WESTERN SYDNEY
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Participant Information Sheet

Project Title: *A proof of concept randomised comparative study of individual versus group yoga interventions for improving mental health in people diagnosed with cancer.*

Project Summary:

You are invited to participate in a research study being conducted by Ms Maria Gonzalez, PhD candidate at NICM Health Research Institute, Western Sydney University.

Psychological distress in people with cancer can have a number of negative consequences for affected people, such as reducing quality of life and increasing the experience of physical symptoms. It is therefore important to address issues such as anxiety and depression to reduce or eliminate these effects.

Yoga interventions have the potential to improve psychological symptoms in people with cancer. A better understanding of the efficacy of yoga interventions will assist in programme development and service delivery. Yoga interventions have the potential to bring significant mental health benefits to you and many people throughout the world.

This clinical trial aims to determine 1) the feasibility of an online yoga program for people diagnosed with breast or gynaecological cancer, 2) the preliminary efficacy of the online yoga program for reducing depression and anxiety, perceived stress, fear of recurrence, physical health and quality of life.

How is the study being paid for?

This study is being funded by NICM Health Research Institute, Western Sydney University and a Research Training Program scholarship, Western Sydney University.

What will I be asked to do?

The initial screening sessions, individual intake sessions and group yoga classes, will be conducted online via the Zoom teleconferencing platform. In order to participate, it is important that you have regular access to a computer or iPad with a web camera, and reliable internet. You will also need access to the Zoom platform; a researcher can assist with this if required.

Online pre-screening

To register your interest to participate in this clinical trial, you will complete and submit an anonymous online survey. The purpose of the survey is to assess your eligibility to participate in this clinical trial. Participants who meet the preliminary criteria to participate will be asked to submit their contact information, which will be used by a clinical trial officer to arrange a teleconferencing screening call.

Teleconferencing (Zoom) screening

To assess your eligibility, you will be asked to read and voluntarily provide written informed consent. At the teleconferencing screening session, you will have the opportunity to discuss your eligibility to participate in this clinical trial.

Once informed consent is given, the clinical trial officer will ask about your demographic information, medical and health history, and current forms of mental health treatment. You will also be asked to complete two questionnaires for mental health symptoms to confirm whether you are eligible to participate.

Intervention

The yoga intervention clinical trial is a six-week study.

Eligible participants will be randomly allocated to either group yoga classes or individual yoga sessions**.**

- *Group yoga sessions*

if you are allocated to group yoga sessions you will be required to attend six (6) yoga classes with a qualified yoga teacher online via the Zoom platform over a 6-week period. You will also be asked to do additional yoga practice between classes, and record your practice weekly.

- *Individual yoga sessions*

If you are allocated to this group you will be required to attend six (6) one-on-one yoga sessions with a qualified yoga teacher online over the Zoom platform over a 6-week period. You will also be asked to to additional yoga practice between sessions, and record your practice weekly.

- *Questionnaires and assessment measures*

At week one, three and six of the study period, participants in both groups will be asked to complete online questionnaires and assessment measures related to physical and mental health. In addition, participants will also be asked to update any changes to their medication and current treatment logs at this time.

How much of my time will I need to give?

The initial teleconferencing screening session will take approximately 45 minutes.

If you are allocated to the group yoga intervention, you will spend six (6) hours in total of online yoga classes over a six-week period, plus regular yoga practice in your own time.

If you are allocated to the individual yoga intervention you will spend six (6) hours in total of online one-on-one yoga sessions over a six-week period, plus regular yoga practice in your own time.

During the program, all participants will complete a short (10 min) weekly survey and 3 sets of questionnaire and assessment measures (approximately 30 min each) as well as having occasional 5–10 min phone calls with a research team member.

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

There is potential that your participation in this clinical trial may improve your quality of life and reduce physical symptoms.

Your participation will allow us to assess the feasibility of online group and individual yoga interventions, and potential to improve depression and anxiety, physical health and quality of life in people with cancer.

Will the study involve any risk or discomfort for me? If so, what will be done to rectify it?

Yoga interventions are generally considered to be safe, with no known risk of physical or psychological harm. The yoga interventions will be conducted by certified yoga instructor. If any coincidental worsening or exacerbation of symptoms is evident, the yoga practices can be modified, so that you do not experience distress or discomfort. Yoga postures included in this study are generally gentle in nature. No extreme yoga practices will be included in the intervention.

Yoga generally has 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 clinical trial 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. Participants with adverse events present at their last visit will be followed-up until resolution of the event.

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, except with your permission.

At completion of the study a summary of results will be made available to participants on request.

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

Please be assured that only the researchers will have access to the raw data you provide. However, your data may be used in other related projects for an extended period of time, such as if we wish to perform a follow-up of participants in this trial. Please note that the minimum retention period for data collection is five years post publication. The data and information you have provided will be securely disposed of in accordance with the Australian privacy and other relevant laws.

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. If you choose to withdraw, the Clinical Trial Officer may ask you for your reason for withdrawing to ensure we follow-up on any unresolved issues.

If you choose to withdraw, any information that you have supplied will remain confidential. You can also advise if you consent for the use of your data, up and until your withdrawal from the study. If you do not give consent, your information and data will be securely disposed of in accordance with the Australian privacy and other relevant laws.

Your withdrawal from this clinical trial will not affect your ability to enrol in other clinical trials at NICM Health Research Institute or Western Sydney University.

Can I tell other people about the study?

Yes, you can tell other people about the study by providing them the contact details of the Chief Investigator, Maria Gonzalez, to discuss their participation in the research project and obtain a copy of the information sheet.

What if I require further information?

Please contact Ms Maria Gonzalez should you wish to discuss the research further before deciding whether or not to participate.

Ms Maria Gonzalez
NICM Researcher and PhD candidate
email: m.gonzalez2@westernsydney.edu.au

Professor Jerome Sarris
PhD supervisor
email: j.sarris@westernsydney.edu.au

What if I have a complaint?

If you have any complaints or reservations about the ethical conduct of this research, you may contact the Ethics Committee through Research Engagement, Development and Innovation (REDI) on Tel +61 2 4736 0229 or email humanethics@westernsydney.edu.au.

Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

If you agree to participate in this study, you may be asked to sign the Participant Consent Form. The information sheet is for you to keep and the consent form is retained by the researcher/s.

This study has been approved by the Western Sydney University Human Research Ethics Committee. The Approval number is H13735