Informed consent form for participation in a research study

Study title: Understanding the experience and impacts of brain fog in veterans

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Project sponsor and funder: Chronic Pain Centre of Excellence for Canadian Veterans

McMaster University project review: This study has been reviewed by the Hamilton Integrated Research Ethics Board under Project # 15382

Contact information:
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Invitation

You are invited to participate in a research study exploring brain fog in Veterans. This consent form provides you with information to help you make an informed choice. As you read this form, and decide whether to participate, please ask all the questions you might have, take whatever time you need, and consult with others as you wish. All your questions should be answered to your satisfaction before you decide whether to participate in this research study.

Your participation in this study is voluntary, and a decision not to participate will not be used against you in any way. You may also choose to withdraw your participation at any time, even during the actual session. Because of the nature of the study, your data cannot be excluded after the session.

What is the background information for this study?

Brain fog is a poorly studied concept that many people with chronic pain experience. People living with brain fog have noted the experience of brain fog changes from day-to-day and moment-to-moment, but often interferes with planning, thinking and memory tasks. These changes may limit their ability and motivation to participate in meaningful daily activities. Veterans with chronic pain are especially at risk of experiencing brain fog because they may have other health risks related to or resulting from their service.

What is the purpose of the study?
The purpose of this study is to understand how brain fog impacts the quality of life and cognitive performance of Veterans with chronic pain.

What will I be asked to do?
This study involves discussing your experience of brain fog with a small group of your peers, over Zoom. You may be asked to recall what events trigger your periods of brain fog, what symptoms you experience, the impact that it plays on your daily life, and what strategies you use to cope with it. We ask that all participants be respectful of other participants' experiences and opinions. No disrespectful language or actions towards other participants will be tolerated. We also ask that participants keep all discussions confidential. We anticipate that the discussion portion of the session should take approximately one hour. Prior to the discussion you will be asked to complete three questionnaires about your pain severity, your quality of life, and your daily activities. Questionnaires can be completed at your leisure with the assistance of someone you trust. Please note that audio and screen recording is part of the data collection for this study, and so a condition of consenting to participate. The audio and screen-recording data will NOT be shared or publicly used and will be destroyed as soon as it is transcribed and analyzed. However, direct quotations from the study may be used in the final publication. The total study will take no more than 2 hours.

How many people will take part in this study?
We estimate that about 40 people will take part in this study. This study should take six months to complete and results should be known in one year.

What are the possible benefits of this study?
You may not receive any direct benefit from your participation in this study. However, your participation may allow researchers to better understand the impact of brain fog in Veterans with chronic pain and will help to promote more research and awareness in this area.

Are the study participants paid to be in this study?
As a token of appreciation, you will receive $25. If you withdraw before finishing the experiment, the amount of compensation will be prorated by time (e.g. if you withdraw halfway through the study, you will receive half the compensation).

Is there a conflict of interest?
There is no conflict of interest in this study.

Are there any risks, inconveniences, costs?

This study will use McMaster University's Zoom platform to collect data, which is an externally hosted cloud-based service. A link to their privacy policy is available here (https://explore.zoom.us/en/privacy/). While the Hamilton Integrated Research Ethics Board has approved using the platform to collect data for this study, there

is a small risk of a privacy breach for data collected on external servers. If you are concerned about this, we would be happy to make alternative arrangements for you to participate, perhaps via telephone. Please talk to the researcher if you have any concerns. Please do not make an unauthorized recording of the session.

Can I withdraw from this study?

During the study session, you have the right to end your participation for any reason, by stating that you do not want to continue. You may privately message the researcher and you will be discreetly excused from the focus group. If you withdraw from the study, your verbal data from the focus group discussions will not be discarded. This is not possible due to the interactive component of the study.

Confidentiality

We will treat your personal information as confidential, although absolute privacy cannot be guaranteed. No information that discloses your identity will be released or published. Research records may be accessed by a member of the Hamilton Integrated Research Ethics Board, this institution, or regulatory authority. You will select a pseudonym so that your identity will not be directly associated with the data you have provided. We will password protect any research data that we store or transfer. Only the research team would have access to the identifiable data, which will be immediately destroyed during transcription. De-identified data, will be kept indefinitely and will be kept in a secure password-protected location. De-identified data may also be used in future research. Please note that all quotes will be de-identified. Thus, your name will not appear in any publications or other venues. Once the project is completed, research data will be kept and potentially used for other research projects on this same topic (but as noted above, video and audio recordings will be destroyed as soon as it is transcribed).

Data Retention

After the study is completed, your de-identified data will be retained for future research use (note that the video and audio recordings will be destroyed once they are transcribed by the research team).

New information during the study

In the event that any changes could affect your decision to continue participating in this study, you will be promptly informed.

No waiver of your rights

By signing this form, you are not waiving any rights or releasing the researchers from any liability.

Ethics review

This study has been reviewed by the Hamilton Integrated Research Ethics Board (HiREB). The HiREB is responsible for ensuring that participants are informed of the risks associated with the research, and that participants are free to decide if participation is right for them. If you have any questions about your rights as a research participant, please call the Office of the Chair, HiREB, at 905.521.2100 x 42013.

Statement of consent – print and sign name

I voluntarily agree to participate in this study. ___Yes ___No

_____ _____

Signature of participant Date

Research team member who interacted with the participant

I have explained the study to the participant and answered any and all of their questions. The participant appeared to understand and agree. I offered to send a copy of the consent form to the participant for their reference.

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Signature of researcher