NEW YORK INSTITUTE OF TECHNOLOGY

DATE: **June 3, 2021**
TO: **Lisa Hoffman, Ph.D., Principal Investigator**
STUDY: **The Efficacy of a Remote Cognitive Remediation Therapy (CRT) Program on Parkinson's Disease Research Proposal**
PROTOCOL #: **BHS-1660**

The New York Institute of Technology Institutional Review Board has approved the above study involving humans as research subjects. This study was approved after an Expedited Category 7 Review. The protocol is approved from 06/01/21-05/31/22.

This approval is for one year. You should receive a courtesy renewal notice approximately six weeks before the expiration of this project's approval. However, it is your responsibility to ensure that an application for continuing review approval has been submitted by the required time. In addition, you are required to submit a final report of findings at the completion of the project. Please see the IRB website (http://www.nyit.edu/ospar/irb) for the appropriate forms and instruction.

Consent Forms: The approved and stamped consent form must be used by all subjects. You are responsible for maintaining signed consent forms for a period of at least three years after study completion.

Recruiting Announcement: The approved and stamped recruitment flyer (*not applicable)* may be used to recruit subjects for the study. Any intended modification of this announcement, or any intended additional advertisement of this study, would require submission of a request for protocol modification to the IRB, and IRB approval of the requested modification, in advance of any change in the announcement.

Progress Statement: You are required to submit a semiannual progress report, which will be due on 12/1/21.

Reporting: You are required to submit reports as shown above. You must also report to the IRB any serious problem, adverse effect, or outcome that occurs with frequency or degree of severity greater than that anticipated, or that prompts the temporary or permanent suspension of the project. In addition, you are required to submit a final report of findings at the completion of the project. See the IRB website cited above for the appropriate forms and instructions.

Modifications: All modifications of protocols involving human subjects must have prior approval except those involving the prevention of immediate harm to a subject which need to be reported within 24 hours to the IRB.

If you have any questions, please do not hesitate to contact me through the IRB Office at 516-686-7737.

Good luck on your project.

Sincerely,

Leslie Goldstein
Leslie Goldstein (Jun 3, 2021 14:27 EDT)

Leslie Goldstein, PharmD
Chair, New York Institute of Technology BHS-IRB

CC: Dawn Grzan, M.B.A., Senior Director Grants and Human Protections Administrator
Nicole Wadsworth, D.O., Dean, College of Osteopathic Medicine

Verification: By signing below, I acknowledge that I have received this letter and am aware of and agree to abide by all of its stipulations in order to maintain active approval status, including prompt reporting of adverse events/serious problems and annual continuing review. I am aware that it is my responsibility to be knowledgeable of all federal, state and NYIT regulations regarding research involving human subjects.

Lisa Hoffman Ph.D. 06/03/2021
Lisa Hoffman Ph.D. (Jun 3, 2021 14:57 EDT)
Signature of Principal Investigator Date

PLEASE RETURN THE SIGNED ORIGINAL LETTER TO OSPAR AND KEEP A COPY OF THIS LETTER FOR YOUR RECORDS.

NEW YORK INSTITUTE OF TECHNOLOGY
Institutional Review Board for the Protection of Human Participants
Northern Blvd, Old Westbury, NY 11568
516-686-7748 ♦ http://www.nyit.edu/ospar/irb/

The Efficacy of Remote Cognitive Remediation Treatment on Parkinson's Disease-A Pilot Study

- You are being asked to join a research study.
- This consent form explains the research study and your part in the study.
- Please read it carefully and take as much time as you need.
- Ask questions about anything you do not understand now, or when you think of them later.
- You are a volunteer. If you do join the study and change your mind later, you may quit at any time without fear of penalty or loss of benefits.
- While you are in this study, the study team will keep you informed of any new information that could affect whether you want to stay in the study.
- If you have any questions about this study, please contact the Principal Investigator. If you have questions about your rights as participant in this research study, contact the Institutional Review Board (IRB).

Principal Investigator: (Last) Hoffman (First) Lisa

Department: College of Osteopathic Medicine Campus: Old Westbury, NY

Address: 600 Northern Blvd, Old Westbury, NY 11568

Telephone: 516-686-1179 1300 Email:Lisa.Hoffman@nyit.edu

Other Researchers:

Institutional Contact: Institutional Review Board
Office of Sponsored Programs and Research
New York Institute of Technology
Northern Boulevard, Old Westbury, NY 11568
Tel: 516-686-7748

Title of Research: **The Efficacy of Remote Cognitive Remediation Treatment on Parkinson's Disease- A Pilot Study**

A. Purpose of the Study

The purpose of this study is to compare memory and thinking abilities before and after a 10-week program of remote group and computer-based thinking exercises. Exercises like these have been shown to improve attention, speed, and memory in other groups. This study will help see if these exercises would be beneficial to individuals with Parkinson's Disease.

B. Subject Participation

People who have Parkinson's disease who are part of the Rock Steady Boxing program may join this study. 50% of enrolled subjects will have no intervention. For the other 50%, your participation will involve approximately 20 hour-long sessions, which will take place over 10 weeks. The first 45 minutes of each session will consist of computer exercises. The last 15 minutes will be a discussion group about the

utility of the cognitive exercises in everyday life skills. You will also complete a brief assessment before beginning the program and after completion of the program. This assessment takes about one hour.

C. Description of the Research

If you agree to be in this study, we will ask you to do the following things:
Participate in a brief cognitive test that measures abilities like attention, memory, and language.
Attend remote memory and thinking training group sessions.

D. Potential Risks and Discomforts

The following are risks and discomforts that you may experience during your participation in this research study:
Some people may find memory and thinking testing frustrating or fatiguing. Study staff will make all efforts to provide breaks and reassurance as needed.
With data collected, there lies the possibility of a breach of confidentiality. Data is stored in a confidential and compliant manner and all efforts are made to reduce the possibility of a breach of confidentiality.

E. Potential Benefits

There is no guaranteed direct benefit to participants. However, this study does involve a treatment component. It is possible that participants may experience an improvement in memory or thinking abilities as a result of the program.

F. Alternatives to Participating in the Study

Your participation is voluntary. You are free to withdraw your consent at any time and for any reason. You do not have to answer any questions that you prefer not to answer.

G. Confidentiality

This section of the consent form describes how your information will be used and shared in this research, and the ways in which NYIT will safeguard your privacy and confidentiality. If you agree to be in this research program, Dr. Hoffman and her study team will ask you to complete a 10-week memory and training group and she will use the information she collects to determine whether this program is beneficial to people with Parkinson's disease.

Other persons and organizations, including co-investigators, federal and state regulatory agencies, and the IRB overseeing the research may receive your information during the course of this study. Except when required by law, study information shared with persons and organizations outside of NYIT will not identify you by name, social security number, address, telephone number, or any other direct personal identifier.

When your study information will be disclosed outside of NYIT as part of the research, the information that can identify you as listed above will be removed and your records will be assigned a unique code number. NYIT will not disclose the code key, except as required by law.

By signing this form, you authorize the use and disclosure of the following information for this research:

- Observations/findings/interviews that you participate in during the course of this study

H. Compensation

This study does not provide any compensation.

I. Voluntary Participation and Authorization.

Your decision to take part in this study is completely voluntary (of your free will). If you decide not to take part in this study, it will not affect the care or services you receive and will not result in any loss of benefits to which you are otherwise entitled.

You will be told of any significant new developments during the course of the research that may influence your willingness to continue to participate in the research.

J. Withdrawal from the Study and/or Withdrawal of Authorization

If you decide to take part in the study, you may withdraw from participation at any time without penalty or loss of benefits to which you would otherwise be entitled.

If you decide to withdraw your consent, we ask that you contact Dr. Hoffman in writing and let her know that you are withdrawing from the study. Her mailing address is Northern Blvd., PO Box 8000, Old Westbury, NY 11568-8000.

Dr. Hoffman will discuss with you any considerations involved in discontinuing your participation in the study. Dr. Hoffman may also decide to remove you from the study if she feels that to do so would be in your best interest. She will discuss with you the reasons for withdrawal.

K. Costs/Reimbursements

There are no costs involved to participants in this study. In case of research-related injury, the costs for care will be billed to you or your insurance. No funds have been set aside for research-related injuries.

Agreement to Participate in Research Study

I have read this consent form OR

It was read to me by:

Any questions I had were answered by:

I voluntarily agree to participate in this research program

Yes

No

I understand that I will be given a copy of this signed Consent Form.

FOR ADULTS CAPABLE OF GIVING CONSENT:

Name of Participant (PRINT):

Signature: Date: / /

FOR ADULTS NOT CAPABLE OF GIVING CONSENT:

Name of Participant (PRINT):

Signature of Surrogate/Guardian: Date: / /

Relationship of Surrogate to Participant:

Signature of Person Obtaining Consent: Date: / /
(Investigator or IRB Approved Designee)

Witness: Date: / /

Note: A copy of the signed, dated consent form must be kept by the Principal Investigator and a copy must be given to the participant.

New York Institute of Technology
Institutional Review Board
Approved
From 06/01/21 to 05/31/22

BHS-1660 Hoffman L-Expedited Category 7 Approval Letter with stamped Consent

Final Audit Report 2021-06-03

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