Study Consent Form

Study #: CRIR-1284-1217

Words on the Brain: Can Reading Rehabilitation for Age-Related Vision Impairment Improve Cognitive Functioning?

Sponsored By: Université de Montréal, School of Optometry

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- Fonds de la Recherche en Santé du Québec
- Canadian Institutes of Health Research (CIHR)

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INFORMED CONSENT FORM

1. STUDY TITLE

Words on the Brain: Can Reading Rehabilitation for Low Vision Improve Cognitive Functioning?

2. PRINCIPAL INVESTIGATORS

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APPROUVÉ PAR LE CÉR
DES ÉTABLISSEMENTS DU CRIR

LE : 7 février 2020

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4. Funding Agency

This study is funded by the *Fonds de recherche en Santé du Québec* (FRQS) and the Canadian Institutes of Health Research (CIHR)

5. Introduction

We are inviting you to participate in a research project. Before agreeing to participate in this project, please take the time to read and carefully consider the following information.

This consent form explains the aim of this study, the procedures, advantages, risks and inconveniences, as well as the persons to contact, if necessary.

This consent form may contain words that you do not understand. We invite you to ask any question that you consider useful to the investigator and the other staff members assigned to the research project and ask them to explain any word or information that is not clear to you.

6. Description of the project and its objectives

Changes in vision and in memory both become more frequent as we age. Problems with vision and memory are often correlated and both may progress more quickly when the brain is not receiving enough stimulation through the senses. What we do not know is if *reading* could improve memory after vision rehabilitation for low vision, by providing the brain with visual stimulation.

We want to follow 150 clients with low vision who will participate in a reading-focused visual rehabilitation for 1 year and 50 control participants who will not undergo visual rehabilitation. These 200 participants will be tested three times for reading, memory, and hearing abilities just before the start of vision rehab, if applicable, as well as six and twelve months after the first testing session.

7. NATURE OF PARTICIPATION

Your participation in this research project will consist in:

- A session before the start of your vision rehabilitation, if applicable, to test your reading, mental, and hearing abilities (approx. 90 min);
- A second session six months after the start of your vision rehabilitation, if applicable, to administer the same tests (approx. 90 min);
- A final session one year after the start of your vision rehabilitation, if applicable, to administer the same tests (approx. 90 min);
- You will have the choice of coming to the laboratory for these tests or of having the research staff member come to your home.
- Some of your responses on the tests will be audio-recorded to confirm the accuracy of the collected data as well as to reduce the testing time. Once all audio recordings have been properly analysed, they will be deleted.

8. PERSONAL BENEFITS OF PARTICIPATING IN THE STUDY

You will not benefit personally from taking part in this study. However, you might contribute to the advancement of science in the fields of low vision rehabilitation and cognition.

9. RISKS AND INCONVENIENCES ASSOCIATED WITH PARTICIPATING IN THE STUDY

RISKS

Because we will be testing your concentration and memory abilities, we may offer you additional rehabilitation services that you can access through one of our rehabilitation centres in case you may benefit from these.

INCONVENIENCES

The travel time from your home to the research site as well as the participation time in the research project may represent an inconvenience for some people.

You may also experience some general fatigue during the testing. You can ask for breaks between sections to minimize this.

Should you have any concerns regarding your mental and/or physical state throughout the testing period, we can refer you to the appropriate individuals to contact.

10. ACCESS TO THE RESULTS AT THE END OF THE RESEARCH

At the end of the study, you will have the possibility to access a written summary of the results of this research project. Below you may indicate if you are interested in receiving

these results and provide an email address or mailing address at which you may receive them.

No ☐

Yes ☐ Email: _____

Mailing address: _____

_____

_____

*Note: Please note that all individual test results cannot be provided to you as they are not collected under clinical conditions.

11. ACCESS TO YOUR MEDICAL RECORD

If you are a client from a rehabilitation center and are part of the vision rehabilitation condition, you authorize the research team to consult your rehabilitation record in order to collect information in relation to your vision (e.g., your diagnostic information, visual acuity, visual field, contrast sensitivity), the type of rehabilitation services you will receive (e.g., orientation & mobility training, type of reading training, assistive devices), as well as demographic information (such as your age, gender) necessary to conduct the research project.

12. CONFIDENTIALITY

All personal information collected concerning you during the study will be coded to ensure its confidentiality. Only the members of the research team will have access to it. However, for research project control purposes, your research record could be consulted by a person mandated by the REB of the CRIR institutions or by the *Direction de l'éthique et de la qualité du ministère de la Santé et des Services sociaux du Québec.* This person adheres to a policy of strict confidentiality. The research data will be kept under lock and key at University of Montreal by the person in charge of the study for a period of 5 years following the end of the project, after which it will be destroyed. In the event that the results of this study are presented or published, no information that can identify you will be included.

13. VOLUNTARY PARTICIPATION AND RIGHT OF WITHDRAWAL

You are free to accept or refuse to participate in this research project. You may withdraw from this study at any time, without having to give a reason and without suffering prejudice of any kind. You simply have to notify the resource person of the research team. In case of withdrawal on your part, the documents concerning you will be destroyed at your request.

If you are a rehabilitation client, It is understood that your participation in the study will not affect the care and services you receive or will receive from your rehabilitation institution.

14. SUBSEQUENT STUDIES

It is possible that the results of this study will give rise to another research project. In this context, do you authorize the persons in charge of this project to contact you again and ask if you would like to participate in this new project?

☐ no
☐ yes, for a period of one year *
☐ yes, for a period of two years *
☐ yes, for a period of three years *

* Note, if you check off one of these three options, your personal contact information will be kept by the Lead Investigator for the period which you have selected.

15. RESPONSIBILITY OF THE RESEARCH TEAM

By accepting to participate in this study, you do not renounce any of your rights nor do you release the investigators or the institution(s) involved from their civil or professional responsibilities.

16. COMPENSATORY INDEMNITY

No compensatory indemnity is offered to participants taking part in this research project.

17. RESOURCE PERSONS

If you have any questions regarding the research project, you may contact the principal investigator, Dr. Walter Wittich, by phone at (514) 343-7962 or by email at walter.wittich@umontreal.ca.

If you have any questions about your rights and recourse regarding your participation in this research study, you can contact the research ethics coordinator of the research centre which oversees this project, the Centre for Interdisciplinary Research in Rehabilitation of Greater Montreal (CRIR):

Mariama Touré, Research Ethics Coordinator
(514) 527-9565, extension 3789
mariama.toure.ccsmtl@ssss.gouv.qc.ca

If you have a complaint to register regarding your participation in this project, we encourage you to contact Mrs Touré listed above as well as the complaints commissioner who works for the institution where you are a client:

For West-Central Montreal Health (which includes MAB-Mackay)
Service Quality and Complaints Commissioner

(514) 340-8222, extension 24222
ombudsman@jgh.mcgill.ca

For CISSS de la Montérégie-Centre (which includes Institut Nazareth et Louis-Braille)
Service Quality and Complaints Commissioner
(450) 466-5434
louise.hardy@rrsss16.gouv.qc.ca

For CIUSSS du Centre-Sud-de-l'Île-de-Montréal (which includes Institut de gériatrie de Montréal)
Téléphone : 514-593-3600
commissaireauxplaintes.ccsmtl@ssss.gouv.qc.ca

18. CONSENT

I declare that I have read and understood this project, the nature and the scope of my participation, as well as the risks and inconveniences to which I may be exposed, as presented in this document. I have had the opportunity to ask all my questions regarding the different aspects of the study and to receive answers to these questions. A signed copy of this information and consent form must be provided to me.

I, undersigned, voluntarily accept to participate in this study. I can withdraw my participation in this study at any time without prejudice of any kind. I certify that I was allowed all the time necessary to make my decision.

PARTICIPANT'S NAME SIGNATURE

_____ _____

Signed at _____, on _____, 20_____

19. COMMITMENT OF THE INVESTIGATOR OR HER/HIS REPRESENTATIVE

I, undersigned, _____, certify:

(a) that I have explained to the signatory the terms of the present form;
(b) that I have answered any questions that she/he asked me in this regard;
(c) that I have clearly indicated that she/he remains, at any time, free to terminate her/his participation in the research project described above;

(d) that I will provide her/him a signed and dated copy of this form.

_____

Signature of the Lead Investigator or his representative

Signed on _____ of _____, 20_____