Centre universitaire de santé McGill | McGill University Health Centre

INFORMATION AND CONSENT FORM

Research Study Title:	**Composition of the gut microbiome in individuals with chronic low back pain vs. healthy controls As part of the Quebec Low Back Pain Study**
Researcher responsible for the research study:	Yoram Shir[1,2], Montreal General Hospital, McGill University, Montreal
Co-Investigator(s)/sites:	[1,2]Jordi Perez; [3]Gaurav Gupta; [1,2]Amir Minerbi, MD, PhD ; [2,4]Laura Stone PhD; [2,4]Stéphanie Grégoire PhD; [1,2]Lilach Eyal Waldman, [1,2]Sylvie Toupin, [1,2]Nuzhat Nipa [1]The Alan Edwards Pain Management Unit (AEPMU), Montréal General Hospital; [2] Alan Edwards Centre for Research on Pain [3] McGill University; Faculty of Medicine [4] McGill University; Faculty of Dentistry

INTRODUCTION

We are inviting you to take part in this research study because you are an adult, suffering from low back pain, or because you are a healthy adult living with an individual who suffers from low back pain.

Before you accept to take part in this study and sign this information and consent form, please take the time to read, understand and carefully examine the following information. You may also want to discuss this study with your family doctor, a family member or a close friend.

This form may contain words that you do not understand. We invite you to speak to the researcher responsible for this study (the "study doctor") or to other members of the research team, and ask them to explain to you any word or information that is unclear to you before you sign this form.

BACKGROUND

Our intestinal system is home to billions of bacteria (germs) that are substantially different from one person to another. Recently, some studies found that the composition of bacteria in the human intestinal system may have effect on our health. Thus, bacteria were found to be linked to different medical conditions such as obesity, diabetes, depression and irritable bowel syndrome. In this study,

we aim to investigate if these bacteria could also be involved in low back pain. We plan to analyze the bacteria found in the stool and saliva, to look for ways in which they can be correlated to low back pain.

PURPOSE OF THE RESEARCH STUDY

The purpose of this study is to evaluate the composition of bacteria found in the intestinal tract in patients suffering from chronic low back pain (i.e. pain which has begun more than six months ago), and to compare it to that of individuals who do not suffer from pain. For this research study, we plan to recruit 50 adult patients suffering from chronic low back pain and 50 healthy individuals who live with an individual with low-back-pain.

DESCRIPTION OF THE RESEARCH PROCEDURES

Participation in this study can be done from your home and does not necessitate a clinic visit. The research study will be conducted from The Alan Edwards Pain Management Unit (AEPMU), at the Montréal General Hospital.

The study will include filling-in a short questionnaire (up to 5 minutes) and giving a stool and a saliva sample.

Study questionnaire:

- The questionnaire will be filled-in using a personal computer, a tablet or a smart-phone, and should take no longer than 5 minutes to complete.
- You will be sent a link to the on-line questionnaire.
- In the questionnaire you will be asked questions about your health and medications which you may use.

Stool and saliva samples:

- Stool and saliva samples will be collected at home, using easy to use kits.
- Kits will be mailed to your home address.
- After collecting the stool and saliva samples, you will be asked to mail them back to us, using a stamped envelope that will be provided to you.

You will not be asked to visit the clinic at any point during the study.

PARTICIPANT'S RESPONSIBILITIES

- Fill-in the study questionnaire once.
- Provide a stool and a saliva sample once.

BENEFITS ASSOCIATED WITH THE RESEARCH STUDY

No direct benefits are expected to you for participating in this research. We hope that the results of this study could contribute to the advancement of scientific knowledge of low back pain and help us find better treatments for this condition.

RISKS ASSOCIATED WITH THE RESEARCH STUDY

No serious risks are expected from your participation in this study.

A possible risk is loss of confidentiality if your data or information are inadvertently disclosed outside of the study. To limit this risk, we will take the steps to protect your confidentiality described in the section on confidentiality below.

VOLUNTARY PARTICIPATION AND THE RIGHT TO WITHDRAW

Your participation in this research project is voluntary. Therefore, you may refuse to participate. You may also withdraw from the project at any time, without giving any reason, by informing the study doctor or a member of the research team.

Your decision not to participate in the study or to withdraw from it will have no impact on the quality of care and services to which you are otherwise entitled, or on your relationship with the study doctor or clinical team.

The study doctor or the Research Ethics Board may put an end to your participation without your consent. This may happen if new findings or information indicate that participation is no longer in your interest, if you do not follow study instructions, or if there are administrative reasons to terminate the project.

If you withdraw or are withdrawn from the study, you may request that the information already collected about you during the study be destroyed if it can be identified as yours. If the data have been anonymized or were always anonymous (e.g. does not contain any information that can be used to identify you), they will continue to be used in the analysis of the study.

Any new findings that could influence your decision to stay in the research project will be shared with you as soon as possible.

CONFIDENTIALITY

During your participation in this study, the study team will collect and record information about you in a study file. They will only collect information required to meet the scientific goals of the study.

The stool and saliva samples that you will provide will be frozen and kept at the AEPMU. All samples will be marked by a serial number only, making it impossible to identify them as yours. All samples will be sent to a specialized laboratory for analysis and may be stored in order to serve the exclusive objectives of this study.

All the information collected during the research project will remain strictly confidential to the extent provided by law. You will only be identified by a code number. The key to the code linking your name to your study file will be kept by the study doctor.

The study data and samples will be stored for 7 years by the study doctor after which they will be rendered anonymous (it will not be possible to identify you.)
The samples and data collected during this study may be accessed by members of the Quebec Low Back Pain Study Consortium and could potentially be use for secondary research purposes, pending approval by the McGill University Health Centre Research Ethics Board

The data of this study may be published or shared during scientific meetings; however, it will not be possible to identify you. You have the right to consult your study file in order to verify the information gathered, and to have it corrected if necessary.

For auditing purposes, the research study files which could include documents that may identify you may be examined by the institution, or the Research Ethics Board. All these individuals and organizations adhere to policies on confidentiality.

MARKETING POSSIBILITIES

The research results, including those following your participation in this study, could lead to the creation of commercial products. However, you will not receive any financial benefits.

COMPENSATION

You will receive $50 after you deliver the stool and saliva samples and complete the questionnaire. The amount will be mailed to your home address as a cheque.

CONTACT INFORMATION

If you have questions or if you have a problem you think may be related to your participation in this research study, or if you would like to withdraw, you may communicate with Dr. Shir, the study doctor, or with someone on the research team at the following number: tel. 514-934-8558.

For any question concerning your rights as a research participant taking part in this study or if you have comments, or wish to file a complaint, you may communicate with the Patient Ombudsman at the Montreal General Hospital at: tel. 514-934-1934, ext. 48306.

OVERVIEW OF ETHICAL ASPECTS OF THE RESEARCH

The McGill University Health Centre Research Ethics Board reviewed this research and is responsible for monitoring the study.

To electronically sign this consent form, please return to the study website. https://minerbi.wixsite.com/clbp