INFORMED CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Full Study Title: Evaluating an ultra-brief virtual group intervention for anxiety during Pregnancy

Short Title: A rapid treatment over the internet for anxiety during pregnancy

Principal Investigator: Dr. S. Grigoriadis, Department of Psychiatry, 416 480 5677

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INFORMED CONSENT

You are being asked to consider participating in a research study. A research study is a way of gathering information on a treatment, or procedure to answer a question about something that is not well understood. This form explains the purpose of this research study, provides information about the study, the tests and procedures involved, possible risks and benefits, and the rights of participants.

Please ask the study staff or one of the investigators(s) to clarify anything you do not understand or would like to know more about. Make sure all your questions are answered to your satisfaction before deciding whether to participate in this research study. If you wish, someone may be available to verbally translate this form into your preferred language.

Participating in this study is your choice (voluntary). You have the right to choose not to participate, or to stop participating in this study at any time.

INTRODUCTION

You are being asked to consider participating in this study because you have anxiety and are pregnant.

Anxiety Disorders or Depressive Disorders with anxiety affect about 3/5 pregnancies. We know if left untreated, these disorders are associated with poor delivery outcomes, ongoing mental illness and negative effects on the child. The COVID-19 pandemic has made this worse because now more women are anxious than before the pandemic. Talk therapy is recommended for treatment but is under used in part because it takes a long time to learn and use. The COVID crisis has added another layer of complexity in that in-person treatment is not routinely available.

Our team has adapted a talk therapy treatment, "Mindful adaptive practice in pregnancy (MAPP)" where women are taught how to reduce anxiety. It is novel because it is: a) ultra-brief in duration (one month); b) specific to pregnancy; c) delivered in a group format; and d) over the internet. The overall objective of this study is to assess if we can successfully recruit women to take part in a study evaluating MAPP on anxiety symptoms among pregnant women. The results of this pilot study will guide the development of a large multi-site randomized controlled trial (RCT) to definitively evaluate MAPP's effect on anxiety.

Women will be recruited from various places including hospital clinics and social media to capture all kinds of pregnant women. They will be randomized to receive MAPP or standard care. We will assess outcomes immediately post treatment, 3, and 6 months after treatment. We want to be able to show we can recruit the participants, that MAPP is acceptable and that it is adhered to. As a secondary outcome, we want to assess the effects of MAPP on anxiety so that we can calculate the right number of participants for the large RCT.

MAPP has the potential to change clinical practice as we will be able to reach women in rural and remote regions; women will learn a technique quickly and then use it right away to reduce their anxiety.

WHAT IS THE USUAL TREATMENT?

Methods to reduce anxiety include using phone applications, bibliotherapy, community resources or a physician visit for specific therapy. Family physicians, obstetricians or midwives can further refer to a psychiatrist. Following a psychiatric consultation, a patient may be given resources and may be further referred for individual or group psychotherapy. Several forms of therapy have evidence that they reduce anxiety. Medication is reserved for moderate to severe anxiety in those diagnosed with an anxiety disorder or depressive disorder with prominent anxiety

WHY IS THIS STUDY BEING DONE?

The purpose of this pilot trial is to determine if we can recruit for this study and collect all the outcome data. We also want to determine how much MAPP can reduce anxiety from the start of the study to the end of treatment in the treatment group versus the control group. We will use the information we gain to plan a large RCT to assess how well MAPP reduces anxiety.

WHAT WILL HAPPEN DURING THIS STUDY?

Participants in this study will be randomly (by chance) placed in one of 2 study groups. Neither you, the study staff nor the investigator(s) can influence which group you are in. You will have a 50% chance of being placed in either group. You and the Trial Coordinator will know which group you are in but the investigators and research staff that will ask you questions about your anxiety, will not.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

It is anticipated that about 60 people will participate in this study at about 2 centres (Sunnybrook Health Sciences and Women's College Hospital) and from social media. The length of this study for participants is 26 weeks. The entire study is expected to take about 2 years to complete and the results should be known in 2.5 years.

WHAT ARE THE RESPONSIBILITIES OF STUDY PARTICIPANTS?

If you decide to participate in this study you will be asked to do the following:

Details to be considered for all participants:

• The results of the first anxiety questionnaire you complete on our study website will determine if you are eligible to participate in the study. You have to have a certain level of anxiety.
• The total time commitment for participation.
• The total number or frequency of visits/contacts. You will be asked to complete questionaries online 4 times.
• You will be able to continue to see your healthcare provider if you have one for your anxiety.

• The Trial Coordinator has spoken to you already and is available to answer any questions you may have. All outcomes will be collected online but there will be 4 times where you will speak to research staff who will not be aware of which group you belong to ask you questions about your anxiety.
• The questionnaires will take about 15-30 minutes to complete.
• We will need the name and contact information of your family doctor and friend so that we have another way of reaching you in case we have not been able to contact you.
Additional details to be considered for the MAPP treatment group:
- If you are in the treatment group, the treatment will take 4 weeks.

• The treatment will occur wherever you choose as it will be delivered online. It is important though to be in a quiet place away from distractions.
• The length of time for each treatment is 2 hours, and there will be 5 sessions in 4 weeks.
• At each treatment session, MAPP will be taught to you if you are in that group. Various techniques will be taught to you to reduce your anxiety.
• In order to make sure our therapists are delivering the therapy in the right way we will record the sessions. You will be given the option of either consent or not to this. If you chose not to, we will ensure your will not be recorded.
• You require a device (i.e., cell phone, table, computer) with internet access.

WHAT ARE THE RISKS OR HARMS OF PARTICIPATING IN THIS STUDY?

We do not anticipate any side effects from receiving the psychotherapy but we will ask you questions about whether you think it has affected you in negative ways just to make sure. We will ask about whether you think the therapy made you worse, and more preoccupied with the anxiety and if the therapy is affecting your personal, family or work life.

You should contact **Dr. Robinson, 416 480 5677** who works in the Women's Mood and Anxiety Clinic: Reproductive Transitions, about any side effects or study related injuries that you experience. You will be told about any new information that might reasonably affect your willingness to continue to participate in this study as soon as the information becomes available to the study staff.

WHAT ARE THE BENEFITS OF PARTICIPATING IN THIS STUDY?

You may or may not benefit directly from participating in this study. **However, possible benefits include your anxiety reducing and you being better able to handle it. You may also be able to continuing applying these techniques in the future if your anxiety returns.** Your participation may or may not help other people with anxiety in the future.

WHAT OTHER CHOICES ARE THERE?

If you decide not to participate in this study, and are concerned about the level of your anxiety, you can see your healthcare provider to determine if you can access psychotherapy for the anxiety or medication.

CAN PARTICIPATION IN THIS STUDY END EARLY?

The investigator(s) may decide to remove you from this study without your consent for any of the following reasons:
• You are much worse and not coping at home or work.
• You are having active thoughts of suicide.
• The investigator(s) decide(s) that continuing in this study would be harmful to you.

• You are unable or unwilling to follow the study procedures.
• If we find evidence that the treatment is not working.

If you are removed from this study, the investigator(s) will discuss the reasons with you and together you will make plans for your continued care outside of the study. You can also choose to end your participation at any time without having to provide a reason. If you choose to withdraw, your choice will not have any effect on your current or future medical treatment or health care. If you withdraw voluntarily from the study or at the request of your doctor or midwife, you are encouraged to contact **Dr. Grigoriadis, 416 480 5677**. If you withdraw your consent, the information about you that was/were collected before you left the study will still be used. No new information about you will be collected.

WHAT ARE THE COSTS OF PARTICIPATING IN THIS STUDY?
There are no costs associated with taking part in this study but you do need to have internet access. Depending on your plan, you may incur additional internet fees.

WHAT HAPPENS IF I HAVE A RESEARCH RELATED INJURY?
If you become sick or injured as a direct result of your participation in this study, your medical care will be provided. Financial compensation for such things as lost wages, disability or discomfort due to this type of injury is not routinely available. By signing this consent form, you do not give up any of your legal rights.

ARE STUDY PARTICIPANTS PAID TO PARTICIPATE IN THIS STUDY?
You will not be paid to participate in this study. However, if you decide to participate in this study, you will be given an Indigo gift card for $15.00 after each time you complete study questionnaires (4 times total) as a token of our appreciation.

HOW WILL MY INFORMATION BE KEPT CONFIDENTIAL?
You have the right to have any information about you and your health that is collected, used or disclosed for this study to be handled in a confidential manner. If you decide to participate in this study, the investigator(s) and study staff will collect only the information they need for this study. We need your name and contact details so as to contact you as well as that of your healthcare provider and friend if we have not been able to reach you.

The following people may come to the hospital to check that the information collected for the study is correct and to make sure the study followed the required laws and guidelines:

- Representatives of the Sunnybrook Research Institute, Sunnybrook Health Sciences Centre or the Sunnybrook Research Ethics Board, because they oversee the ethical conduct of research studies at Sunnybrook; and access to your data will take place under the supervision of the Principal Investigator. “Study data" is health information about you that is collected for the study, but that does not directly identify you.

- The investigator(s), study staff and the other people listed above will keep the information they see or receive about you confidential, to the extent permitted by applicable laws. Even though the risk of identifying you from the study data is very small, it can never be completely eliminated.

- The Principal Investigator will keep any personal information about you in a secure and confidential location for 10 years and then destroy it according to Sunnybrook policy.

- When the results of this study are published, your identity will not be disclosed. You have the right to be informed of the results of this study once the entire study is complete. If you would like to be informed of the results of this study, please provide your name, address and telephone number to the assistant in the Women's Mood and Anxiety Clinic: Reproductive Transitions (416, 480 - 5677)**.**

- A description of this clinical trial will be available on 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 Web site at any time.

- Collecting data using technology over the internet can increase potential risks to privacy and confidentiality. This study will be using the internet to collect data for this study. The data will reside on an external server and no assurance can be made about its confidentiality or that it will only be used for this research purpose. Please read the terms and agreement of the service provider for further information regarding data security and confidentiality of the technology being used.

- This study will be using U.S. based internet service providers which means that the electronic data will be stored and accessed in the U.S. and is therefore subject to U.S. laws including the U.S Freedom Act. The Freedom Act allows authorities access to the records of internet service providers. It is therefore possible that this information could be disclosed to U.S. federal officials.

ARE THERE ANY CONFLICTS OF INTEREST/RELATIONSHIPS?

A conflict of interest exists if there is a potential benefit or the perception of a benefit to the investigator(s), study staff, member of their immediate family and the institution beyond the professional benefit from academic achievement or presentation of the results. Examples include, but are not limited to, speaker's fees, travel assistance, consultant fees, honoraria, gifts, and intellectual property rights such as patents.

There are no conflicts of interest to declare related to this study.

COMMUNICATION WITH YOUR FAMILY DOCTOR

Your family doctor may be informed that you are taking part in this study if we cannot reach you or if we have concerns for your health. If we have concerns for your health, the study doctor and family doctor can help you make informed decisions about your medical care.

WHAT ARE THE RIGHTS OF PARTICIPANTS IN A RESEARCH STUDY?

You have the right to ask questions and to receive answers throughout this study. If you have any questions about this study you may contact the person in charge of this study (Dr. S. Grigoriadis, 416 480 5677). The Sunnybrook Research Ethics Board has reviewed this study. If you have questions about your rights as a research participant or any ethical issues related to this study that you wish to discuss with someone not directly involved with the study, you may call the Chair of the Sunnybrook Research Ethics Board at (416) 480-6100 ext. 88144.

DOCUMENTATION OF INFORMED CONSENT
You will be given a copy of this informed consent form after it has been signed and dated by you and the study staff.

Name of Participant (print): _____

Participant
By signing this form, I confirm that:
• This research study has been fully explained to me and all of my questions answered to my satisfaction
• I understand the requirements of participating in this research study
• I have been informed of the risks and benefits, if any, of participating in this research study
• I have been informed of any alternatives to participating in this research study
• I have been informed of the rights of research participants
• I have read each page of this form
• I have agreed, or agree to allow the person I am responsible for, to participate in this research study
• I understand that my family doctor may be informed of my participation in this research study.
• This informed consent document may be placed in my medical records.

_____	_____	_____
Name of participant (print)	Signature	Date

Person obtaining consent
By signing this form, I confirm that:
•This study and its purpose has been explained to the participant named above
•All questions asked by the participant have been answered
• I will give a copy of this signed and dated document to the participant

_____	_____	_____
Name of Person obtaining Consent (print)	Signature	Date

Statement of Investigator
I acknowledge my responsibility for the care and well being of the above participant, to respect the rights and wishes of the participant as described in this informed consent document, and to conduct this study according to all applicable laws, regulations and guidelines relating to the ethical and legal conduct of research.

_____	_____	_____
Dr. S. Grigoriadis	Signature	Date