WESTERN SYDNEY
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Participant Information Sheet

Project Title: The feasibility of yoga therapy for people with lung cancer: A pilot randomised controlled study

Project Summary:

You have been invited to participate in a research study led by PhD student Asli Papurcu under the supervision of Associate Professor Bobby Cheema at Western Sydney University.

The most common symptom of lung cancer is shortness of breath, which can affect quality of life and may lead to mental health issues such as anxiety and depression. Therefore, it is important to address shortness of breath to improve overall health. Yoga has been shown to improve common symptoms and treatment-related side effects in people with different types of cancer. In the limited research on the benefits of yoga for people with lung cancer findings have indicated better physical and psychological health and improved quality of life.

This clinical trial aims: 1) to determine the feasibility of yoga therapy for people diagnosed with lung cancer and 2) to evaluate the preliminary effects of an 8-week yoga therapy intervention on measures of dyspnoea, physical functioning, quality of life, mental health status, and circulating haematological (i.e. inflammatory-, immune- and endocannabinoid markers) and cancer-related markers in patients with lung cancer.

How is the study being paid for?

This study is being funded by Western Sydney University, and the PhD student (Asli Papurcu) is funded by a scholarship awarded by the Republic of Türkiye (Turkey), Ministry of National Education.

What will I be asked to do?

You will be asked if you agree to a member of the research team to contact you for a screening session.

Screening
Before you decide to participate in this research study, we need to ensure it is OK for you to take part. You will be asked to take part in a screening session with a member of the research

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team, to be conducted in person or over the phone. You will also be asked to complete two questionnaires for physical symptoms to confirm whether you are eligible to participate. At the screening session, you will have the opportunity to discuss your eligibility to participate in this clinical trial.

If you are eligible for the study, you will be randomised to either the yoga intervention group or the control group.

Yoga group: If you are allocated to the yoga group, you will be required to attend 1-day face-to-face and 1-day online yoga sessions, additionally one online class as an option for 8 weeks. This will be a total of 16 yoga sessions over 8 weeks. Each class will be approximately one hour in duration. All classes will be led by a qualified yoga instructor. The face-to-face classes will be at the National Institute of Complementary Medicine (NICM), at Westmead, NSW) and online sessions can be done from your own home or another location of your choice. There will also be some instructions provided for self-directed practice on other days of the week.

Control group: If you are allocated to this group, you must attend questionnaires and assessment measures and continue your usual care.

Questionnaires and assessment measures: At Week 1 and 9 of the study, participants in both groups will be asked to complete questionnaires and assessment measures. Most assessments will be completed at the National Institute of Complementary Medicine (NICM), Westmead NSW while the blood samples will be taken at a local pathology lab.

You will be asked to complete the following questionnaires:

- The International Physical Activity Questionnaire – Short Form (Week 0 only);
- The Cancer Dyspnoea Scale;
- The European Organization for Research and Treatment of Cancer Quality of Life Scale (QLQ-C30);
- The Depression Anxiety Stress Scale.

You will also be asked to complete the following assessments:

- Respiratory parameters using spirometer,
- Muscular strength using dynamometer,
- Exercise capacity using the 6-min walking test.

Blood samples will be collected at a local pathology collection centre (i.e. Douglass Hanly Moir

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Pathology Centre) in weeks 0 and 9.

You will also be asked to maintain a journal, to record symptoms and any changes to medications and treatments over the course of study.

How much of my time will I need to give?

The initial screening session will take approximately 45 minutes. If you are allocated to the yoga group, you will spend one (1) hour in total of face-to-face/online yoga classes over an eight-week period, plus regular yoga practice in your own time. During the program, all participants will complete a short (10 min) weekly logbook and having occasional 5–10 min phone calls with a research team member. The total commitment of time from the recruitment process to the completion of the study for the participants is 10 weeks.

Additional costs
There are no additional costs associated with participating in this research project, nor will you be paid for your participation. The intervention will occur alongside your usual medical care. You will be reimbursed for all parking expenses, and you will also receive a $100 gift card if you complete the study.

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

There is potential that your participation in this clinical trial may reduce shortness of breath and improve quality of life. Your participation will allow us to evaluate the feasibility of yoga interventions and their potential to reduce breathlessness and improve mental health and quality of life in people with lung cancer.
The intervention and control group participants will not receive any formal intervention after completing the study. However, participants randomised to the yoga practice will be encouraged to continue with their practice on their own, if they wish. Video recordings of the yoga sessions will be taken during the intervention period and will be provided to the control group participants at the end of the study (i.e. after the final assessment).

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

A certified instructor will lead the yoga sessions and prioritise your safety and comfort. We will modify the yoga practices to ensure your well-being if there are any unexpected symptoms or discomfort during the trial period. We do not anticipate any adverse events but will thoroughly document and address any unexpected signs or feelings of distress. Contact the clinical trial

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officer if you experience any symptoms after consenting to the study. In an adverse event, the Investigator may recommend that you seek medical advice from a general practitioner or other health professional, and you will receive follow-up until the issue is resolved.

If you experience any difficulties during or after the intervention, you may also consider contacting one of the support services listed below:

- Lifeline: 13 11 14, https://www.lifeline.org.au
- Cancer Council Helpline: 13 11 20, https://www.cancer.org.au/contact-us

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

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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 enroll in other clinical trials at 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, Asli Papurcu, 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 Asli Papurcu should you wish to discuss the research further before deciding whether to participate.

Ms Asli Papurcu
WSU PhD candidate
email:20004255@student.westernsydney.edu.au

A/Professor Bobby Cheema
PhD supervisor
email: B.Cheema@westernsydney.edu.au

Privacy Notice

Western Sydney University staff and students conduct research that may require the collection of personal and/or health information from research participants.
The University's Privacy Policy and Privacy Management Plan set out how the University collects, holds, uses and discloses personal or health information. Further details about the use and disclosure of this information can be found on the Privacy at Western Sydney webpage.

What if I have a complaint?

If you have any complaints or reservations about the ethical conduct of this research, you may email the Ethics Committee through Research Services: humanethics@westernsydney.edu.au.
Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.

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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 H16272.

Explanation of Consent

What will happen to my information if I agree to it being used in other projects?

Thank you for considering being a participant in a university research project. The researchers are asking that you agree to supply your information (data) for use in this project and to also agree to allow the data to potentially be used in future research projects.
This request is in line with current University and government policy that encourages the re-use of data once it has been collected. Collecting information for research can be an inconvenience or burden for participants and has significant costs associated with it. Sharing your data with other researchers gives potential for others to reflect on the data and its findings, to re-use it with new insight, and increase understanding in this research area.
You have been asked to agree to Extended consent.

What does this mean?

When you agree to extended consent, it means that you agree that your data, as part of a larger dataset (the information collected for this project) can be re-used in projects that are

- an extension of this project
- closely related to this project
- in the same general area of this research.

The researchers will allow this data to be used by members of the research team in the case that a follow-up of participants is performed to examine the long-term effects of the yoga intervention, for example.
To enable this re-use, your data will be held at the University in its data repository and managed under a Data Management Plan. The stored data available for re-use will have information in it that makes you identifiable. The re-use of the data will only be allowed after an ethics committee has agreed that the new use of the data meets the requirements of ethics review.
The researchers want to keep the data for 15 years for possible re-use. After this time the data will be securely destroyed.

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You are welcome to discuss these issues further with the researchers before deciding if you agree. You can also find more information about the re-use of data in research in the National Statement on Ethical Conduct in Human Research – see Sections 2.2.14 - 2.2.18.
https://www.nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018

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