MONASH University

EXPLANATORY STATEMENT

Project:	**The Gut-Brain Axis in Huntington's Disease**
Chief Researchers:	**Professor Julie Stout, Dr. Yifat Glikmann-Johnston**
Associate Researchesr:	**Mr Cory Wasser, Dr. Sonja McKeown**
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You are invited to take part in this study. Please read this Explanatory Statement in full before deciding whether or not to participate in this research. If you would like further information regarding any aspect of this project, you are encouraged to contact the researchers via the phone numbers or email addresses listed above.

My name is Cory Wasser, and I am conducting this research project under supervisor of Professor Julie Stout and Dr. Yifat Glikmann-Johnston within the School of Psychological Sciences as part of completing a Doctorate in Clinical Neuropsychology at Monash University. From this research, I will produce a thesis and aim to publish several research reports.

Why were you chosen for this research?

You have been invited to participate in this research project because you have been diagnosed with Huntington's disease (meaning you have tested positive to the Huntington's gene).

The purpose of this research

The aim of this study is to investigate gut function in Huntington's disease. We are specifically looking to investigate how certain gut flora can influence cognition and mood. We aim to document if, and how altering the gut microbiome via probiotic intervention can result in changes in cognitive performance and mood.

Consenting to participate in the project and withdrawing from the research

If you are interested in participating in the study, you can contact the associate researcher Cory Wasser through either phone or email as listed above. Follow-up calls to ascertain interest to participate will also be made to participants who have been sent this explanatory statement. If you decide to participate in the project, an initial consultation time will be arranged for you to meet with the researcher at Monash University, Clayton. During the initial consultation you will be asked to sign a consent form and will complete some tasks to establish a testing baseline.

Participation in this study is entirely voluntary and you are under no obligation to consent to participation. If you do provide consent, you may withdraw from further participation at any stage during the testing with no consequences. You may leave blank any questionnaires you do not wish to answer and you are free to decline taking part in any part of this study without providing reason. You can request for your data to be disposed of at any time. You will only be able to withdraw your individual data prior to the publication of a report of the project, which we anticipate to will occur in 2019.

Possible benefits

As this is an exploratory study, we do not anticipate any long-term personal benefits from participating in this study, however your participation is greatly appreciated as it contributes to the growing body of research in Huntington's

disease. We are aiming to gain an understanding of gut and cognitive function in Huntington's disease. As yet, no research has investigated the efficacy of a probiotic in Huntington's disease.

What does the research involve?

Participation in the study will involve the completion of a number of tasks over two testing sessions. After expressing interest in participating in this study, the researcher will contact you to arrange an initial consultation session, which can be conducted at Monash University Clayton, 18 Innovation Walk, Clayton, 3800. During this session you will be asked to complete a number of tasks, including a test of reading, a number of questionnaires regarding behaviour and mood, a coding task, and computerised tasks looking at memory and an emotion recognition task.

After providing informed consent, you will be assigned to either an intervention or placebo group. You will initially undergo a pre baseline assessment session to control for practice effects. You will receive either a probiotic capsule (intervention) or placebo capsule (placebo group) for a period of 6 weeks to be taken once daily. You will be requested not to alter your physical activity, diet or nutritional supplement intake during this time. You will provide a stool sample and complete cognitive tasks at baseline and 6 weeks post-intervention. During these testing sessions you will be asked to complete a number of tasks, fill out questionnaires regarding behaviour and mood, and complete a coding task, and computerised tasks looking at spatial memory. Species of certain bacteria (Prevotellaceae and Enterobacteriaceae) and total amount of E. coli will be analysed from your stool sample at baseline and post-intervention.

Approximately 4-6 weeks after the first testing session the researcher will contact you to arrange a time for the second testing session. The second session will involve completing the same questionnaires and cognitive tasks that were completed at baseline. You will also be asked provide a second stool sample for gut microbiome analysis.

How much time will the research take?

The two testing sessions conducted at Monash University require about 1.5-2 hours each. You will be reimbursed with $30 per testing session to thank you for your time.

What will you be taking?

If you are assigned to the intervention group, you will be taking a probiotic capsule containing Saccharomyces cerevisiae, Lactobacillus rhamnosus and Bifidobacterium animalis sip lactic (2 × 109 colony forming unit/gram), once daily for 6 weeks. Dosages are based on the recommendations from past research. Probiotic supplements will be supplied Ethical Nutrients in Australia and have been approved by the Therapeutic Goods Administration.

If you are assigned to the placebo group, you will be taking a normal sugar capsule (maltodextrin), once daily for 6 weeks.

Inconvenience/Discomfort

There are no anticipated discomforts or inconveniences associated with consuming these probiotics or placebo. These capsules have been rigorously tested and have been approved by the therapeutic goods administration for use.

Some participants may experience fatigue during the testing session – if you feel tired during the testing session please let the researcher know and we can take a break from testing.

Some of the questionnaires might cause you to feel upset, as they ask about the presence of depressive and anxious symptoms. If these are a concern to you, you will have the opportunity to discuss these with the researcher. Under the 'counselling' section you will find the contact details of counselling services if you would like to talk about any feeling or emotions raised by any of the tasks used in the study at a later date. You will be informed of your results

on these questionnaires only if they are indicative of high levels of depression or anxiety; in which case you will be contacted by the researcher who will recommend some courses of action you can take to address them.

Your personal information will be kept confidential and your information will not be made available to any third parties without your consent. Results from this study will be presented in a group format such that your individual data cannot be individually identified by name.

Confidentiality

Your personal information and responses to testing will be kept strictly confidential and only researchers involved in the study will have access to it. All paper files will be kept in a locked filing cabinet in a lockable room at the Monash University Clayton campus, and electronic files will be password protected. If the chief researchers cease to be actively involved in research at Monash University, responsibility for the privacy of personal information stored on the premises will be formally handed over to another researcher. A report of this study may be submitted for publication, but data will only be published in a group format and individual participants will not be identifiable in such a report.

Storage of data

Data collected will be stored in accordance with Monash University regulations and kept on University premises for a period of 5 years after collection. After this time, paper files will be shredded and disposed of, and electronic files will be securely deleted.

Use of data for other purposes

Your individual data will not be used for any purposes without your prior consent.

Counselling

If participation in any part of this research causes you to feel upset or distressed, or you would like to talk to someone, Life Supports provides counselling services at various locations across Melbourne. You can contact these service on Tel: 1300 785 569 or via their website at www.lifesupports.com.au. You can also call Lifeline on Tel: 13 11 14 or visit www.beyondblue.org.au for further assistance.

If you would like to participate in the research project; be informed of the aggregate research findings; or have any queries or issues during participation in this study, please contact Cory Wasser on Tel: 0448 774 420 or by Email: cory.wasser@monash.edu. The findings are accessible for a period of five years, but we cannot give you information about your individual results.

If you have a complaint concerning the manner in which this research 2017-8031-14699 is conducted, please contact:

Executive Officer, Human Research Ethics, Monash University Human Research Ethics Committee (MUHREC), Building 3E, Room 111, Research Office, Monash University VIC 3800. Tel: +61 3 9905 2052 .Fax: +61 3 9905 3831. Email: muhrec@monash.edu

Thank you,

Cory Wasser