WESTERN SYDNEY
UNIVERSITY

Participant Information Sheet

Project Title: A randomised comparative mixed methods pilot study of yoga interventions for reducing depression and anxiety.

Project Summary:

You are invited to participate in a research study being conducted by the NICM Health Research Institute. The research is a randomised comparative mixed methods pilot study which aims to 1) explore the relative effectiveness of different yoga interventions for reducing symptoms of depression and anxiety, and 2) to examine how the effectiveness of these different intervention modalities may be influenced by patient preference.

How is the study being paid for?

This study is being funded by the Western Sydney University Researcher Development Program.

The yoga sessions in this study are offered free of charge for eligible participants. There is no payment made to you for your participation or travel costs.

What will I be asked to do?

This is a 2-arm randomised comparative mixed methods pilot study, comparing mental health outcome measures from participation in either 1) individual one-to-one yoga sessions and home yoga practice, or 2) group yoga classes.

There will be an initial online pre-screening survey to collect basic information and assess whether or not this trial is suitable for you to participate in. All information collected will remain confidential. If you are interested and are potentially eligible, you will be asked to attend a face-to-face intake session at the NICM Health Research Institute, Westmead Campus, Western Sydney University.

Informed consent

At the initial intake session, you will meet with the Research Assistant and have the opportunity to further discuss the possibility of your participation in the trial. Before confirmation of your participation, you will be invited to voluntarily provide written informed consent. If you have further questions, you will also be offered the opportunity to speak on the telephone with the Chief Investigator of the trial, Dr Michael de Manincor.

After you have provided informed consent, we will to ask you a few more questions related to demographic information, your medical and health history, and current forms of mental health treatment. We will also ask you to complete a questionnaire called the Depression, Anxiety, and Stress Scale (DASS-21), so that we can confirm whether or not you are eligible to participate.

The intake session will take approximately 30 minutes.

Inclusion and Exclusion Eligibility criteria:

Inclusion Criteria: aged 18-65 years, inclusive; ability to read and write in English; DASS-21 scores demonstrating at least mild severity of depression or anxiety; adequate general health and ability to be involved in the yoga program; medication (including herbal medications, such as St John's wort) and professional mental health assistance being unchanged for 3 months.

*Exclusion Criteria: s*erious injury or physical ailment (which yoga may negatively exacerbate), medical or psychological disorder likely to preclude completion of the trial; frequent alcohol or recreation drug use; have been undertaking yoga classes or a personal yoga practice, an average of more than once a week, over the past 3 months.

If your eligibility to participate in the trial is confirmed, you will be registered for participation and then randomly allocated to either the individualised one-to-one yoga sessions, or the group yoga classes.

If you are randomised to the individualised one-to-one yoga sessions, you will be asked to attend four (4) x 1 hr one-to-one yoga sessions with a yoga teacher, over a 6-week period, plus asked to do a suitable personalised yoga practice at home.

If you are randomised to the group yoga classes, you will be asked to attend six (6) x 90 minute weekly yoga classes.

All initial intake sessions, individual one-to-one yoga sessions, and group yoga classes, will be conducted at the NICM Health Research Institute, Westmead Campus, Western Sydney University situated at 158-160 Hawkesbury Rd, Westmead (located 130m from Westmead train station).

At the first and final yoga sessions, you will also be asked to complete questionnaires and assessment measures for the trial. These are a series of questionnaires related to physical and mental health.

How much of my time will I need to give?

The initial intake session will take approximately 30 minutes.

If you are randomised to the individualised yoga group, you will spend four (4) hours in total of one-to-one yoga sessions over a 6-week period, plus regular yoga practice at home.

If you are randomised to the group yoga class, you will spend nine (9) hours in total of weekly yoga classes delivered over a 6-week period.

Completion of questionnaires before the first yoga session, and after the final yoga session, will take approximately 30 minutes on each occasion.

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

As concerns related to mental health continue to emerge and be recognised throughout the world, and the limitations of current treatment approaches are acknowledged, development of a range of different evidence-based approaches for the needs of different people is critical. A better understanding of the effectiveness of different approaches, including differences in group versus individualized intervention delivery approaches and patient preferences, will assist in programme development and service delivery for different people, who currently may remain under- or even untreated. Yoga interventions have the potential to bring significant mental health benefits to you and many people throughout the world.

Findings from this research project will be used to support an NHMRC application or partnership funding with research-based mental health organisations, such as the Black Dog Institute, for a fully powered randomised controlled trial. Partnership and funding opportunities will also be explored through further collaboration with organisations such as The Yoga Foundation and other service and funding providers, where partnering relationships are already being established.

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

The yoga intervention is generally considered to be safe, with no known risk of physical or psychological harm. If any coincidental worsening or exacerbation of symptoms is evident, the yoga practices are modified for each person so that the person does not experience distress or discomfort. Yoga postures included in this study are generally gentle in nature, and there are no extreme yoga practices included in the intervention.

Although yoga generally has low rates of adverse events, and occurrences 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 (AEs) that occur between consent and the last visit for the study will be recorded in detail.

If any symptoms do develop, you will be instructed to contact the Investigator at any time after consenting to join the trial. In the case of an AE, the Investigator may recommend that you seek medical advice from a GP or other health professional. Participants with AEs present at their last visit will be followed up until resolution of the event.

How do you intend to publish or disseminate the results?

This trial is a pilot study. It is anticipated that a summary of the findings of this study will be published and/or presented in a variety of forums, including professional conferences. 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. Results will also be used to design and seek funding for a larger study.

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 and that your data will not be used in any other projects. 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, you have the right to request access to your information that we have collected and stored by the research team.

If you would like access to your information, please contact the Chief Investigator, Dr Michael de Manincor. Contact details provided below.

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 study investigator or other staff may ask you for your reason for withdrawing to ensure we follow up on any unresolved issues. If you withdraw, you can advise us if 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 relationship with the research or NICM staff.

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, Dr Michael de Manincor, to discuss their participation in the research project and obtain a copy of the information sheet. Contact details provided below.

What if I require further information?

The Chief Investigator for this study is Dr Michael de Manincor, Research Fellow, NICM Health Research Institute. If you wish to discuss the research further before deciding whether or not to participate, please contact Dr de Manincor or a Research Assistant for the study.

Email: m.demanincor@westernsydney.edu.au

Phone: 0456 916 139

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 (Approval number: H12929**). This study is supported by an Early Career Fellowship Grant from Western Sydney University.**