Written Consent to Participate in a Research Study

Project Title: Cognitive strategy training in Post-COVID-19 Syndrome: A feasibility trial
Principal Investigator Name: Anna E. Boone, PhD, MSOT, OTR/L
IRB Assigned Project Number: 2096158
Funding Information: National Institutes of Health, National Center for Medical Research and Rehabilitation

Key Information About the Study

You are being asked to participate in a research study. The purpose of the research study is to evaluate how well a telehealth cognitive intervention works to improve activity performance, cognition (i.e., thinking abilities), and quality of life in individuals with post-COVID syndrome who are experiencing cognitive impairment that affects everyday life activities. You are being asked to take part in in 10 virtual sessions. You are also being asked to complete a series of tests before and after the intervention. \

Possible benefits include performing everyday life activities better and/or experiencing fewer cognitive symptoms. Some possible risks may include: (1) a breach (i.e., break) of confidentiality where identifiable health information related to the participants is accidentally made available to individuals outside of the research team; (2) emotional distress while talking about changes in your abilities due to post-COVID syndrome; or (3) physical injury. Participants will be encouraged to perform their activity-related goals at home. Some of these goals involve physical activity, (e.g., cooking), in which the participant could sustain a physical injury such as a cut on the hand. These activities will all be common everyday life activities that the participant is already doing at home.

Please read this form carefully and take your time. Let us know if you have any questions before participating. The research team can explain words or information that you do not understand. Research is voluntary and you can choose not to participate. If you do not want to participate or choose to start then stop later, there will be no penalty or loss of benefits to which you are otherwise entitled.

Purpose of the Research

You are being asked to participate in this study because you are (1) between the ages of 18-60 years, (2) are experiencing persistent symptoms associated with COVID-19, (3) are experiencing cognitive symptoms that impact your ability to perform everyday activities, (4) have no neurological/psychiatric diagnoses, and (5) are able to read, write, and speak English. The purpose of the research study is to evaluate how well a telehealth cognitive intervention works to improve activity performance, cognition (i.e., thinking abilities), and quality of life in individuals with post-COVID syndrome who are experiencing cognitive impairment that affects everyday life activities.

What will happen during the study?

You are being be asked to complete the following activities:

- **Pre-intervention tests** for approximately 2.5 hours that will consist of questionnaires, interviews, and thinking tests.
- **10, 45-minute telehealth intervention sessions**. These will either consist of the cognitive intervention or weekly contact with the study team. You will be randomized to one of two study groups: a treatment group or a control group. Within the cognitive intervention, we will work together to identify problems and possible solutions to the everyday life activity problems you are having over 10, 45-minute intervention sessions. The weekly contact with the study team will involve discussion about things you may have done in the past week that could have impacted your post-COVID syndrome symptoms and will last approximately 20 minutes. Each intervention session will be videorecorded.
- **Post-intervention tests:** for approximately 2 hours that will consist of questionnaires, interviews, and thinking tests.

Your participation is expected to last a total of 12 weeks.

There will be about 65 subjects participating in this study.

What are the expected benefits of the study?

You may or may not benefit as a result of your participation in the study. Information learned from the study may help other people in the future. You may potentially experience improvement in your ability to perform everyday life activities better and/or experience fewer cognitive symptoms.

What are the possible risks of participating in this study?

There are minimal risks expected when taking part in this study. There are some that we know about and some may not know about yet. Some possible risks include (1) a breach (i.e., break) of confidentiality where identifiable health information related to the participants is accidentally made available to individuals outside of the research team; (2) emotional distress while discussing potentially sensitive topics such as changes in one's abilities due to post-COVID syndrome or suicidal thoughts; or (3) physical injury.

To help lower these possible risks, we will keep your information in a password protected file on a secure network that has restricted access. All data obtained by the study team will be for research purposes only and will be de-identified prior to data entry into our secure electronic database. Additionally, only select members of the research team will have access to videorecordings; these recordings will also be stored on a password protected, secure electronic platform on Mizzou Servers. Any hard copy data will be locked in filing cabinets in the private offices of the PI. All electronic data will be maintained on one web-based, secure, centralized database. The database will use the REDCap® platform and can only be accessed through two

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password protected portals. All data entered into the REDCap® database will be stored on University of Missouri secure servers and will have access restricted to only members of the research team. In the rare event participants experience emotional distress when answering questions during assessments, they will be reminded that they can choose not to answer any questions that may make them uncomfortable and that participation is completely voluntary. Additionally, researchers have a list of available mental health resources that can be provided.

We will tell you about any new important information we learn that may affect your decision to continue to participate in this study.

What other choices do I have if I don't want to be in this study?

You are not required to be in this study. You can simply choose not to participate. You can look for other research projects you may be interested in instead of this study.

Will I receive compensation for taking part in this study?

You will be compensated (i.e., paid) for taking part in this study. For your time and effort, you will receive $60 via check payment within one month of your pre-tests and post-tests for a total of $120. Compensation is provided for completion of the pre-intervention tests and post-intervention tests; therefore, payment will be prorated if a participant withdraws from the study prior to the post-tests.

Are there any costs for participating in this study?

You should not expect any additional costs by participating in this study.

Other costs to you from being in this study may include childcare and/or time off work.

You should discuss any questions about costs with the researchers before agreeing to participate.

Will information about me be kept private?

The research team is committed to respecting your privacy and keeping your personal information confidential. We will make every effort to protect your information to the extent allowed by law. Your records will be given a code number and will not contain your name or other information that could identify you. The code number that connects your name to your information will be kept in a separate, secure location.

When the results of this research are shared, we will remove all identifying information so it will not be known who provided the information. Your information will be kept as secure as possible to prevent your identity from being disclosed.

What we collected from you as part of this research will not be used or shared for future research studies. It will only be used for purposes of this study.

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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, see below); 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.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law of child abuse and neglect or harm to self or others.

Where can I get more information about this clinical trial?

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. 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.

Who do I contact if I have questions or concerns?

If you have questions about this study or experience a research-related injury, you can contact the University of Missouri researcher at (573) 882-7023 or booneae@umsystem.edu.
If you have questions about your rights as a research participant, please contact the University of Missouri Institutional Review Board (IRB) at 573-882-3181 or muresearchirb@missouri.edu. The IRB is a group of people who review research studies to make sure the rights and welfare of participants are protected.

If you want to talk privately about any concerns or issues related to your participation, you may contact the Research Participant Advocacy at 888-280-5002 (a free call) or email muresearchrpa@missouri.edu.

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Do I get a copy of this consent?

You will receive a copy of this consent for your records.
We appreciate your consideration to participate in this study.

Consent Signatures

Subject's Signature	**Date**

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