Letter of Information and Consent Form

Assessing feasibility and sensitivity of using VoxNeuro as an objective measure of cognitive function in cancer survivors receiving neurofeedback for post-cancer cognitive impairment and cancer-related fatigue

Purpose:

You are invited to participate in a research study assessing a method to measure cognitive function in cancer survivors. Participants will be breast cancer survivors who report post-cancer cognitive impairment and cancer-related fatigue and have completed their cancer treatment within the last 5 years. Your participation in completing this study is voluntary. You may decide not to participate or withdraw from the study.

We aim to evaluate the VoxNeuro Cognitive Health Assessments™ as a tool to measure thinking processes (e.g. memory and concentration), before and after participants receive a series of neurofeedback training sessions, to determine if VoxNeuro is sensitive enough to measure improvements in thinking processes due to the neurofeedback therapy. This study is funded by Sigma Foundation for Nursing which provides grants to encourage nurses to contribute to the advancement of nursing through research.

Procedures:

The study involves you participating in the following:

1. Initial VoxNeuro assessment (75 minutes): completing cognitive tasks alongside visual stimulation
2. Initial survey (20-30 minutes): completion of five brief questionnaires about Cognition, Fatigue, Sleep, Cancer-related Symptoms and Fear of Cancer Recurrence.
3. Twenty neurofeedback sessions using the NeurOptimal™ neurofeedback brain training system (45 minutes each): 2 sessions per week over a 10-week period, delivered by a Registered Nurse
4. Follow-up surveys (20-30 minutes): at weeks 5, 10 and 20.
5. Follow-up VoxNeuro assessment (75 minutes) within the week following completion of the 20 neurofeedback sessions

Basic demographic information will be collected at the initial assessment to describe the sample of study participants. You can decline to answer any question or withdraw from the study at any time without penalty. Any data collected prior to your withdrawal will be destroyed.

To ensure the maintenance of safety with regards COVID-19 we are following Queen's University and Ministry of Health guidelines: wearing of personal protective equipment, minimising episodes of person to person contact and utilizing screening assessment for each visit.

Risks:

There is minimal risk associated with your participation in this study. It is not anticipated that participation in this study will incur any risk, and by consenting you have not waived any legal rights in the event of research-related harm. NeurOptimal Neurofeedback is a safe therapy that has been used for over 20 years with over 3 million hours of use worldwide. The training sessions promote relaxation with side effects being rare. The most common side effects noted from examination of prior neurofeedback therapy were temporary symptoms such as headache, fatigue, dizziness, nausea, and restlessness.

Benefits and compensation:

Some studies compensate for participant's expenses. You will receive 20 neurofeedback sessions free of charge for participating in this study. You may or may not benefit through improvements in cognitive impairment, fatigue, sleep, and psychological symptoms.

Withdrawal from the Study

Participants will be provided with any new information/incidental findings/testing results that may be relevant to their decision to continue or withdraw from study participation (as applicable). Participants may choose to withdraw from the study for any reason and have their data withdrawn prior to data analysis and publication stages of the research by contacting the research assistant or primary investigator. Additionally, the researchers may remove a participant from the study without the participant's consent should any medical issues develop related to or not related to the neurofeedback therapy.

Confidentiality:

The researchers are guided by, and must adhere to, professional and ethical guidelines concerning research that involves people. All information provided by you will be kept strictly confidential to the extent permitted by applicable laws. Only non-identifiable data will be entered into the study database. All responses will be pooled for analysis. All data will be stored securely on an encrypted, password protected computer using Queen's OneDrive for secure data storage and transfer. Stored data will be stripped of participant identifiers, and thus be blinded to the researchers.

There is a remote possibility that during your research activities you could come into contact with someone with COVID-19. If this highly unlikely event were to occur, we are required by the Public Health Unit to retain on file your email address or phone number to share with them for contact tracing purposes.

Access to study data:

Only the researchers will have access to the study data. The Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (HSREB) may require access to study-related records to monitor the ethical conduct of the research. All data will be destroyed five years after the completion of the project and all reporting. Should you be interested, you are entitled to a copy of the findings, which can be obtained by emailing the research assistant or principal investigator.

Questions:

For ethics concerns please contact the Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (HSREB) at 1-844-535-2988 (Toll free in North America) or hsreb@queensu.ca.

Questions about the research may be directed to: the Principal Investigator (PI) Dr. Marian Luctkar-Flude at mfl1@queensu.ca or 613-533-6000, Ext. 77383.

Investigators:

Dr. Marian Luctkar-Flude (PI), Associate Professor, Queen's University: mfl1@queensu.ca

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This Letter of Information provides you with the details to help you make an informed choice. All your questions should be answered to your satisfaction before you decide whether or not to participate in this research study. You have not waived any legal rights by consenting to participate in this study. This study has been reviewed for ethical compliance by the Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board.

Participant Statement of Consent:

I _____ have read the above statements and freely consent to participate in this research.

Signature: _____ Date: _____

Statement of Informed Consent:

I _____ have conducted an informed consent discussion with the participant prior to obtaining their signature on the participant statement of consent.

Signature: _____ Date: _____