Participant Information Sheet/Consent Form

Title	MindOnLine: a mindfulness program for people with breast, bowel or prostate cancer.
Short Title	MindOnLine
Principal Investigator	Prof Trish Livingston
Location	Deakin University

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project, because you have received treatment for breast, prostate or bowel cancer. This research project is testing an online mindfulness-based program for people who have completed their treatment.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the procedures involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or healthcare worker.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to provide consent online. By agreeing you are telling us that you:
- Understand what you have read
- Consent to take part in the research project
- Consent to have the tests and treatments that are described
- Consent to the use of your personal and health information as described.

2 What is the purpose of this research?

Following treatment for cancer, many people feel anxious and scared about the cancer coming back. This is one of the most common fears of cancer survivors, and it can affect people's ability to enjoy life

and plan for the future. In some people, this fear can decrease over time, but most people find that they worry at certain times. The mindfulness program aims to help cancer survivors to manage their fears and worries once treatment is completed.

Research has shown that mindfulness-based programs can help people cope with anxious thoughts about their cancer. The internet allows people to use the program from the comfort of their home, and at their most convenient times. We have tested an online mindfulness program for people who received treatment for melanoma, with promising results. This research is to find out whether mindfulness can help people with breast, prostate or bowel cancer.

This research is being conducted across healthcare services and cancer organisations and is led by researchers at the School of Nursing and Midwifery at Deakin University.

In this research project we will be testing a mindfulness program among people who meet the following criteria:

- People who are over 18 years of age
- People who speak English well enough to understand videos and surveys presented in English
- People who have access to a computer or device to receive the program
- People who received treatment for breast, bowel or prostate cancer
- People who finished chemotherapy, radiotherapy or surgery treatment within the last five years
- People who experience a high level of fear of cancer recurrence.

You will be asked some questions after providing consent to determine if you meet the eligibility criteria above. To measure your fear of cancer recurrence you will be asked 9 questions about how your thoughts and feelings towards cancer may impact on your everyday living.

3 What does participation involve?

To participate in this study, each participant will need to have access to a computer, a smartphone, or a similar tablet device, and internet. If you agree to take part in this project you will be allocated to either receive the mindfulness program (intervention group) or stay in your usual care (control group). We need to compare responses from people in these two groups to see if the mindfulness program provides any benefits to cancer survivors. In order to make sure the groups are the same, participants are put into one of the two groups by chance (random).

If you decide to take part in this study, you will need to provide your consent to participate by accessing the following website: https://mindonline.org.au Before providing your consent you will be asked a number of questions to make sure you are eligible for the study.

After consenting to take part in the study, you will be asked to complete a survey before being randomly allocated to the intervention or control group. The same survey will be completed again 9 weeks and 9 months later. The survey asks you questions about possible fears of the cancer coming back, how stressful and worrisome you perceive your life to be, and the type of thoughts you generally focus on. We will also collect your email address and contact number. Your email and contact number will be used to send you reminders and other information related to the study.

If you are randomised to the mindfulness program, you will receive an email informing you of your allocation group with instructions on how to access the website. Your participation will involve using the program for 9 weeks. The program is designed to help you understand and experience potential benefits of using mindfulness in your day to day life. You will be invited to:

- Watch short videos at the start of each week. The videos will introduce a new topic about mindfulness.
- Practice short meditations twice a day. We will help you create a meditation routine by emailing you a direct link to guided meditations at times you will have chosen.
- Apply mindfulness skills in your day-to-day life.

If you are assigned to the mindfulness program we will monitor how often the mindfulness program is used. This will be recorded by your study identification number, and no personal information such as your Internet Protocol (IP) address linked to your computer or device will be collected.

If you are randomised to the control group you will receive an email informing you of your allocation group and you will continue to receive your usual care from your healthcare providers. You will receive emails to ask you to complete the questionnaires at 9 weeks and 9 months. After the 9-month survey you will be able to use the mindfulness program.

We will compare the results between those in the mindfulness program and those who are not, to see if there are any differences in wellbeing between the two groups.

There are no additional costs associated with participating in this research project, nor will you be paid.

4 Other relevant information about the research project

This study will show if the mindfulness program is helpful for people with breast, prostate or colorectal cancer. If successful the program we be made open to the wider population.

For this study, approximately 400 people will be invited to participate from online and social media advertisements and from healthcare services.

5 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part you don't have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your relationship with those treating you or involved in your follow-up care, or your relationship with Deakin University, Breast Cancer Network Australia, or Prostate Cancer Foundation of Australia.

6 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits for the community may include additional support for people who have completed treatment for cancer.

7 What are the possible risks?

Some people may feel uncomfortable or upset when answering questions in this survey. If you do not wish to answer a question you may skip it and go to the next question, or you may stop immediately. In the event that you become upset or distressed as a result of your participation, the researcher can arrange for counselling or other appropriate support provided by staff who are not members of the research team. In addition, you may want to contact an external support service such as Lifeline services on 13 11 14, or www.mindhealthconnect.org.au or the Cancer Council 13 11 20 telephone service.
If you have any concerns or are unsure whether you should participate in this project, you may wish to speak to your healthcare professional about your feelings.

8 What if I withdraw from this research project?

If you decide to withdraw, please notify a member of the research team about this decision. This notice will ensure that we can remove you from our records and will mean you will not receive any notices about the project.

If you decide to withdraw from the project, we would like to keep the personal and health information about you that has been collected. This is to help us make sure that the results of the research can be measured properly. If you want to withdraw your data from the study as well, please let them know when you tell them about withdrawing from the study.

9 What happens when the research project ends?

If you wish to obtain a final copy of the research report describing the results of this study, please contact the project manager (Dr Natalie Heynsbergh on 03 9246 8225, or email n.heynsbergh@deakin.edu.au) and she will arrange for a copy to be sent to you after completion of the study in December 2022.

Part 2 How is the research project being conducted?

10 What will happen to information about me?

Any information obtained in connection with this research project that can identify you (e.g. email address) will remain confidential and will only be used for the purpose of this research project. It will only be disclosed with your permission, except as required by law.

All the information you provide will be coded so you cannot be identified by name, and only the research team will have access to the list that can link your name to your data. All identifying information will be stored in password-protected electronic files or in a locked filing cabinet in the office of the research staff, and will be disposed of as confidential waste after five years.

You will not be identified in any report or publication from this study. Information will be provided in such a way that you cannot be identified.

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. You also have the right to request that any information with which you disagree be corrected. Please contact one of the researchers named in the last section below if you would like to access your information.

11 Who is organising and funding the research?

This research project is being managed by Dr Natalie Heynsbergh at Deakin University, and is being funded by a National Health and Medical Research Council (NHMRC) grant.

12 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been

approved by the Peter MacCallum Human Research Ethics Committee (Reference number 20/53) and the Deakin University Human Research Ethics Committee.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

13 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact:

- The principal investigator: Prof Patricia Livingston on 03 9244 6609, or email trish.livingston@deakin.edu.au
- The project manager: Dr Natalie Heynsbergh on 03 92468225, or email: n.heynsbergh@deakin.edu.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC name	Peter MacCallum Cancer Centre Ethics Committee
Project reference number	20/53
HREC Executive Officer	Ethics Coordinator
Telephone	03 8559 7540
Email	ethics@petermac.org

14 What do I do if I want to participate?

If you would like to participate in this study, please log on to https://mindonline.org.au, to answer the eligibility questions and provide your consent to participate.