Letter of Information and Consent Form

Exploring feasibility of using nonlinear dynamical neurofeedback to alleviate Long COVID cognitive impairment, fatigue, and other persistent symptoms.

Principal Investigator: Marian Luctkar-Flude
Co-Investigator: Jane Tyerman, Matthew Brooks, Sarah Walker

Purpose:

You are invited to take part in a research study assessing people that report feeling decreased mental function and having long-term side effects after having COVID-19, known as post COVID-19 condition or long COVID. You may be able to join the study if you report having continuing symptoms including thinking difficulties/ cognitive impairment. It must be at least three months since the confirmed diagnosis of COVID-19 by rapid antigen test (RAT) or polymerase chain reaction (PCR) testing.

Some earlier work using a practice called electroencephalogram (EEG) neurofeedback, using equipment called NeurOptimal, looked at using this equipment with a population who had problems with thinking ability, memory problems, understanding, focus, attention, and tiredness.

Neurofeedback training may help to train the brain and be helpful when individuals have long COVID.

Participation is voluntary, and you can decline to participate in any aspect of the research without any penalty or impact on your medical care.

Your participation in completing this study is voluntary. You may decide not to participate or withdraw from the study.

We aim to evaluate the NeurOptimal system of neurofeedback with individuals experiencing long COVID cognitive impairment and other long-lasting symptoms and to gather early evidence of its impact. This data will inform protocols for a larger clinical trial of neurofeedback to manage long COVID symptoms.

This study is funded by the Queen's University School of Nursing Research Development Fund 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 survey (20-30 minutes): completion of five brief questionnaires about cognition, fatigue, sleep, psychological symptoms, anxiety and depression.
2. 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
3. Follow-up surveys (20-30 minutes): using the same five questionnaires at weeks 5, 10 and 20.

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.

Risks:

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.
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.

Privacy risks for you include encountering other study participants when arriving and leaving the clinic for study sessions, with the associated risk of others knowing you have a diagnosis of long COVID.

There is also a privacy risk of you being re-identified as being a study participant due to the small number of participants enrolled in the area.

To minimise these risks, you will have your own appointment for each session and we have increased the study enrollment to 20 participants.

Benefits and compensation:

You may or may not benefit through improvements in cognitive impairment, fatigue, sleep, and psychological symptoms. Positive results cannot be guaranteed because everyone's central nervous system is unique. While you may not benefit directly from this study, results from this study may improve the understanding of effects of neurofeedback on long term symptoms in other people living with long COVID in the future.

Some studies compensate for participant's expenses. You will receive 20 neurofeedback sessions free of charge for participating in this study.

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.

Access to study data:

Only the researchers within the research team 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.

Findings will be shared with study participants, researchers, clinicians and people living with long COVID interested in therapies and/or management of long COVID symptoms including fatigue and cognitive impairment. Research results will be presented at conferences and a manuscript will be prepared for publication in peer-reviewed journals. 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
Dr. Jane Tyerman, Assistant Professor, University of Ottawa: jtyerman@uottawa.ca

Sarah Walker, Research Assistant, Queen's University:
sarah.walker@queensu.ca

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 Letter of Information/Consent Form (LOI/CF).
I have had all my questions answered.
I have been provided a copy OR directed to maintain a copy of the LOI/CF for my records.
A signed copy of the LOI/CF will be kept by the Researcher.
By consenting, I have not waived any legal rights in the event of research-related harm.

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:_____