IRB APPROVED
AS MODIFIED
Jun 28, 2022

STUDY INFORMATION

TITLE: ACT I: Assessment of Cancer Related Brain Fog using the Test of Strategic Learning

PROTOCOL NO.: U21-08-4519
WCG IRB Protocol #20220226
U21-08-4519

SPONSOR: Inova Schar Cancer Institute

INVESTIGATOR: Adam Cohen, MD
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Fairfax, Virginia 22031
United States

STUDY-RELATED PHONE NUMBER(S): 571-472-1380

Detailed Information

The purpose of this study is to see how good the Test of Strategic Learning (TOSL) is for measuring cognitive deficits in people who have had breast cancer and are experiencing symptoms of brain fog.

We expect about 55 people at Inova will be in this research study.

What happens if I say yes, I want to be in this research?

- *Once you sign this consent form, you will be asked questions about yourself and your medical history.*
- *You will then complete two questionnaires about your symptoms of brain fog called* Patient's Assessment of Own Functioning Inventory (PAOFI), *and The Functional Assessment of Cancer Therapy—Cognition (FACT-Cog)*
- *You will then partake in neurocognitive assessments called the Visual Selective Learning Task, and the* Test of Strategic Learning (TOSL)
- *The total amount of time for the visit will be 1-2 hours. This can be completed on a computer or in person.*
- *Finally, you will complete the same three assessments in three months.*

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Do I have to be in this research?

No. Your participation in this study is voluntary. You do not have to be in this study if you do not want to, and you can leave the study at any time and there will be no penalty or loss of benefit to which you are otherwise entitled. You will not lose any services, benefits, or rights you would normally have if you choose not to be in the study or if you leave the study early.
This is not a treatment study and your alternative to being in this research is not to participate.

Is there any way being in this study could be bad for me? (Detailed Risks)

Minimal risk is associated with the assessments. Boredom, fatigue, or emotional discomfort may occur during the assessments, but participants may take breaks or ask to stop at anytime during the testing sessions.

Privacy and record keeping: all of the information participants provide to investigators as part of this research will be protected and held in confidence within the limits of the law and institutional regulation however, there is the potential risk of a loss of confidentiality of your research-related information.

What are the benefits to being in this study?

You may not directly benefit from this research; however, we hope that your participation in the study may help us identify tools that can better detect subtle cognitive changes to produce targeted training on these deficits that will improve the symptoms of brain fog.

What happens to the information collected for the research?

We will do our best to limit the use or disclosure of your personal information, including information from this research study, to people who have a need to review this information. We cannot promise complete confidentiality. Some organizations may be required to inspect and copy your information including the Institutional Review Board (IRB), the Department Health and Human Services, and other Inova Health System representatives responsible for the management or oversight of this study.

We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, phone number, and other information that can identify you.

The following is a list of individuals who may access your records:

- Members of the research team
- Offices and committees responsible for the oversight of research
- Collaborating researchers outside of the Inova Health System, including researchers at UT Dallas.

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The principal investigator and research team may publish the results of this research. However, they will keep your name and other identifying information confidential.

Federal law provides additional protections of your medical records and related health information. These protections are described in the Inova Health System HIPAA Research Authorization, which you will be provided with and asked to sign separately.

Will the information collected be used in future research?

Information collected about you will be used for this research and may also be used for other research studies here at the Inova Health System. There may also be collaborative research efforts with other entities, such as universities, the government, and private companies where we may share your information. Before using the information for other research, the study team will remove information that identifies you so the individuals performing the research will not know who the information came from. We will not ask for additional consent from you to use your information for the additional research.

Payment

If you agree to be in this research study, we will pay you a $25 Amazon gift card for your time and effort. The card will be given after completion of the second visit.

What happens if I want to leave the study?

If you decide to leave the research, contact the study team so the investigator can work with you for your withdrawal. Data that have already been collected will not be removed from the study database if you stop participating in the research.

Can I be removed from the research without my OK?

The researchers may take you out of the study, even if you want to continue, if:

- Your health changes and staying on the study is no longer in your best interest;
- You do not follow the study rules, or you no longer meet the requirements to be in the study; or
- The study is stopped by the researchers.

Contact Information

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the Study Doctor or Study Contact.

Study Doctor |Adam Cohen, MD **Phone Number** | 571-472-1380

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Inova's Office to help protect you in this Research Study is called Human Research Protections Office (HRPO). You are welcome to call HRPO if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

Human Research Protections Office (HRPO) | 1-888-534-6682
This research has been reviewed and approved by an Institutional Review Board ("IRB"). The IRB of Record for this study is:
IRB of Record | WCG IRB **Phone Number** | 855-818-2289

You may talk to WCG IRB at 855-818-2289 or researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

PARTICIPANT'S STATEMENT/SIGNATURE

- *I have read this form and the research study has been explained to me.*
- *I have been given the chance to ask questions, and my questions have been answered. If I have more questions, I have been told who to call.*
- *I agree to be in the research study described above.*
- *I will receive a copy of this consent form after I sign it.*

_____	_____	_____
Signature of Participant	Printed Name	Date

_____	_____	_____
Signature of Person Conducting Informed Consent Discussion*	Printed Name	Date

**The person conducting the informed consent discussion has signed above as witness.*