about your condition and how to manage it, if you and your family so choose.

    This will require about one hour of your time each week up to 18 months. You will also be asked to join a small support group with other study participants, which will require about one hour of your time each month for up to 18 months. All EST sessions are audio taped for purposes of monitoring your progress. If you receive EST, we will track your attendance. In addition, the research staff will document your progress with notes in your medical record at UPMC.

Monitoring/Follow-up Procedures:

During this time, we will ask you to repeat the cognitive tests and interviews listed above at the 6-, 12- and 18-month study time points.

In addition, 3 months and one year after your participation in CET or EST concludes (21 and 30-month time point), we will ask you to participate in additional "follow-up" or "post-experimental intervention" interviews and cognitive tests.

Storing, Retention, and Access to Videotaped Data:

Videotaped data will be collected as part of this research. These data will be stored in a locked facility at the University of Pittsburgh, separate from your consent form and other research data that includes your name and other identifiable information. Videotapes will be labeled with your study ID only. These data will be kept indefinitely. Only the primary investigators and study team involved in this research will have access to videotaped data.

What are the possible risks, side effects, and discomforts of this research study?

Cognitive Enhancement Therapy:
There are no known risks of CET to our knowledge. However, some participants might from time to time become anxious about working with a computer or feel overwhelmed by certain tasks. If you feel this way, your clinician will stop the exercise and try to find a task that you enjoy and are comfortable performing. You will never be asked to advance to more difficult tasks until you and your treating clinician both feel that you are ready to do so.

Enriched Supportive Therapy:
There are no known risks of EST to our knowledge. However, some participants might from time to time become anxious or feel overwhelmed when discussing certain issues. If you feel this way your clinician will stop the discussion or support you in discussing the issue in a way that is comfortable for you. You will never be asked to advance to more difficult parts of the study treatment until you and your treating clinician both feel that you are ready to do so.

Cognitive Testing:
Cognitive tests may become tiresome. If needed, you may take a break at any time.

Interviews:
Some people may find the interview questions uncomfortable. There is also a risk that someone may learn your identity from information recorded during these interviews. All identifiable data will be stored in locked cabinets accessible only by the research team. All videotaped interviews will be stored in locked cabinets separate from your paper interview data and consent form.

Breach of Confidentiality:
In very rare cases, people not associated with this research study may inadvertently see the identifiable research results. Study staff will attempt to prevent this from happening by keeping all research records in locked files, and by identifying all medical information by a research record number, rather than by name. The file that links your research record number to your name and personally identifiable information will be kept in a locked facility, accessible only by members of the research team. Text Messages and Emails may not be encrypted or secure during transmission or storage and may be intercepted and used by others not in the study.

What are possible benefits from taking part in this study?

It is possible that you may benefit from the study interventions, CET or EST, if you are selected to participate in this research study, but we cannot guarantee you will benefit from taking part in the research interventions. Your participation may also lead to knowledge that will help others.

Who is being asked to take part in this research study?

People invited to participate in this study are adults between 18 and 60 who have been diagnosed with schizophrenia or schizoaffective disorder with significant and persistent negative symptoms. The study will include a total of 90 individuals.

What treatments or procedures are available if I decide not to take part in this research study?

The usual care you receive for your condition will continue to be available to you regardless of whether you participate in this study.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?

You will be promptly notified if, during the conduct of this research study, any new information develops which may cause you to change your mind about continuing to participate.

Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study?

Neither you, nor your insurance provider, will be charged for the costs of any of the procedures performed for this research study (i.e., the Screening Procedures, Experimental Procedures, or Monitoring/Follow-up Procedures described above). You will be charged, in the standard manner, for

any procedures performed for your routine medical care.

Will I be paid if I take part in this research study?

You will be paid up to $975 if you complete all parts of this study. The breakdown of payments is in accordance with the following schedule:

1. $75 for completing all of the eligibility screening procedures. Should you be found ineligible during the screening procedures, the procedures will be discontinued, and you will be paid $25 for completing the partial screening.
2. $150 for completing the cognitive testing and interviews. You will be asked to complete the cognitive tests and interviews at the beginning of the study, and at 6-month, 12-month, 18-month, 21-month (3-month follow-up) and 30-month (one year follow-up) time points. You will be paid $150 for the testing and interviews you complete during the time points.

If, for whatever reason, you complete part but not all of the study, the terms of this payment schedule will be as follows:

1. $75 for completing all of the screening procedures;
2. $150 for completing the cognitive testing and interviews for each time point.

You will be paid through the University's approved payment system. The study team will discuss payment options with you.

All compensation is taxable income to you regardless of the amount. If you receive $600 or more in a calendar year from one organization, that organization is required by law to file a Form 1099 – Miscellaneous with the IRS and provide a copy to the taxpayer. Individuals who do not provide a social security number may still participate in the research, but the IRS requires that 24% of the payment be sent by the institution to the IRS for 'backup withholding;' thus you would only receive 76% of the expected payment.

In addition, any parking fees related to your participation in this study will be paid for by the study.

Who will know about my participation in this research study?

Any information about you obtained from this research will be kept as confidential (private) as possible. All records related to your involvement in this research study will be stored in a locked file cabinet. Your identity on these records will be indicated by a case number rather than by your name (de-identified), and the information linking these case numbers to your identity will be kept separate from the research records.

Videotapes of study procedures will be kept in a separate locked file cabinet. You will not be identified by name in any publication of the research results unless you sign a separate consent form giving your permission (release).

Will this research study involve the use or disclosure of my identifiable medical information?

This research study will involve the use of your past, current and future identifiable medical information. The research staff will use your medical information from the Western Psychiatric Institute

and Clinic (WPIC) to help determine whether you are eligible to participate. Additionally, if you are found eligible, Dr. Eack and the members of his research team will continue to access your medical record and monitor your clinical progress for the duration of this study.

If identifiable medical information from a non-UPMC provider is requested, the staff member will ask you to sign a release of records authorization form.

We may obtain information about you (for example, your symptoms and your birth history) from your treatment team. We will place information that is collected in this study about your adherence to your prescribed medications, and about your emotions and the way you think about social situations into your psychiatric records.

This research study will not involve the disclosure of your identifiable medical information to individuals who are not investigators or research staff members for this research study. If you wish to withdraw your consent to use your medical record information, you must submit it in writing to Dr. Eack at the address on page 1. This will not allow you to continue in the study.

Who will have access to identifiable information related to my participation in this research study?

In addition to the investigators listed on the first page of this consent form and their research staff, the following individuals will or may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study:

Authorized representatives of the University of Pittsburgh Office of Research Protections may review your identifiable research information (which may include your identifiable medical information) for the purpose of monitoring the appropriate conduct of this research study.

In unusual cases, the investigators may be required to release identifiable information (which may include your identifiable medical information) related to your participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies. We may share de-identified data with other researchers in the future. Authorized representatives of the sponsor of this research study, the National Institute of Mental Health, may review and/or obtain identifiable information (which may include your identifiable medical record information) related to your participation in this research study for the purpose of monitoring the accuracy and completeness of the research data and for performing required scientific analyses of the research data. This study has a data sharing plan consistent with NIH policy. Final data that has not yet been published will be shared after acceptance of publication of the relevant paper. Data will be de-identified before sharing on the agreement that once the data analysis is complete, the data will be returned or destroyed. While the study sponsor understands the importance of maintaining the confidentiality of your identifiable research and medical record information, UPMC and University of Pittsburgh cannot guarantee the confidentiality of this information after it has been obtained by the study sponsor. The investigators involved in the conduct of this research study may receive funding from the sponsor to perform the research procedures and to provide the sponsor with identifiable research and medical record information related to your participation in the study.

Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to identifiable information (which may include your identifiable medical information) related to your participation in this research study for the purpose of (1) fulfilling orders, made by the investigators, for hospital and health care services (e.g., laboratory tests, diagnostic procedures) associated with research study participation; (2) addressing correct payment for tests and procedures ordered by the investigators; and/or (3) for internal hospital operations (i.e. quality assurance).

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings; if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?

The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your identifiable medical information) related to your participation in this research study for a minimum of seven years after final reporting or publication of a project.

Is my participation in this research study voluntary?

Yes, your participation in this research study is completely voluntary. You may choose to discuss this study with your family or your personal physician prior to agreeing to participate. You may refuse to take part in this research study, or you may stop participating at any time, even after you sign this consent form. Your decision will not affect your relationship with or the care you receive from Western Psychiatric Institute and Clinic, the University of Pittsburgh Medical Center or the University of Pittsburgh.

May I withdraw, at a future date, my permission for participation in this research study?

Yes. To withdraw from this study, you will need to contact the investigator listed on the first page of this consent form. If you withdraw from this study, we will continue to use the information we have collected from your medical records and any of the interviews and/or group sessions.

FDA Clinical Trial Registry [21 CFR 50.25]

A description of this clinical trial will be available on http://www.clinicaltrials.gov, as required by US 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.

If I agree to take part in this research study, can I be removed from the study without

my consent?

It is possible that we may remove you from the research study, if you cannot complete the study as requested, such as failure to consistently attend therapeutic sessions. Also if you have a severe relapse(s) or continued abuse of alcohol or other drugs.

My I speak to the principal investigator of this study before agreeing to participate?

You may speak to the principal investigator of this study, Dr. Eack before signing this consent form and agreeing to participate in this study if you would like. You may contact Dr. Eack using the information provided on the cover of this form, or an appointment with him can be arranged for you if you would prefer.

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VOLUNTARY CONSENT

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during this study, and that such future questions will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator.

I understand that I may contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations in the event that the research team is unavailable.

By signing this form, I agree to participate in this research study and authorize the use of my medical records. A copy of this consent form will be given to me.

_____	_____	_____
Participant's Signature	Printed Name of Participant	Date

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s) and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____	_____
Printed Name of Person Obtaining Consent	Role in Research Study

_____ _____

Signature of Person Obtaining Consent Date

PROXY CONSENT

_____
Participant Name (Print)

The above-named individual is unable to provide direct consent for study participation. Therefore, by signing this form, I give my consent for his/her participation in this research study.

_____ _____
Representative's Name (Print) Representative's Relationship to Participant

_____ _____
Representative's Signature Date

_____ _____

VOLUNTARY ASSENT: This research has been explained to me, and I agree to participate.

_____ _____
Participant's Signature Date

VERIFICATION OF EXPLANATION
I certify that I have carefully explained the purpose and nature of this research to the above-named participant in appropriate language. S/he has had an opportunity to discuss it with me in detail. I have answered all his/her questions and s/he provided affirmative agreement (i.e., assent) to participate in this research.

_____
Signature of Person Obtaining Assent

_____
Date