

MANAGE YOUR STRESS AND ANXIETY: IMPROVE YOUR HEALTH

RANDOMIZED CONTROLLED TRIAL OF A SMARTPHONE INTERVENTION TO HELP PATIENTS NEWLY DIAGNOSED WITH CANCER COPE BETTER: PILOT STUDY

Information and consent form to participate in a research study

PRINCIPAL INVESTIGATORS:

Melissa Henry Ph.D., Assistant Professor, Depts. of Oncology and Psychology (Professional), Faculty of Medicine, McGill University
Psychologist, Otolaryngology – Head and Neck Surgery Department, Jewish General Hospital
Clinician-Scientist, Lady Davis Institute for Medical Research, Jewish General Hospital

CO-INVESTIGATORS:

Please see Appendix 1.

This study is being conducted at the McGill University Health Centre (MUHC) and the Jewish General Hospital.

DESCRIPTION:

You are being invited to take part in this study because of your personal experience with cancer. Experiencing the diagnosis and treatment of cancer can be very stressful. Sometimes people find it useful to receive additional information and strategies about how to prevent or cope with this anxiety. The purpose of this study is to evaluate whether a new smartphone application would be helpful for patients coping with the diagnosis and treatment of cancer. Your participation is voluntary, you can choose to take part or not of this study without affecting your care.

PROCEDURE:

We intend to recruit 60 participants for this study. If you choose to participate in this study, after having completed a first set of questionnaires, you will be randomly assigned to one of three groups:

Group 1: the new smartphone application including four modules which should be done over a period of 3 weeks during your waiting time in the hospital;
Group 2: a game application which will be used over a period of 3 weeks during your waiting time in the hospital; or
Group 3: usual care alone, i.e., only completing questionnaires, structured interviews and giving biological samples

Someone from our research team will inform you to which group you will be assigned.

GROUP 1:

- If you are assigned to receive a smartphone application (Group 1), there will be an introduction meeting as soon as possible after completing the first set of questionnaires.
- The application will then be downloaded onto your (or a study-provided) mobile device or tablet and you will be shown how to use the app.
- You will be asked to complete the four modules within 3 weeks during your waiting time for at least one hour and you are welcome to use the application outside of the hospital as much as you want.
- We will ask that you complete a diary indicating when you use the app during this 3-week timeframe.

For the purpose of this research, it is important that you do not talk with other patients about the content of the application you receive.

GROUP 2:

- If you are assigned to receive a game application (group 2), there will be an introduction meeting as soon as possible after having been assigned to your group.
- The game application will then be downloaded onto your (or a study-provided) mobile device or tablet and you will be shown how to use the app. You will be asked to use the app over a period of 3 weeks during your waiting time in the hospital.
- We will ask that you complete a diary indicating when you use the app during this 3-week timeframe.

GROUP 3:

- If you are assigned to usual care alone (Group 3), you will only be asked to complete the questionnaires, structured interviews and to give biological samples.

ALL GROUPS:

- All participants in this study will be asked to complete a set of questionnaires at the first meeting as well as at 1, 3 and 6 months after study enrolment. Each set of questionnaires will take approximately 30 minutes to complete. You may complete each set of questionnaires at home and mail them back to Dr. Melissa Henry within 72 hours.
- A pre-addressed stamped envelope will be provided, and you will be reminded of when to complete the questionnaires.
- The questionnaires to be completed include information about your background and your thoughts and feelings related to your experience of cancer.
- All participants in this study will be asked to come for a structured interview at the first meeting, as well as at 3 and at 6 months. The structured interviews will be administered by our research coordinator and will take approximately 30 minutes to complete.

In addition, we are collecting blood and saliva samples in this study, with the goal of analyzing biological indicators of stress and anxiety in relationship to the intervention.

Blood sampling:

- You will have 4 ml of blood (1 tube) taken at the first meeting, as well as at 1, 3 and 6 months.
- The blood will be taken from your arm. We will do our best to coordinate the collection of blood so that it occurs at the same time as your routine blood tests. The research coordinator will help you to coordinate this.
- We ask you to abstain from alcohol use, recreational drug use and caffeinated beverages on the day of the blood draw.

Saliva sampling:

- This will take place 4 times per day over 2 days (at awakening, 30 min after being awake, 4 p.m. and 9 p.m.) via a swab at the first meeting, as well as at 1, 3 and 6 months.
- You will be asked to place the swab in your mouth and keep it in place for 1-2 minutes to ensure that it is saturated and then place it in a container.
- An hour prior to sample collection, we will ask you to avoid caffeine, alcohol, and nicotine: not to brush or floss your teeth; and not to use mouthwash, drink anything except water, or eat.
- Prior to saliva collection, we will also ask you to rinse your mouth out with water and wait at least 10 minutes after rinsing to avoid sample dilution before collecting saliva.
- We will ask you to bring the samples directly to Dr. Henry's lab upon your next hospital visit in a cooler provided by the research associates.

If you agree to take part in this study, your medical chart will be reviewed in order to obtain information about your disease status that is relevant to this study. Information such as date of diagnosis, stage of cancer and medical treatments you have received (if applicable) will be obtained.

STORAGE AND SAFEKEEPING OF BIOLOGICAL SAMPLES COLLECTED IN THIS STUDY:

We will protect the confidentiality of the samples by assigning them a specific code. Your saliva and blood samples will not be specifically identified but a code will link you to the samples. The principal researcher can only perform decoding or a person authorized by the principal researcher. If you no longer want your samples to be used as part of the research you can contact Dr. Melissa Henry, who will have your samples destroyed. Please note that any analysis done before the destruction of the samples will be kept to ensure the scientific integrity of the study.

Blood and saliva samples will be kept in a laboratory freezer of a research collaborator at the Jewish General Hospital under the responsibility of Dr. Melissa Henry until 10 years after the end of the research project (i.e., 10 years after the last recruited patient completed participation). After this time, all samples will be destroyed. All vials containing biological samples will be annotated with your participant number to ensure your confidentiality. The analysis of these samples will be done by a Canadian institution that will sign a contract with the Jewish General Hospital and the investigator, and the confidentiality of your samples will be assured.

BENEFITS:

We do not know if the application proposed in this study will be helpful for people with head and neck cancer. However, it has been found helpful for people with other types of cancer. We hope the application will help you cope with the experience of cancer.

The results of this study could help health professionals better understand and design ways to help people with cancer. All assigned conditions are important in this respect.

RISKS:

Occasionally one or more of the following potential side effects of taking blood samples may occur: pain, bruising, slight bleeding, light-headedness, fainting and (rarely) an infection. A trained technician will be drawing the blood. The treatment or procedure may involve risks that are currently unforeseeable. There are no known risks or discomforts from the saliva collection technique.

There are no other known risks associated with this study. However, you may feel sad during some of the modules because of the nature of the topic. You are free to stop the usage of the app, continue at a different time, or withdraw from the study at any time. You will be provided with the name of a psychologist or nurse should you wish to have further follow-up at the end of the study.

CONFIDENTIALITY:

For the data collected by our research team:

While you take part in this research study, the researcher in charge and study staff will collect and store personal identifiable information about you in a file for the purpose of the research study. Only information necessary for the research study will be collected.

All the information collected about you during the study will remain confidential within the limits of the Law. To protect your identity, your name and identifying information will be replaced with a code (numbers and or letters), the link between the code and your identity will be held by the researcher in charge of the study. No information that discloses your identity will be allowed to leave the institution. All research information will be permanently destroyed 10 years after the study ends.

The study results could be printed/published in medical journals or shared with other people at scientific meetings. Rest assured that your identity will not be revealed.

A copy of this consent form will not be placed in your medical record file but a copy will be given to you.

For the purpose of monitoring this research, your research study file as well as your medical records identifying you could be checked by people authorized by the Research Ethics Committee of the CIUSSS du Centre-Ouest- de-l'Île de Montréal and the MUHC. These people and groups are obliged to respect your privacy.

You have the right to look at your study file in order to check the information gathered about you and to correct it, if necessary, as long as the study researcher or the institution keeps this information. However, you may only have access to certain information once the study has ended so that the quality of the research study is protected.

For the data collected via the app:

Please note that the data you will be entering in the app will be securely stored on a server at the Jewish General Hospital. Only the study researchers and research staff will have access to the data. Security of the app is only as secure as the phone/device itself. Please use the security features on your device if you are concerned about the privacy of your information. You are free to share data, but as the self-monitoring data belong to each user, privacy rules and regulations do not apply while the data are stored or shared.

Research Study Registry:

A description of this study will be posted on the website <http://www.ClinicalTrials.gov>. 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.

FINANCIAL COMPENSATION:

You will not be receiving financial compensation through this study.

SHOULD YOU SUFFER ANY HARM:

Should you suffer harm of any kind related to the research study, you will receive the appropriate care and services as required by your state of health. By agreeing to participate in this research study, you do not give up any of your legal rights nor discharging the doctor in charge of this research study, the sponsor or the institution, of their civil and professional responsibilities.

STUDY PARTICIPANT RIGHTS:

Your participation in this study is completely voluntary. Refusal to participate will involve no penalty or loss of benefit and will not affect your care in any way. You have the right to ask questions at any time. You have the right to refuse to answer any question or withdraw from the study altogether. Should you need more help, you will be referred to the appropriate resource.

For any complaints about your participation in this research study you may contact the Commissioner of Complaints & Quality of Services for the CIUSSS du Centre-Ouest-de-l'Île de Montréal at (514) 340-8222 ext. 25833.

If you have more questions about the study, please feel free to call the research coordinator for the study at (514) 340-8222 ext. 26755, or Melissa Henry PhD (514) 340-8222 ext. 22252. You will be given a copy of this form for your records. At the end of the study, you may receive a written summary of our findings at your request.

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Statement of the participant

By signing this form, I agree to participate in this study as outlined above. I am satisfied with the information that I have received about the study. My decision to be a part of this study is completely voluntary. I also have had an opportunity to ask questions and they were answered to my satisfaction. I do not waive my legal rights by signing this consent form. I will receive a copy of this consent form for my records.

_____	_____	_____ / _____ / _____
Name of Participant (print)	Signature of Participant	Yr Mo Day

Consent form administered and explained in person by:

_____	_____	_____ / _____ / _____
Name of Research Coordinator or Research Assistant (print)	Signature of Research Coordinator or Research Assistant	Yr Mo Day

APPENDIX 1.

CO-INVESTIGATORS:

- Zeev Rosberger, PhD., Associate Professor of Oncology and Psychology, McGill University
Director of the Louise Granofsky-Psychosocial Oncology Program, Jewish General Hospital
- Nader Sadeghi, M.D., Chair and Full Professor of Otolaryngology–H&N Surgery, McGill University; Surgeon, McGill University Health Centre (MUHC)
- Saul Frenkiel, M.D., B.Sc., Full Professor of Otolaryngology–H&N Surgery, McGill University; Surgeon, Jewish General Hospital
- Michael Hier, M.D., Associate Professor of Otolaryngology, McGill University
Chief and Surgeon, Otolaryngology–H&N Surgery, Jewish General Hospital
- Anthony Zeitouni, M.D., Associate Professor, McGill University; Surgeon, Otolaryngology–H&N Surgery at the MUHC
Director, McGill Head and Neck Cancer Program
- Karen Kost, M.D., Associate Professor of Otolaryngology, McGill University
Surgeon, Director of the Voice and Dysphagia Laboratory of the McGill University Health Centre
- Alex Mlynarek, M.D., M.Sc., Assistant Professor of Otolaryngology, McGill University; Surgeon, Otolaryngology–H&N Surgery, Jewish General Hospital
- Gabrielle Chartier, B.Sc., M.Sc. (cand.), Nurse Navigator, Otolaryngology–H&N Surgery, Jewish General Hospital
- Michael Antoni, PhD., Full Professor, Psychology Department, University of Miami; Director of the Center for Psycho-Oncology Research
- Eric Kuhn, PhD., Assistant Professor, Psychiatry and Behavioral Sciences Department, Stanford University; U.S. Department of Veterans Affairs, National Center for PTSD
- Daren Heyland, M.D., M.Sc., Full Professor of Medicine and Epidemiology at Queen's University, Kingston, Ontario Canada
Surgeon, Kingston General Hospital
- Robert Platt, PhD., Full Professor, Epidemiology, Biostatistics, and Occupational Health Department, McGill University
- Fabienne Fuehrmann, B.Sc., M.Sc. (cand.), international graduate student in psychology from the Otto-von-Guericke University Magdeburg
Trainee at McGill University and Jewish General Hospital