PROJECT TITLE: Self-Administered Gut-Directed Hypnotherapy for Functional Dyspepsia

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LOYOLA UNIVERSITY CHICAGO
HEALTH SCIENCES DIVISION
MAYWOOD, ILLINOIS
DEPARTMENT OF MEDICINE

INFORMED CONSENT

Participant's Name: _____

Medical Record Number: _____

PROJECT TITLE: Self-Administered Gut-Directed Hypnotherapy for Functional Dyspepsia

THE APPROVAL FOR THIS PROJECT EXPIRES ON 02/03/2021.

Participant Information

About this research study
Scientists do research to answer important questions which might help change or improve the way we do things in the future. You are being asked to participate in a research study.

Taking part in this research study is voluntary
You may choose to not take part in this study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled and will not affect your relationship with Loyola University Medical Center.

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.

Overview and Key Information

This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

1. Why am I being asked to take part in this research study?
We are asking you to take part in this research study because you were referred for gastrointestinal behavior therapy by your gastroenterologist and have a diagnosis of functional dyspepsia.

2. Why is this research being done?

The purpose of this study is to develop and test a psychological treatment called gut-directed hypnotherapy for functional dyspepsia. Based on the effectiveness of hypnotherapy for other gastrointestinal conditions, we expect that this treatment will be beneficial for functional dyspepsia.

The study will provide the hypnotherapy treatment via online audio recordings so that patients are able to participate from home, making it an inexpensive and easily accessible treatment option.

The online hypnotherapy program is considered an investigational device under the Food and Drug Administration (FDA) regulations and is categorized as a nonsignificant risk device. "Investigational" means that it is not approved by the FDA. The hypnotherapy program has not been approved for other indications.

3. What will happen to me during the study?

Participation in the study will require one in-person visit to Loyola Medical Center to meet with Dr. Sarah Kinsinger, principal investigator for the study, to determine your eligibility for hypnotherapy treatment. If you are eligible, the hypnotherapy treatment will take place in your home via the Internet. Hypnotherapy treatment will involve listening to 7, 30 minute pre-recorded audio sessions that can be streamed through a secure website. The treatment sessions will take place over 12 weeks. You will also be asked to listen to a shorter, 10 minute hypnotherapy practice session 5 times per week. You will be asked to complete a set of study questionnaires prior to beginning treatment, midway through treatment, immediately following treatment, and 3 months after completing treatment.

For more information, please see the Description and Explanation of Procedures section below.

4. How long will I participate?

Your participation in this study may last up to 26 weeks. You will be asked to complete one study visit with Dr. Kinsinger prior to beginning the hypnotherapy treatment to confirm your eligibility. This visit will last approximately 60 minutes.

5. Will I benefit from the study?

We do not know if you will benefit from participating in this study. For more information, please see Benefit section below.

6. What are the risks?

This research is considered no more than minimal risk, which means that there is no more expected risk to you than what you might experience during a typical day or during a routine physical exam. For details and a list of risks you should know about, please see the Risks/Discomforts section below.

7. Do I have other options besides taking part in this study?

Participation in research is completely voluntary. You decide whether or not to participate. If you choose to not participate, there will be no penalty to you or loss of benefit to which you are entitled.
There may be other options for treatment of your functional dyspepsia, such as creating a treatment plan with your doctor that may include medications or dietary changes.

8. Will I be paid to participate?
We will compensate your for completing study questionnaires with Amazon gift certificates if you decide to take part in this study. For more information, please see the Financial Information section below.

9. Will it cost me anything to participate?
You will not be responsible for any costs related to the research; however, you or your insurance company will still be responsible for the cost of your normal medical care. For more information, please see the Financial Information section below.

End of Overview and Key Information

Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research.

PURPOSE OF RESEARCH:
You are being asked to participate in this study because you were referred for gastrointestinal behavioral therapy by your gastroenterologist and have a diagnosis of functional dyspepsia.

The purpose of this study is to evaluate the effectiveness of a psychological intervention called gut-directed hypnotherapy for treating symptoms of functional dyspepsia. Functional dyspepsia is a chronic digestive disorder that is associated with reduced quality of life. There are few medical treatments for the condition and psychological interventions, such as gut-directed hypnotherapy, are a promising approach for many gastrointestinal disorders. Latest research indicates that the brain plays an important role in influencing gut symptoms, especially in conditions like functional dyspepsia where no abnormal findings on medical tests can account for the symptoms. Hypnotherapy is a verbally guided intervention that is delivered by a licensed mental health professional. Hypnotherapy encourages a state of focused attention and deep relaxation during which images and verbal suggestions are used to positively influence emotional and physical symptoms. Patients typically find hypnotherapy very comfortable and relaxing. Hypnotherapy treatment for digestive disorders typically entails 7 appointments with a mental health professional experienced in treatment of gastrointestinal conditions. Unfortunately, very few patients have access to this treatment due to the limited number of specialists providing the treatment as well as the cost and burden associated with repeat appointments. The purpose of the current study is to develop and test the effectiveness of a gut-directed hypnotherapy treatment for functional dyspepsia that can be self-administered by patients in their home.

The study is being conducted by Sarah Kinsinger, PhD and Mukund Venu, MD at Loyola

University Medical Center and Olafur Palsson, PsyD at the University of North Caroline at Chapel Hill. It is sponsored by the Loyola University Research Funding Committee.

Approximately 23 people will participate in this research.

DESCRIPTION AND EXPLANATION OF PROCEDURES: If you agree to participate in this study, you will be asked to do the following things:

You will first be asked to read and sign this informed consent document.

You will then be asked to attend a one hour screening visit with Dr. Kinsinger, the study investigator. At that visit she will ask questions related to your gastrointestinal symptoms, medication use, the impact of gastrointestinal symptoms on your daily life, and your current and past mood symptoms and psychological treatment.

If after this screening visit you are determined to be a good fit for the study, you will be asked to complete several study questionnaires. These will include questions related to your gastrointestinal symptoms, medication use, the impact of gastrointestinal symptoms on daily life, and mood symptoms. All questionnaires will be completed on a password-protected on-line website using a unique study ID. Questionnaire data will be collected in a fully de-identified manner that neither obtains nor stores any information that could identify you. We anticipate that the forms will take approximately 20-30 minutes to complete.

You will be asked to watch an instructional video within one week of completing this consent form. The video is conducted by the study PI (Dr. Kinsinger) and will provide an overview of the hypnotherapy treatment, explanation of why it is relevant for your condition, and instructions for using the study website. The video will take approximately 15 minutes.
You will receive an email with a link to a password protected website containing the online forms and video. You will receive reminder calls if you do not respond to the email within 48 hours.

You will be asked to participate in 12 weeks of self-administered hypnotherapy treatment. The treatment will involve listening to 7 audio files that have been pre-recorded by the study PI (Dr. Kinsinger) guiding you through hypnotherapy sessions that were specifically designed for functional dyspepsia. The audio files can be accessed on any computer or mobile device. Each hypnotherapy audio session will be approximately 30 minutes in length. You will have access to a new audio recording every 2 weeks. In between these treatment sessions, you will be asked to listen to a shorter (10- 12 minute recording) 5 times per week.

You will receive a phone call or MyLoyola message every two weeks to encourage continued use of the practice recordings and to address any difficulties with the treatment or website. If you do not log into the online system to complete a hypnosis exercise for 7 consecutive days or longer you will be contacted by the research coordinator for the study to discuss whether you want to continue with the trial.

You will be asked to complete additional survey questionnaires at mid-treatment (week 6) and at the end of hypnotherapy treatment (week 12) as well as 3 months following the end of treatment. These will include questions related to your gastrointestinal symptoms, medication use, the impact of gastrointestinal symptoms on daily life, and mood symptoms. All survey questionnaires will be accessible through the same online platform that you are using to access the hypnotherapy files. You will receive reminder calls or MyLoyola messages if you do not complete the surveys within 3 days.

You will be offered the opportunity to provide verbal feedback about your experience with the treatment and online platform at the end of the trial. This interview will take place over the phone with the research coordinator. We anticipate this interview will take approximately 30 minutes of your time. Participation in this interview is completely optional

If during your participation in the research project new information becomes available which would affect your being in the research project (such as better treatments or the side effects of the treatments), your doctor will discuss this new information with you and will help you make a decision about your continuing in the research.

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

RISKS/DISCOMFORTS: Your risks in this study are minimal. Participation in this study will not affect the clinical care you receive. There are no known risks of participating in hypnotherapy treatment for digestive conditions.

It is possible that the treatment may not help. It is possible that participants may experience emotional discomfort or increased anxiety as a result of participating in the study or completing study questionnaires. Should you experience discomfort or harm during treatment, Dr. Sarah Kinsinger will be available to discuss this with you and will discontinue treatment if necessary. Study staff can provide referrals for additional counseling sessions if needed. You do not have to answer any questions that may make you uncomfortable on any forms.

There may be other side effects that we cannot predict or are currently unknown.

If you disclose actual or suspected abuse, neglect, or exploitation of a child, or disabled or elderly adult, the researcher or any member of the study staff must, and will, report this to Child Protective Services (i.e. Department of Family and Human Services), Adult Protective Services, and/or the nearest law enforcement agency.

BENEFITS: We do not know if you will benefit from participating in this study. It is possible that you might experience improvements in your digestive symptoms, better quality of life, and a reduction in stress. It is possible that you may not benefit from participating. The information learned in this study may benefit future patients with chronic digestive conditions.

ALTERNATIVE TREATMENTS: You do not have to participate in this research project to receive care and treatment at Loyola University Medical Center. You can choose to participate in treatment with Dr. Kinsinger without participating in this research project. Furthermore, your gastroenterologist can discuss with you other treatment options for functional dyspepsia, such as medications or dietary changes.

FINANCIAL INFORMATION: Taking part in this study may or may not cost your insurance company more than the cost of getting treatment without being in this study. Some health plan insurers will not pay the costs for people taking part in studies. Check with your health plan insurer to find out what they will pay for. Depending on your health insurance coverage, there may be out-of-pocket costs for you like co-payment of the standard visits, co-insurance, or deductibles. You will be responsible for these expenses.

You or your insurance company will not be billed for the hypnotherapy treatment provided. You or your insurance company will not be billed for the cost of the supplies and the personnel related to providing hypnotherapy treatment.

If you agree to take part in this research study, we will compensate you for completing study questionnaires with Amazon gift certificates. We will provide you with a $25 gift certificate each time after you complete the screening, week 6, and 3 month follow up questionnaires and $50 for completing the week 12 questionnaires. You will also be compensated $5 to cover the cost of parking for the screening visit with Dr. Kinsinger.

If you receive a total of $600 or more in payment for participating in research at Loyola University of Chicago, personal information about you, including your name, address, and Social Security number, will be released to the Loyola University of Chicago Accounting Office for the purpose of recording the payment and for tax reporting to the United States Internal Revenue Service (IRS). You will be sent a W-9 form which will need to be reported to the IRS. This form will need to be included with your tax forms.

RESEARCH RELATED INJURY:
In the event that you are injured or have side effects as a result of participating in this research project, your doctor will take the necessary steps to treat the problem. There are no funds available from Loyola University Medical Center, Gottlieb Memorial Hospital, Loyola University Health System or Loyola University of Chicago to pay for the cost of care of the problem. You will be financially responsible for the cost of care of any problems. By signing this form, you are not giving up any legal rights to seek to obtain compensation of injury.

INFORMATION COLLECTED AND WHAT WILL HAPPEN TO IT: In order to meet the goals of the research study (see Purpose of Research section of this consent), we will collect information on you, your test results, and how you do from you and your Loyola University Medical Center or Gottlieb Memorial Hospital medical records. The information will be collected by Dr. Kinsinger, the research assistant for the project, and data administrators.

Information about you will be provided to Loyola University of Chicago data collection and study verification agencies; and/or government regulatory agencies such as the Food and Drug Administration.

In this way, we will learn about gut-directed hypnotherapy treatment that is self-administered for functional dyspepsia.
During your participation in this study, you may not be able to access your medical records. Once your participation has been completed, access to your medical record will be reinstated.

The information we will collect and send includes:

__X__ DEMOGRAPHIC INFORMATION (e.g., name, address, phone number)

__X__ MEDICAL RECORD (including, but not limited to, history and physical exam notes, progress notes, consultation reports, laboratory test results, AND/OR operative reports)

_X___ INFORMATION RELATING TO MENTAL OR BEHAVIORAL HEALTH OR PSYCHIATRIC CARE EXCLUDING PSYCHOTHERAPY NOTES

We will collect and provide this information about you for as long as you are in the stud*y*.

Once the information is disclosed outside of Loyola University Medical Center or Gottlieb Memorial Hospital, it may no longer be protected by federal privacy laws.

De-identified data from this study may be shared with others for research purposes. We will remove or code any personal information that could identify you before data are shared with other researchers to ensure that no one will be able to identify you from the information we share, however this cannot be guaranteed. Once identifying information is removed, the information and samples cannot be withdrawn from further use. You will not be asked to sign an additional consent for this use.

It is possible that the sponsor, research nurses, data collection and/or study verification agencies, data administrators or staff, or the Food and Drug Administration will come to Loyola University Medical Center or Gottlieb Memorial Hospital and view the medical record (see above for description of content) and the research records. They may take notes or copy pages of the medical record. This is done to verify the accuracy of the information Loyola University of Chicago is sending to them.

The results of this research study may be published in a journal for the purpose of advancing medical knowledge. You will not be identified by name or by any other identifying information in any publication or report about this research.

Consent for LUMC to use and disclose your medical information is required in order for you to participate in the study.

This authorization does not expire.

WITHDRAWAL OF CONSENT: Your consent to use and disclose your medical information for the purpose of this research study is completely voluntary. You can withdraw your consent to use and disclose your information and your consent to participate in this study at any time without affecting your ability to receive care and treatment at Loyola University Medical Center or Gottlieb Memorial Hospital, as applicable, unrelated to the research study. Withdrawal means that all study procedures and follow-up will stop and we will not send any more information about you to the sponsor of this research or its designees. However, information already used and disclosed to the research sponsor prior to the time of your withdrawal from this study may continue to be used and disclosed by Loyola University of Chicago and the sponsor.

If you withdraw from the study, we will ask that you sign the form attached to this consent and give it to the study staff. Your withdrawal from the study will not have any effect on any actions by Loyola University Medical Center, Gottlieb Memorial Hospital, or Loyola University of Chicago taken before the attached form is received by Loyola University of Chicago.

Your study doctor or the Institutional Review Board, the regulatory authorities, may terminate the study at any time with or without your consent.

Your study doctor may choose to take you out of the study because of unexpected or serious side effects or treatment non-compliance. You may also be removed from the study if your study doctor feels that you are not benefiting from the study treatment.

CONSENT

I have fully explained to _____ the nature and purpose of the above-described procedure and the risks that are involved in its performance. I have answered and will answer all questions to the best of my ability. I may be reached at 708-216-0464.

_____Date:____/_____/____
Signature

Dr. Sarah Kinsinger, the principal investigator for this study, or her associates will be available to answer any questions you may have. Dr. Kinsinger can be reached at 708-216-0464

If you ever feel that you have been injured by participating in this study or if you have any questions concerning your rights as a research participant, you may contact either Kenneth Micetich, MD, Chair of the Institutional Review Board for the Protection of Human Subjects-Loyola University Chicago Health Sciences Division, at 708-216-2633 or Cynthia Tom-Klebba, MA, CIP, Director of the Human Research Subjects Protection Program at 708-216-4608.

Although you have the right to revoke this authorization, you accept that such revocation will not apply to any uses and disclosures of your information that are described in the Loyola University

Health System Notice of Privacy Practices or otherwise allowable under any Federal or State laws.

You will receive a signed copy of this informed consent document.

You have been fully informed of the above-described research program with its possible benefits and risks. Your signature below indicates that you are willing to participate in this research study and agree to the use and disclosure of information about you as described above. You do not give up any of your legal rights by signing this consent document.

_____Date:____/_____/____
Signature: Participant

PROJECT TITLE: Self-Administered Gut-Directed Hypnotherapy for Functional Dyspepsia

REVOCATION OF AUTHORIZATION TO
RELEASE PROTECTED HEALTH INFORMATION (PHI)

I, _____, hereby revoke my consent to participate in the study titled, "Self-Administered Gut-Directed Hypnotherapy for Functional Dyspepsia", at Loyola University Medical Center, Gottlieb Memorial Hospital, or Loyola University of Chicago, as applicable. I also revoke my consent to release information I provided to Loyola University Medical Center, Gottlieb Memorial Hospital, or Loyola University of Chicago, as applicable, that allowed use and disclosure of my medical information to Loyola University Chicago as outlined on the consent form, which I signed on ____/_____/____ (INSERT DATE CONSENT WAS SIGNED ORIGINALLY). I understand that this revocation does not apply to any action Loyola University Medical Center, Gottlieb Memorial Hospital, or Loyola University of Chicago, as applicable, have taken in reliance on the consent I signed earlier.

_____Date:____/_____/____
Signature: Participant

Please return this form to:

Sarah Kinsinger, PhD
Loyola University Medical Center
2160 South First Avenue
Maywood, Illinois 60153