RUSH

CONSENT/AUTHORIZATION FOR PARTICIPATION IN A RESEARCH STUDY

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Protocol Title: Enhancing the Efficacy of Evidence-Based PTSD Treatment via Microbiota-Directed Prebiotic
Sponsor(s): Cures Within Reach

Name of Participant: _____

Key Information:

You are being invited to participate in a research study. Research studies answer important questions that might help change or improve the way we do things in the future.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

Taking part in this research study is voluntary. You do not have to participate in this study and may choose to leave the study at any time. If you decide not to participate in this study or leave the study at a later time, your health care, benefits, or relationship with Rush University Medical Center will not change or be affected.

The purpose of this study is to determine if consuming prebiotics (plant fibers that promote the growth of specific bacteria) will improve outcomes associated with Cognitive Processing Therapy. In this study, prebiotics will come in the form of a prebiotic bar that is "Generally Recognized as Safe" by the United States Food and Drug Administration.

If you agree to participate in this study, your participation may last up to 12 weeks and you will be asked to complete a total of three study visits. These visits will occur at study enrollment, two weeks and 12 weeks, respectively.

During these visits, you will be asked to complete nine questionnaires regarding your diet, medical history, surgical history, stool, sleeping habits and gastrointestinal health. You will also be asked to collect stool samples and maintain a log recording your consumption of the prebiotic bars. For a detailed description of study procedures, please see the "*What are the activities you*

will be doing if you participate in this study?" section of this consent form.

There are risks to participating in this study. There is a risk of loss of confidentiality of your medical information or your identity, if it is obtained by someone other than the investigators, but precautions will be taken to prevent this from happening. For a detailed description of risks you should know about, please see the "*What are the risks and discomforts of participating in this study?*" section of this consent form.

You may not directly benefit from taking part in this study, but we hope that knowledge gained from this study may benefit others with post-traumatic stress disorder and other conditions that affect veterans and their families in the future.

If you are assigned to treatment with placebo, you are not expected to get any health benefits from participating in this study. You should not expect your condition to improve as a result of participating in this study.

You have the option to not participate in this study.

Detailed Information: Please review the rest of this document for details about the above topics and additional information you should know before making a decision about whether or not you will participate in this study.

Why are you being invited to participate in this study?
You are being asked to participate in this study because you are a veteran or service member participating in the Road Home Program Intensive Outpatient Program.

How many participants will take part in this study?
Approximately 78 participants are expected to take part in this study.

What are the activities you will be doing if you participate in this study?
If you agree to participate in this study, you will be randomly assigned to a group receiving either the prebiotic bar or a placebo bar. You have a 50 percent chance of being assigned to each group.

You will be asked to eat one bar per day for the first week of the study, and two bars per day for the remaining duration of the study (the next 11 weeks). You will be instructed to maintain a log to record your consumption of the bars.

Below are the activities involved with Visit 1 (enrollment) and Visit 2 (two weeks after enrollment).

- Questionnaires (see below for list detailed list of questionnaires)
- Stool collection

At Visit 3 (12 weeks after enrollment), you will be asked to complete a final set of questionnaires and complete an at-home stool collection with a kit provided to you.

List of questionnaires to be used in this study:

- GI Symptom Severity Questionnaire
- Bristol Stool Score
- Medical & Surgical History Form
- Mediterranean Eating Patterns III Screener
- Dietary History Questionnaire III
- Prebiotic Bar Diet Log
- Food Timing Screener
- Munich Chronotype Questionnaire
- Post-Bar Feedback Survey

Between Visit 2 and Visit 3, a member of the study staff will be in contact with you biweekly to complete the GI Symptom Severity Questionnaire.

Does this study involve tissue/blood banking?

Yes, it does. Tissue and/or blood banking is the long-term storage of your samples into a repository (or sample bank). In most cases, your samples will remain part of the Biorepository indefinitely, since they will continue to be very useful to scientists performing research on posttraumatic stress and other conditions that affect veterans and their families.

You are invited to donate your biological sample to a biorepository for research purposes. Your decision to donate your fecal sample for future research is entirely voluntary. The *repository*, or storage bank, consists of a freezer, where your fecal sample will be stored, and a computer database. The specimens will be in the locked laboratory of the Center for Integrated Microbiome and Chronobiology Research.

To protect confidentiality, each participant is assigned a unique code for these fecal samples. No data sources will contain information that will personally identify participants. Only study personnel will be able to link your name to the identification number. All information and data collected in the study will be kept in a password protected computer file on the Center for Integrated Microbiome and Chronobiology Research secure server or in a secure locked cabinet in the Center for Integrated Microbiome and Chronobiology Research. Fecal samples will be kept in a freezer in a locked room in the Center for Integrated Microbiome and Chronobiology Research. Only approved study staff will have access to this data.

Whether or not you participate in this study will have no effect on your relationship with Rush University Medical Center or the quality of your care.

What do you need to know regarding the collection of biospecimens?

Biospecimens may include blood, tissue, urine, bone marrow, saliva, cells, etc. In this study, we will collect fecal samples.

Most biospecimens contain DNA. We will not use biospecimens collected as a part of this study for whole genome sequencing, which involves mapping (identifying the location of genes and the distance between them) of all of your DNA.

Fecal specimens: The gut-brain-axis (GBA) refers to the communication between the central nervous system and the gastrointestinal tract. The GBA is a complex communication system that impacts gastrointestinal health, immune response, and recent research proposes it plays a role in higher brain functioning and mental health. Microbiota are microorganisms in your gut that impact the GBA. Microbiota research will help us better understand the role of microbiota in PTSD. You must opt-in to fecal sample collection to be a part of this study.

To protect confidentiality, each participant is assigned a unique code for these biological samples. No data sources will contain information that will personally identify participants. Only study personnel will be able to link your name to the identification number. All information and data collected in the study will be kept in a password protected computer file on the Center for Integrated Microbiome and Chronobiology Research secure server or in a secure locked cabinet in the Center for Integrated Microbiome and Chronobiology Research. Biological samples will be kept in a locked cabinet or a freezer in a locked room in the Center for Integrated Microbiome and Chronobiology Research laboratory. Only approved study staff will have access to this data.

Whether or not you participate in this study will have no effect on your relationship with Rush University Medical Center or the quality of your care.

I agree to the use of my fecal specimens for the biorepository.

____Yes ____No Initial_____

Will your information or biospecimens be used for research in the future?

Information or biospecimens collected from you for this study may be used for future research or shared with other researchers. If this happens, information which could identify you will be removed before any information or biospecimens are shared. Since identifying information will be removed, you will not be asked for additional consent.

Will your cells, tissues, blood, or other biological materials (biospecimens) be used to develop commercial products?

Yes, your biospecimens may be used to develop a commercial product. If a commercial product is developed from the fecal samples collected as part of this study (even if your identifying information is removed), the commercial product will be owned by the researcher or organization that develops the product. You will not profit financially from such a product.

Will you be contacted about participating in future research?
If you agree, we may contact you after your participation in this study about participating in future research. Please initial and date one of the following options:

_____ _____ Yes, I agree to be contacted about future research.
Initials Date

_____ _____ No, I do NOT agree to be contacted about future research.
Initials Date

What are the risks and discomforts of participating in this study?
Side effects, risks, and/or discomforts from participation in this study may include:

- Loss of confidentiality of your medical information or your identity is obtained by someone other than the investigators, but precautions are taken to prevent this from happening. All data collected will be de-identified and stored on password protected data collection tools (REDCap and VioScreen).
- You may experience emotional stress related to collecting your own stool.
- You may experience mild bloating due to consumption of the bar.

There may be other risks that happen that we cannot predict.

What if there is new information that may affect your decision to participate in this study?
During this study, you will be told about important findings (either good or bad), such as changes in the risks or benefits of participation in the study or new choices to participation that might cause you to change your mind about being in the study. If new information is shared with you, you may be asked to sign a revised consent form in order to continue participating in this study.

Will you receive your individual results from the study?
No. Activities you are being asked to do are only for research purposes and are not meant to provide clinical information.

Can you leave or be removed from this study?
You have the right to leave a study at any time without penalty. For your safety, however, you should consider the study doctor's advice about how to leave this study. If you leave this study before the final study visit, the study doctor may ask you to complete the final steps. There is no risk for withdrawing from this study.

The researchers and Sponsor also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interests;
- You do not follow the instructions;
- The study is cancelled for any reason.

What about confidentiality of your medical information?

This authorization is voluntary. Rush University Medical Center and its affiliates ("Rush") will not withhold or refuse your treatment, payment, enrollment, or eligibility for benefits if you do not sign this authorization. You do not have to sign this authorization, but that means that you cannot be in the study or receive study-related treatment.

By signing this document, you voluntarily authorize (give permission to) Dr. Robin Voigt-Zuwala, her study team, and other Rush personnel involved with the conduct and review of this study (which may include off-site personnel) to use or disclose (release) health information that identifies you for the study described in this document.

During the study, Dr. Robin Voigt-Zuwala and her study team will collect Protected Health Information (PHI) about you for the purposes of this research. PHI is your health information that includes your medical history and new information obtained as a result of this study. The health information that Rush may use or disclose for this research includes:

- Name
- Address
- Date of Birth
- Phone Number
- E-mail address
- Medical Record Number

Dr. Robing Voigt-Zuwala and her study team may share your health information and the results of your study-related procedures and tests with people outside of Rush who assist with the conduct and review of this study. The persons who receive your health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission, but only if permitted by the laws governing them. Your health information described above may be used or disclosed to:

- To the Researchers
- The study Sponsor, Cures Within Reach and its representatives
- Monitoring agencies such as the Food and Drug Administration (FDA), the National Institutes of Health and the Rush Institutional Review Board (IRB).

While you participate in the study you will have access to your medical record, but Dr. Robin-Voigt-Zuwala is not required to release to you study information that is not part of your medical record. Rush is required by law to protect your health information, and study records that identify you will be kept confidential. Any study information in your medical record will be kept indefinitely. Your identity will not be revealed on any report, publication, or at scientific meetings.

You have a right to inspect and copy the information to be disclosed with this authorization and you may obtain a copy of the information by contacting the office listed below.

If you no longer want to be in the study and do not want your future health information to be used, you may change your mind and revoke (take back) this authorization at any time by writing to Dr. Robin Voigt-Zuwala at 1725 W. Harrison St. Suite 206, Chicago, IL 60612. If the authorization is revoked, you will no longer be allowed to participate in the study and previously authorized individuals/entities may still use or disclose health information that they have already obtained about you as necessary to maintain the integrity or reliability of the current study.

This authorization is valid for the entirety of this research study. It will expire upon completion of the study or if you revoke (take back) the authorization.

If you withdraw from this study, the data already collected from you may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Records of participation in this study will be maintained and kept confidential as required by law. All study questionnaires, test results, and biospecimens will be coded with a study ID. None of these records will contain any of your PHI.

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human participants.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What are the costs to participate in this study?

There are no costs to you for participating in this research. All costs for the required study will be paid by the study sponsor.

Will you be paid for your participation in this study?

You will be paid in the form of electronic gift card as compensation for your time and effort. You will receive $10 each for your baseline and 2 week visits, (Visit 1 & 2). You will be paid $30 for completing Visit 3. You will be paid within approximately 1 week of your visit date. We may need to collect your social security number or Taxpayer Identification Number (TIN) in order to pay you and for tax reporting purposes to the United States Internal Revenue Service (IRS).

Your participation in this study may contribute to the development of commercial products from which the Sponsor company or others may derive financial benefit. There are no plans to pay you for any of these developments.

What if you are injured as a result of your participation in this study?
If you get ill or injured as a direct result from being in the study, Rush University Medical Center will help you get medical treatment. You should let the study doctor know right away that you are ill or injured. If you believe you have become ill or injured from this study, you should contact Dr. Robin-Voigt Zuwala at telephone number (312) 942-8973.

You should let any health care provider who treats you know that you are in this study. If you do seek medical treatment, please take a copy of this document with you because it may help the doctors where you seek treatment to treat you. It will also provide the doctors where you seek treatment with information they may need if they want to contact your study doctor.

You or your health insurance plan will be billed. No money has been set aside to pay the costs of this treatment. Health insurance plans may or may not cover costs of research-related injury or illness. You should check with your insurance company before deciding to participate in this research study. Costs not covered by insurance could be substantial.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

By signing this form, you are not giving up any legal rights to seek compensation of injury.

What other information should you know about?
This research study is supported by a product (prebiotic bar) manufactured by BetterBiotics, Inc. Dr. Keshavarzian (an investigator on this study) is co-owner of BetterBiotics, Inc. and has equity with BetterBiotics, Inc. These activities are not a part of this study. It was determined that the relationship is considered unlikely to affect your safety and/or the scientific quality of the study. This decision was given to the IRB for its review and approval of the study. If you would like more information, please contact Dr. Keshavarzian at (312) 563-4175.

Who can you contact for more information about this study?
Questions are encouraged. If you have further questions about this study, you may call Robin-Voigt-Zuwala at (312) 942-8973 or email her at Robin_Voigt@rush.edu.

Who can you contact if you have concerns about your rights as a study participant?
Questions about the rights of research participants may be addressed to the Rush University Medical Center Office of Research Affairs at 1-800-876-0772.

What are your rights as a study participant?
Taking part in this study is voluntary. If you choose not to participate in this study or to leave the study at any time, your health care, benefits or relationship at Rush University Medical Center will not change or be affected.

If you choose to leave this study and you do not want any of your information to be used, you must inform Dr. Robin Voigt-Zuwala in writing at the address on the first page. Dr. Robin Voigt-Zuwala may still use your information that was collected prior to your written notice.

SIGNATURE BY THE PARTICIPANT

By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent/authorization form. You will be given a signed copy of this document.

Name of Participant	Signature of Participant	Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:

I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the participant. I further attest that all questions asked by the participant were answered to the best of my knowledge.

Signature of Individual Obtaining Consent	Date of Signature