Title: Impact of Brain Connectome and Personality on Cognitive Rehabilitation in Multiple Sclerosis
Title of research study: Impact of Brain Connectome and Personality on Cognitive Rehabilitation in Multiple Sclerosis

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Investigator: Dr. Ralph H.B. Benedict, PhD

Why am I being invited to take part in a research study?
You are being invited to take part in a research study because you have a clinical diagnosis of Multiple Sclerosis (MS) and over the age of 18, with at least 9 years of education.

What should I know about a research study?
- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Who can I talk to?
If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 716-859-7077. You may also contact the research participant advocate at 716-888-4845 or researchadvocate@buffalo.edu.

This research has been reviewed and approved by an Institutional Review Board (“IRB”). You may talk to them at (716) 888-4888 or email ub-irb@buffalo.edu if:
- You have questions about your rights as a participant in this research
- 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 want to get information or provide input about this research.

Why is this research being done?
The objectives of the study are: [a] determine whether high Conscientiousness predicts greater overall cognitive improvement following cognitive rehabilitation in people with MS. [b] identify structural and functional brain connectome characteristics which predict successful improvement in sub-domains of cognition following rehabilitation.

How long will the research last?
We expect that you will be in this research study for 90 days.
How many people will be studied?

We expect to enroll approximately 50 people in this research study.

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

You will be asked to make a total of two (2) visits, approximately 90 days apart. Each visit will involve: neuro-performance testing, and self-report questionnaires. Each study visit is expected to take approximately 1-2 hours. Between the two visits, we ask that you complete a 12 week, computer-based cognitive training program. This includes 1 hour of training each day for 5 days each week. This training program will be provided to you for free.

On Visit 1, you will undergo a full battery of neuro-performance tasks including tests and questionnaires that measure your memory, thinking speed, fatigue, and personality. This visit is expected to take approximately 1-2 hours. We may also ask you to have close friend or family member complete similar surveys. A self-addressed envelope containing these questionnaires will be provided for you to take with you. You can pass it onto a close friend or family member to be completed and mailed back.

In addition, you will be asked to take part in the 12 week computerized cognitive training program. This can be done at home, or anywhere you have access to a computer and internet. This cognitive training has been shown to improve cognitive performance in people with multiple sclerosis. The training involves a variety of interactive exercises which adapt to your abilities. We ask that you complete 1 hour of training each day, for 5 days each week.

At 90 days, you will return for the 1-2 hours follow-up visit where you will complete the same cognitive testing and questionnaires which you had completed during visit 1.

All study visits will take place at Buffalo General Hospital. All of the procedures described above will be performed by a trained member of the research team as part of the research study.

What are my responsibilities if I take part in this research?

If you take part in this research, you will be responsible for coming to Buffalo General Hospital and completing the tasks and surveys described above during each study visit. Additionally, you will be responsible for completion of the cognitive training program described above. This can be done at home, or anywhere you have access to a computer and internet. The training program consists of a variety of exercises which are presented to you by the training software. The exercises include visual and auditory processing and memory tasks. The exercises adapt to your success as you progress each day, such that exercises become more difficult if you are doing well and easier if you are struggling.

What happens if I do not want to be in this research?

Your participation in this research study is voluntary. You may choose not to enroll in this study.
What happens if I say yes, but I change my mind later?
You can leave the research at any time it will not be held against you.
If you decide to leave the research, contact the investigator so that the investigator can withdraw you from the study.

Is there any way being in this study could be bad for me?
There are minimal risks associated with the procedures of this study. Since you are being asked to perform cognitive and manual tasks as part of the study, you may experience some stress or fatigue associated with mental and physical exertion.
While all reasonable efforts are made to prevent a breach of confidentiality, this risk is still exists, though highly unlikely.

Will being in this study help me in any way?
You may experience improved cognitive performance and perceived cognition after completing this study. We cannot promise any benefits to others from your taking part in this research.

What happens to the information collected for the research?
Efforts will be made to limit the use and disclosure of your personal information, including research study and medical or education records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization.
Information related to you will be treated in strict confidence to the extent provided by the law. Your identity will be coded and will not be associated with any published results. Your code number, identity, and test scores will be kept in a password-protected file and/or in a locked file cabinet. In order to monitor this research study, representatives from the Health Sciences Institutional Review Board may inspect research records.
Federal law provides additional protections of your medical records and related health information. These are described in the HIPAA section of this document.

Can I be removed from the research without my OK?
The principal investigator of the study can remove you from the research study without your approval. Possible reasons for removal include: inability/unwillingness to complete the study procedures, and/or inability to contact you for scheduling purposes.

What else do I need to know?
If you agree to take part in this research study, we will compensate you for your time and effort. We will pay you $50 for your time and effort during your first assessment, and then we will pay you another $50 for the second assessment. You will receive your compensation in the form of a check that will be mailed to the address of your choice. Payment requests will be submitted to the accounting department the day of your visit. It can take up to 6 weeks for the accounting department to process and mail the check. Additionally, you will be provided with the cognitive training program for free.

HIPAA: Authorization for the Use and Disclosure of Identifiable Health Information for Research Purposes
Permission to Take Part in a Human Research Study

This section describes information about you and about your health that will be obtained by the researchers when you participate in the research study. Health information is considered "protected health information" when it may directly identify you as an individual. By signing this form you are agreeing to permit the researchers and/or other parties (described in detail below) to have access to this information. If there are any parts of this form that you do not understand, please be sure to ask us for further clarification.

A. What protected health information will be collected about you as part of this research study?

   □ Information from your full medical records, such as disease course, disease duration, etc. (if applicable).

   □ New Health Information created from study related tests, procedures, visits, and/or questionnaires as described in this consent form.

B. Who is authorized to provide or collect this information?

   □ Principal Investigator or designee

C. With whom may your protected health information be shared?

Your information may also be shared with individuals or entities responsible for general administration, oversight and compliance of research activities. Examples of this include the institution's Privacy and Security Officers or other internal oversight staff, Safety Monitoring Boards, an Institutional Review Board, The Research Foundation of the State University of New York, University at Buffalo Foundation Services, and accrediting bodies, or with certain government oversight agencies that have authority over the research including the Department of Health and Human Services (HHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH), and the Office of Human Research Protections (OHRP). Your information may also be shared with other entities as permitted or required by law. All reasonable efforts will be used to protect the confidentiality of your individually identifiable health information that may be shared with others as described above.

All reasonable efforts will be used to protect the confidentiality of your protected health information. There is the potential for individually identifiable information and the associated health information obtained with this authorization to be re-disclosed by the recipient(s). After such a disclosure, the information may no longer be protected by the terms of this authorization against further re-disclosure.

D. How long will this information be kept by the Principal Investigator?

   □ a. This authorization has no expiration date. The researchers may continue to rely on this authorization to obtain and use protected health information about you unless you revoke this authorization in writing.

   □ b. Your protected health information will go into a database that will be maintained indefinitely. Any future study using this information that falls outside the scope of this current study will be required to follow guidelines designed to govern access to that information and to protect the privacy of that information.
E. What are your rights after signing this authorization?

You have the right to revoke this authorization at any time. If you withdraw your authorization, no additional efforts to collect individually identifiable health information about you will be made. You should know, however, that protected health information acquired using this authorization prior to its withdrawal may continue to be used to the extent that the investigator(s) have already relied on your permission to conduct the research. If you chose to withdraw this authorization, you must do so in writing to the following individual(s):

Dr. Ralph H.B. Benedict  
Conventus Building  
UBMD Neurology  
1001 Main Street, 4th Floor  
Buffalo, NY 14203

If you send us a request to withdraw your authorization, we will forward that request to the institutions we have shared it with in order to collect your individually identifiable health information.

F. What will happen if you decide not to sign this authorization?

Refusing to sign this authorization will not affect the present or future care you receive at this institution and will not cause any penalty or loss of benefits to which you are otherwise entitled. If you decide not to sign this authorization, you will not be able to participate in the research study.
Signature Block for Capable Adult

Your signature documents your permission to take part in this research. By signing this form you are not waiving any of your legal rights, including the right to seek compensation for injury related to negligence or misconduct of those involved in the research.

_____________________________________________   ______________________  
Signature of subject                             Date

_____________________________________________   ______________________  
Printed name of subject                          Date

_____________________________________________   ______________________  
Signature of person obtaining consent            Date

_____________________________________________   ______________________  
Printed name of person obtaining consent