

EXPLANATORY STATEMENT

Project title: CanCope: Testing A Brief, Online Information Sheet on the Role of Emotions After Cancer

Project ID: 20660

Project E-mail: psych.cancope@monash.edu

Dr. Joshua F. Wiley

Chief research investigator

School of Psychological Sciences

Phone: 03 990 59598

E-mail: joshua.wiley@monash.edu

Isabelle Smith

PhD student (Clinical Psychology)

School of Psychological Sciences

E-mail: isabelle.smith@monash.edu

You are invited to take part in a research project on the feasibility, satisfaction, and impact of a brief information sheet to help people who have had cancer to gain a better understanding of their emotions.

This Explanatory Statement and Consent Form explains what is involved to help you decide if you would like to take part. Please read this information carefully. Ask questions about anything that you do not understand or want to know more about. Before deciding whether to take part, you might want to discuss it with a relative, friend, or health professional.

Participation in this study is voluntary; you do not have to take part if you do not want to. If you do agree to take part, please fill in the Consent Form below. This will show that you understand what the study is about, give your consent to take part, and consent to the use of your personal and health information as described.

This study is led by a team of researchers, psychologists, and psychiatrists from Monash University and the University of Arizona who have a particular interest in improving the mental health of people affected by cancer.

What is the purpose of this study?

Finding out that you have cancer and experiencing cancer treatment can cause a number of uncomfortable emotions (e.g. sadness, anger, anxiety, guilt etc.) This study aims to assess the effectiveness of a brief information sheet in helping individuals to better understand these difficult emotions. This study is preliminary, and therefore, it also aims to gain participant feedback about how satisfied participants were with the information they received.

This current study is one part of a larger, future intervention which aims to improve people's coping ability and reduce depression and anxiety after cancer. To develop this larger intervention, we are testing each intervention part separately, where each part has a different focus (e.g., enhancing mindfulness, making behavioural change). We will use the feedback we gain from this current study to help us to build and improve on the future intervention to improve mental health among cancer survivors.

To take part, you need to:

- Have completed all primary cancer treatment within the previous two years (i.e., completed any chemotherapy, radiation therapy, and/or surgery planned). If you are currently taking hormonal therapies, you can still take part in the study. If you are currently undergoing or have planned chemotherapy, radiotherapy, or surgery, you are not currently eligible.
- Be over 18 years of age
- Have access to a computer or laptop / smartphone / iPad
- Have regular E-mail and internet access
- Be able to provide informed consent
- Be able to understand and speak English
- Be experiencing a minimum threshold of depression or anxiety symptoms.

What does participation in this study involve?

Screening questionnaire

If you decide you would like to take part in this study, you will firstly be asked a set of questions to assess whether this study is suited to you (e.g., your age, type of cancer(s), and date(s) of treatment). You will then be asked questions about

your thoughts and emotions. This will take ~5-10 minutes to complete. If we think you are suited to participating in this study, you will be E-mailed a link to start the baseline questionnaire and you will receive a brief phone call to orient you to the study and answer any questions you may have. We will notify you through an E-mail if we believe you are not suited to taking part in this study.

Time it will take to complete the study

If you are eligible to take part in the study, it will take you ~2 hours to complete the entire study over 2 weeks.

Baseline and post-study questionnaires

First, you will be required to complete two questionnaires – one before being sent the information sheet, and one two weeks later, after having completed the information sheet. Each questionnaire will take 20-25 minutes to complete. In both the baseline and post-study questionnaires you will be asked a set of questions about your thoughts and beliefs about emotions and how you currently manage your emotions. You will also be asked questions at the end about how satisfied you were with the information sheet (e.g., what you liked and disliked). These questionnaires are our way of assessing how effective the information sheet was for you.

Information sheet

After you have completed the baseline questionnaire, you will be sent an E-mail with an information sheet about the function of emotions (Part 1) and about the different parts that make up an emotional experience (Part 2). This information sheet will take about 20 minutes to carefully read. There are also two videos included at the end to summarise the information you have read. You will be E-mailed a link to complete online activities related to Part 1 and Part 2. Whilst the reading is important, the real learning comes from applying what you learned in the activities.

- **Activity 1** (5-10 minutes) asks you to think about distressing emotions you have recently experienced, label them, and write briefly about the purpose of these emotions in your life.
- **Activity 2** (5-10 minutes each time) asks you to think about a recent situation where you experienced some strong emotions (pleasant or

unpleasant). Then you will write down what you were thinking, feeling, and doing when experiencing these emotions. We will ask you to try and complete this second activity everyday throughout the two weeks.

After completing the activities, your activity responses will be sent to The CanCope Study research team. This information will guide us in knowing how useful the information sheet has been for you.

Why were you chosen for this research?

You were chosen because you responded to one of our postings or advertisements about the study.

Source of funding

This study is not funded by any external source.

Consenting to participate and withdrawing from the research

Taking part in this project is voluntary. If you do not wish to take part, you do not have to. To consent to participate, please read this explanatory statement and complete and digitally sign the consent form.

If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. If you decide to withdraw from the project, please notify a member of the research team. You should be aware that data collected up to the time you withdraw will form part of the research project results. If you do not want your data to be included, you must tell the researchers when you withdraw from the research project.

What are the possible benefits?

For you as a participant

By taking part, you will learn about your emotions and their functions. Understanding and identifying your emotions is the first step in learning to cope with difficult emotions and you may find the information and activities helpful in this regard.

For the wider community affected by cancer

The findings from this preliminary study will help to improve the content

and delivery of a future, larger intervention, which will also be remotely-delivered (e.g., via internet and phone calls) . By developing an online intervention, we hope this research will help to improve equal access to mental health services allowing people to take part without needing to live in a city or travel. This is particularly important for individuals living in rural/remote areas where there is limited mental health support. Overall, this research will contribute to our knowledge of ways to best support people experiencing depression and anxiety after cancer.

What are the possible risks?

There are no significant risks involved in taking part in this study. Completing the activities requires thinking about recent emotions you have experienced and situations that triggered strong emotions. Reflecting on these events to complete the activities may make you feel those emotions more strongly for a little while. Most people find that these feelings pass quite quickly.

It is also possible that when answering some questions about your feelings on the online questionnaires you might start to think about things that make you feel upset. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop at once.

If you are feeling distressed, depressed, or anxious we encourage you to speak to your doctor, who will be able to link you to appropriate support. If you are in crisis and would like to speak to a trained professional urgently, please call **Lifeline on 13 11 14.**

Other forms of telephone support include:

- Cancer Council - 13 11 20
- Beyond Blue - 1300 224 636 (anxiety and depression)
- Obsessive Compulsive Disorder and Anxiety Helpline - 1300 269 438 or 9886 9377
- MensLine – 1300 789 978 (support for men)
- The Compassionate Friends - 1800 641 091 or 9888 4944 (grief and loss)

Confidentiality and Storage of data

Any information you supply us, including those via questionnaires and the activities will remain confidential. We store all information on REDCap, a secure, password protected online platform managed by Monash University that is often used for protected health information.

Only members of the research team will have access to any information that identify you (e.g., name, E- mail). Any publications or reports that arise from this study will include only combined results from many participants, so you or any information that might identify you (e.g., name, E- mail) will not be released.

Following 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 ask that any information with which you disagree be corrected. Please contact one of the researchers named at the end of this document if you would like to access your information.

The information you supply will be held for 7 years from the end of the study per Monash policy at which point all data will be destroyed.

Results

As this is a preliminary study, most of the findings will be used to inform and improve the design of a broader intervention. We will send all participants a newsletter within 12 months of study completion with a short summary of how we used these results to refine and improve the broader intervention. At the end of the study, you may request more detailed findings by contacting the research team.

Complaints

Should you have any concerns or complaints about the conduct of the project, you are welcome to contact the Executive Officer, Monash University Human Research Ethics Committee (MUHREC):

Executive Officer Monash University Human
Research Ethics Committee (MUHREC)
Room 111, Chancellery Building D,
26 Sports Walk, Clayton Campus
Research Office
Monash University VIC 3800

Tel: +61 3 9905 2052
E-mail: muhrec@monash.edu
Fax: +61 3 9905 3831

Thank you,

A handwritten signature in black ink that reads "Joshua Wiley". The script is fluid and cursive, with the first letter 'J' being particularly large and stylized.

Dr. Joshua F. Wiley