Participant Information Sheet/Consent Form

Project Title: Online mindfulness for people diagnosed with cancer (OM-C) study

Project Summary:

You are invited to participate in a research study into the feasibility and effectiveness of a seven-week online mindfulness course for people with cancer.

Mindfulness therapy in the health system is a treatment modality that uses the practice of attentional regulation as a means to self-sooth and regulate emotions, develop greater body and mental awareness, and create a change in perspective on the self. Mindfulness has been shown to be safe and effective for a range of symptoms such as fear of cancer reoccurrence, depression, anxiety, stress, mood disturbance, sleep disturbance, quality of life, and blood pressure in multiple trials. While mindfulness is now well accepted in the health system as an evidence based therapeutic intervention, there are barriers for people with cancer to accessing this therapy.

This study is being undertaken by Chris O'Brien Lifehouse and Western Sydney University to determine 1) the feasibility of an online mindfulness program for people diagnosed with cancer, 2) the effectiveness of the online mindfulness program on measures of distress, physical health and quality of life.

What will I be asked to do?

If you agree to participate in this study, you will be asked to complete an initial screening process, attend a seven-week online group mindfulness course (90 minutes each class), and complete study questionnaires at the start and completion of the course.

Initial appointment: If you agree to participate in this study, you will be asked to attend an appointment, this will be either face-to-face, by phone or on the ZOOM video conferencing platform to determine your eligibility to participate in this clinical trial. To assess your eligibility, you will be asked to read the participant information sheet and voluntarily provide written informed consent. Once informed consent is given, the research officer will ask about your demographic information, and send you a questionnaire to complete to ensure you can safely undertake the program. If your responses on our questionnaires indicate that you are experiencing clinical levels of depression, anxiety, or stress, this study may not be suitable for you and you will be offered a referral to psycho-oncology if it's been less than 12 month since active treatment at Lifehouse. If it's been greater than 12 months since active treatment, it will be recommended that you contact your GP for referral to a psychologist. When enrolled in the study, instruction will be given to ensure that you understand how to use the ZOOM online technology at home.

Online Mindfulness program: The program involves seven weekly group mindfulness classes Participants will be required to attend seven mindfulness classes online with a qualified mindfulness teacher. You will also be asked to do a mindfulness practice at home.

How much of my time will I need to give?

The initial screening will take approximately 20-30 minutes. You will attend seven group mindfulness sessions conducted face to face online (using ZOOM), once a week for seven weeks (90 minutes per class), plus a regular mindfulness practice and learning using web-based resources at home. You will need to complete seven questionnaires at the start and completion of the study. These forms will be completed electronically and take an estimated 20-30 minutes to complete.

Is there any cost?

The course is provided free of charge, and participation in the study will cost you nothing, nor will you be paid.

What benefits will I, and/or the broader community, receive for participating?

Your participation will allow us to assess the effectiveness of an online mindfulness intervention, to improve coping skills, empowerment levels, psychological and physical health and quality of life in people with cancer. Positive outcomes in these measures will not only benefit you but provide the basis for future research and delivery of this intervention to other people with cancer.

Will the study involve any risk or discomfort for me?

The risks of participating in this study are of a minimal nature and only constitute inconvenience to you for having to take time to participant in the course and complete the study measures. There are no other anticipated risks to you. Mindfulness generally has very low rates of adverse events, and occurrences of these are not anticipated in this study. An adverse events record form will be used to record any unexpected signs, symptoms or feelings of distress or discomfort during the trial period. All reported adverse events that occur between consent and the last visit for the study will be recorded in detail. If any symptoms do develop after consent and during the trial, you will be instructed to contact the Research Officer. In the case of an adverse event, the Investigator may recommend that you seek medical advice from a general practitioner (GP) or other health professional.

How do you intend to publish or disseminate the results?

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that the participant cannot be identified, such as tables and graphs showing the overall information.

Will the data and information that I have provided be disposed of?

Please be assured that only the researchers will have access to the data you provide. Deidentified information collected about you will be kept for future use for research studies currently unknown and may be shared with National and International research collaborators however ethical approval will be obtained prior to their use.

All web-based information transmission is encrypted. This study will collect data in Research Electronic Data Capture (REDCap). REDCap was developed specifically around HIPAA-Security guidelines and is implemented and maintained according to Western Sydney University guidelines. The deidentified data will be stored on a secure a fire-wall protected server within RedCAP under the license of Western Sydney University. Access is restricted the Research team named on the Ethics. We will store all information collected for this study securely and destroy it 15 years after the results are published in accordance with university policy and the Australian Code for the Responsible Conduct of Research.

Can I withdraw from the study?

Participation is entirely voluntary, and you are not obliged to be involved. If you do participate you can withdraw at any time you withdraw, you can advise us that you do not consent for us to use the data we collected up until your withdrawal. We will only use the information that you give consent for us to use. Whatever your decision, it will not affect your treatment or your relationship with the research or medical staff.

What if I require further information?

Please contact *Dr Suzanne Grant* should you wish further information.

Dr Suzanne Grant, Email: suzanne.grant@lh.org.au

Phone: 0419126209

What if I have a complaint?

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 approving this research and Research Officer details

Reviewing HREC name	St Vincent's Hospital HREC
Position	Research Officer
Telephone	02 8382 4960
Email	SVHS.Research@svha.org.au

Local Research Office contact the Chris O'Brien Lifehouse Research Governance Officer)

Name	Research Governance Officer
Position	Research Governance Officer
Telephone	02 8514 0410
Email	sarah.amos@lh.org.au

Ethics Approval

This study has been approved by the St Vincents Human Research Ethics Committee. The Approval number is HREC ETH02594.

PARTICIPANT CONSENT FORM

Project Title: Online mindfulness for people diagnosed with cancer (OM-C) study

Declaration by Participant

I hereby consent to participate in the above named research project+

On the next screens, you will view the informed consent document. Please read all sections of the informed consent document. After each section, you may be asked to answer some questions before continuing onto the next section.

I hereby consent to participate in the above named research project.

I acknowledge that:

• I have read the Participant Information Sheet (or where appropriate, have had it read to me) and have been given the opportunity to discuss the information and my involvement in the project with the researcher/s

• The procedures required for the project and the time involved have been explained to me, and any questions I have about the project have been answered to my satisfaction.

I consent to:

Q1 *Providing demographic information through self-report including gender, race/ethnicity, age*

☐ Yes

Q2 *Attending mindfulness sessions online via the Zoom videoconferencing platform, and completing personalised mindfulness practice if directed*

☐ Yes

Q3 *Providing information for research purposes by completing self-report assessment measures and questionnaires related to physical and psychological health and well-being*

☐ Yes

Q4

I consent for my data and information provided to be used for this project.

I understand that my involvement is confidential and that the information gained during the study may be published, but no information about me will be used in any way that reveals my identity.
I understand that I can withdraw from the study at any time without affecting my relationship with the

researcher/s, or any persons or organisations involved, now or in the future.

☐ Yes

Q5 Optional:

I consent for my treating oncologist being informed of my participation in this study.

☐ Yes ☐ No

☐

Q6 Name of treating oncologist:

_____

Q6 Signed:

Q11 Name:

_____

Q9 Date:

This information is for you to keep.