Title: Telehealth and Memory Study

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CONSENT TO PARTICIPATE IN A RESEARCH STUDY

TITLE: Mobile Device CBT for Chemotherapy-Related Cognitive Dysfunction: A Multi-Center Randomized Controlled Trial

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KEY INFORMATION

You are being asked to take part in a research study. Your participation in this research study is completely voluntary. The study team will explain the study to you and will answer any questions you might have. You should take your time to make your decision.

The purpose of this research study is to compare two types of behavioral treatments to see if one is more effective than the other in breast cancer survivors that are experiencing memory and attention problems as a result of cancer and/or cancer treatments.

If you choose to participate in this study, you will be randomized (like a flip of a coin) to one of two experimental behavior therapies, “experimental” meaning that we are not sure which behavioral therapy will work better or if either will work at all. You will receive a total of 8 videoconference visits, lasting 45 minutes, once a week, with a licensed clinical psychologist. You will also be asked to complete questionnaire assessments pre-, post-, and 6 months post-therapy, each visit lasting approximately 1 hour. You will also be asked to complete a brain MRI scan pre- and post-therapy, each visit lasting approximately 2 hours.

Risks related to participation in this study include:

- Experimental therapy – psychological stress, including frustration and fatigue
- MRI – claustrophobia, anxiety, noise that may harm hearing
- Questionnaire assessments – breach of confidentiality

Your cognitive symptoms may improve as a result of participating in this study; however, there is no guarantee.

Why is this research being done?
Memory and attention problems can be a consequence of cancer and cancer treatment for some breast cancer survivors, including those who have received chemotherapy. Researchers at the UPMC Hillman Cancer Center are conducting a multi-site research study to compare two types of experimental behavioral treatments for these problems, to see if one is more effective than the other. The two therapies are 1) Memory and Attention Adaptation Training (MAAT) and 2) Supportive Therapy (ST). By completing this study, we hope to identify an effective treatment for cognitive problems in cancer survivors that can be incorporated into routine care.

Who is being asked to participate in this study?
You are being asked to take part in this research study because you are a breast cancer survivor who received chemotherapy, and you have noticed problems with cognitive functioning (for example, attention or memory). We will ask 200 people to participate in this multi-site research study, 100 at UPMC. If you choose to participate, you will complete some assessments (questionnaires and cognitive tests) by phone/internet at the beginning of the study, and then you will be randomly assigned to one of the two treatments.

Randomization is a process that assigns you by chance, rather than by choice, to either the MAAT or ST group. Randomization is like the flip of a coin and gives you equal possibility of being in either group. We will use a computer to randomly assign you to one of the groups.

You will participate in weekly therapy sessions with a trained clinical psychologist by videoconferencing using a computer or mobile device for eight (8) weeks. You will complete the cognitive assessments and questionnaires again by phone/internet at the end of the therapy and then a third time, six (6) months later. You will also be asked if you are willing to complete a special kind of brain MRI scan, called a functional MRI scan, at in-person visits before you start the therapy and after you complete it. The scans will help us understand how the therapies work.

What procedures will be performed for research purposes?
Your participation in this study will involve about fourteen (14) hours over about nine (9) months, including the follow-up assessments. Most study procedures will be conducted over the phone or internet. If you participate in neuroimaging (the fMRI scan), you will be asked to come to our center two (2) times, once before you start the study treatment, and once after you complete the study treatment. This will involve about four (4) additional hours of study procedures.

Baseline Assessments (approximately 1 hour):
Research staff will contact you by phone to conduct the cognitive testing with you at a time when you can talk to the study staff without distraction in a quiet space at your home for about an hour. This will include brief measures of attention, information processing speed, and memory. You will also complete some questionnaires asking about things like cognitive symptoms, mood, anxiety, overall mental and physical health, and fatigue. These will take about an hour and can be completed over the internet or on the phone with study staff if you prefer.

Baseline fMRI (approximately 2 hours):
All eligible participants will be invited to undergo fMRI scanning. This is an optional component of the study. If you agree to participate you will come to our center to complete a scan before you start treatment, and again after treatment is completed. Each scan will take about two (2) hours and can be arranged at a time that fits your schedule. There will be no invasive

procedures (e.g., no contrast injections or shots) for this scan. The fMRI scan takes threedimensional pictures of brain structure and function using magnetic waves while you are performing cognitive tasks. First you will be given instructions about how to complete the tasks in the scanner. You will be asked to listen to, look at, or remember letters or pictures for these tasks. Then you will have to lie inside the MRI scanner and hold still for about one hour. Foam padding may be used to help keep your head still during the examination.

After these assessments are completed you will be randomized to MAAT or ST, and study staff will work with you to set up your computer or mobile device to meet with the study therapist.

Study Treatment (MAAT or ST) one (1) 45-minute session each week for eight (8) weeks: The study therapist will coordinate with you to conduct weekly videoconference therapy sessions for eight (8) weeks. Each session will last about 45 minutes. You can do this from your home, where you will link through a secure and private videoconference network using a computer or mobile device. During these visits, the therapist will conduct either MAAT or ST therapy, which may include teaching you strategies to manage attention or memory problems in daily life, engaging you in supportive discussions about cognitive concerns you are having or about thoughts and feelings regarding your cancer experience, or other therapeutic activities. Between therapy appointments you may have brief questionnaires or homework to complete, to help you apply the skills you are learning in therapy.

Post-treatment assessments (approximately 1 hour):
After you have completed the eight (8) therapy sessions, research staff will contact you by phone to conduct cognitive testing with you, just like you did at the baseline assessments before treatment. This will be scheduled at a time when you can talk to the study staff without distraction in a quiet space at your home for about an hour, and will again include brief measures of attention, information processing speed, and memory. You will also complete the same questionnaires asking about things like cognitive symptoms, mood, anxiety, overall mental and physical health, and fatigue. These will take about an hour and can be completed over the internet or on the phone with study staff if you prefer.

Post-treatment fMRI (approximately 2 hours):
If you completed fMRI before treatment, you would come to our center to complete a second scan after treatment is completed. This will follow the same procedures as the pre-treatment scan. Again, the scan will take about two (2) hours and can be arranged at a time that fits your schedule.

Follow-up assessments (approximately 1 hour):
Six months after the post-treatment assessment, research staff will contact you by phone to conduct cognitive testing with you, just like you did at the baseline and post-treatment assessments. This will be scheduled at a time when you can talk to the study staff without distraction in a quiet space at your home for about an hour, and will again include brief measures of attention, information processing speed, and memory. You will also complete the same questionnaires asking about things like cognitive symptoms, mood, anxiety, overall mental and physical health, and fatigue. These will take about an hour and can be completed over the internet or on the phone with study staff if you prefer.

At conclusion of the study, all participants will be offered treatment of their choice via clinical referral. This will not be paid for by the study.

What are the possible risks, side effects, and discomforts of this research study? Study assessments: The possible risks and discomforts of this research study include a chance you might become tired during the testing. You may also feel frustration after answering questions related to your thinking skills. If this happens, you may stop or take a break as needed. There is also a potential for breach of confidentiality (privacy) due to use of computerbased testing. However, we make every effort to protect your information so only authorized persons can see your information.

Another risk is telephone privacy. Most land line and cellular telephones are secure so that others may not listen in on conversation. We recommend using a land line phone for the brief testing that has a cord to the main phone. If this is not convenient, or you only have cellular telephone service, this will also work. However, there is a slight risk of cordless phone signals being heard by neighbors if the channels on the phone are not changed.

Study treatments: Given that the behavioral treatments in this study have not been found to be harmful in any way, there may be few risks in participation. You may become more aware of any attention or memory problems that you may experience. This is unlikely to provoke significant problems, but if you or someone else is upset by participation, the study Principal Investigator is available for evaluation and referral to appropriate behavioral care if needed.

Videoconference technology used in this study is secure and meets all requirements for privacy by law. This technology has been used for several years without problems at UPMC. "Encryption" is a process by which the signal between videoconference devices is coded so that others cannot "hack" or intercept private health information. However, there still remains a highly unlikely but real possibility that the signal could be intercepted, which is a slight risk to your privacy.

Potential psychological risks: It is possible that there may be some psychological stress from being in a study. For example, some individuals may find their attention is drawn to memory problems after chemotherapy and can become upset. If you are experiencing any psychological stress related to the study, please let us know. You should contact the Principal Investigator for any questions, and he can help evaluate if further attention and treatment is required. You would be responsible for any additional cost of such care.

MRI scanning:

1. Metal: The MRI machine produces a strong magnetic field, so if you have metal implants, fragments, or clips within your body, they may be influenced by the magnetic field and shift in position. If you have such implants, you should inform us and not participate in the scan. Metal earrings and necklaces must be removed prior to entering the scanning room. You should not bring credit cards or other cards containing magnetic strips into the scanner because they might be erased.
2. Women of childbearing potential: The risks of an MRI to an unborn baby are unknown. Pregnant and breast-feeding women may not participate in this part of the study. A urine pregnancy test will be required for females of childbearing potential.
3. Hearing: MRI scanning produces a loud high frequency tone that can cause hearing damage if appropriate hearing protection is not used. You will be provided with earplugs and/or headphones to protect your hearing and required to use them during the scan.
4. Claustrophobia: The MRI scan involves lying quietly inside a narrow tube for about an hour. A staff member will be available to accompany you to the scan and provide relaxation

training. You will also be in voice contact with the researchers at all times. If you become anxious in confined spaces, you may not want to participate in the scan. If you decide to participate, and at a later time decide to withdraw, just let us know and we will stop the scan.

Collection of medical record information: There is a potential for breach of confidentiality.

What are the possible benefits of this research study?
Your cognitive symptoms may improve as a result of participating in this study; however, there is no guarantee. By participating in this study, you will be helping the researchers learn whether these treatments help improve cognitive functioning after cancer treatment.

What are the alternatives to participating in this research study?
You can choose not to participate. There is currently no clear standard of care (common treatment plan) for cognitive problems after cancer treatment. Some people get better on their own as time goes by. There is the possibility of seeing psychologists in hospitals or private offices who work with cancer survivors

Will I or my insurance provider be charged for the costs of any procedures performed as part of this research study?
It will not cost you anything to be in the study, other than the costs of traveling to and from our facility if you participate in the fMRI. Neither you nor your insurance provider will be charged for any of the procedures performed for the purpose of this research study

Will I be paid if I take part in this research study?
You will not be paid for your participation in the treatment and assessments. If you participate in the fMRI scans, you will be paid $50 for each scan to help compensate you for your time and travel expenses.

All compensation is taxable income to the participant regardless of the amount. If a participant receives $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 28% of the payment be sent by the institution to the IRS for 'backup withholding'; thus you would only receive 72% of the expected payment.

Who will pay if I am injured as a result of taking part in this research study? If you believe that the research procedures have resulted in an injury to you, immediately contact the Principal Investigator who is listed on the first page of this form. Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation. You do not give up any of your legal rights by signing this form.

Who will know about my participation in this research study?
Any information about you obtained from this research will be kept as confidential as possible. All physical records related to your involvement in this research study will be stored in a locked file cabinet. Electronic records will be password-protected. Your identity on these records will be

indicated by a case number rather than by your name, and the information linking these case numbers with your identity will be kept separate from the research records. 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).

In addition to the investigators listed and their research staff, the following individuals may have access to your information related to your participation in this research study:

- Authorized representatives of the study sponsor, federal regulatory agencies, and the University of Pittsburgh Office of Research Protections may review your identifiable research information for purposes of monitoring the conduct of this research study.
- If investigators learn that you, or someone with whom you are involved is in serious danger or potential harm, they will need to inform the appropriate agencies, as required by Pennsylvania law.
- Information collected from this study may be shared with other investigators; however, this information will be shared in a de-identified manner (i.e., without identifiers).

Research records will be maintained for at least 7 years following final reporting or publication of a project.

Although every reasonable effort has been taken, confidentiality during Internet communication activities cannot be guaranteed and it is possible that additional information beyond that collected for research purposes may be captured and used by others not associated with this study.

A federal Certificate of Confidentiality has been issued for this research to add special protection for information and specimens that may identify you. With this certificate, unless you give permission (such as in this form) and except as described above, the researchers are not allowed to share your identifiable information or identifiable specimens, including for a court order or subpoena. Other researchers receiving your identifiable information or specimens are expected to comply with the privacy protections of the Certificate. The Certificate does not stop you from voluntarily releasing information about your participation in this study. Even with these measures to protect your privacy, once your identifiable information is shared outside UPMC, we cannot control all the ways that others use or share it and cannot promise that it will remain completely private. Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your identifiable information does not expire. The results of this research may be published in a medical book or journal or used to teach others. However, your name or other identifiable information will not be used for these purposes without your specific permission.

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.

HIPAA Authorization for Disclosure of Protected Health Information (PHI)
As part of this study, we are requesting your authorization (your permission) to review your medical records to confirm your breast cancer diagnosis, the date of diagnosis, your cancer treatment and how long you were treated, and any medicines or health conditions that could

affect memory or attention. This authorization is valid for an indefinite period of time. We will not be placing research information in your medical record.

This identifiable medical record information will be made available to members of the research team for an indefinite period of time.

Your medical information, as well as information obtained during this research study, may be shared with other groups, possibly including authorized officials from the study sponsor, federal regulatory agencies, and the University of Pittsburgh Office of Research Protections, for the purpose of monitoring the study. Authorized representatives of UPMC or affiliated health care providers may also have access to this information to provide services and addressing operational issues.

We will protect your privacy and the confidentiality of your records, as described in this document, but cannot guarantee the confidentiality of your research records, including information obtained from your medical records, once your personal information is disclosed to others outside UPMC or the University.

You can always withdraw your authorization to allow the research team to review your medical records by contacting the investigator listed on the first page and making the request in writing. If you do so, you will no longer be permitted to participate in this study. Any information obtained from you up that point will continue to be used by the research team.

Is my participation in this research study voluntary?
Your participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above, is completely voluntary. Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship or care with the University of Pittsburgh or UPMC.

You may withdraw, at any time, your consent for participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above. Any identifiable research information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.

To formally withdraw your consent for participation in this research study you must provide a written and dated notice of this decision to the principal investigator listed on the first page of this form.

If I agree to participate in this research study, can I be removed from the study without my consent?
It is possible that you may be removed from the research study by the researchers if it is determined you no longer meet the criteria to participate in this study or if the investigators feel it is in your best interest. Participants may also be withdrawn from the study if they refuse to complete the assessments. Also, the sponsor may stop the study at any time.

VOLUNTARY CONSENT
The above information has been explained to me and all my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this

research study during the course of 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 (866-212-2668) to discuss problems, concerns, and questions; obtain information; offer input; or discuss situations that have occurred during my participation.

By signing this form, I consent to participate in this research study and provide my authorization to share my medical records with the research team.

_____ _____

Printed Name of Participant Date

_____

Participant's Signature

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual, and I have discussed the potential benefits and possible risks of study participation. Any questions the individual has 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

_____

Participant's Signature