Participant Information Sheet / Consent Form

ZENERGISE

Cancer Survivors experiencing Cancer-Related Fatigue: A Phase 2 study evaluating a Combined Physical Activity and Mindfulness program

Patient Information Sheet / Consent Form

Coordinating Centre: Sydney Cancer Survivorship Centre
Concord Cancer Centre

Coordinating Centre Staff

Clinical Lead Ashanya Malalasekera

Co-Investigators Sue Butler, Jane Turner, Eliza McDonald, Kim Kerin-Ayres, Janette Vardy

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Part 1 What does my participation involve?

1 Introduction

Cancer Related Fatigue (CRF) is the feeling of exhaustion associated with cancer and its treatment.

You are invited to take part in this research project to test a new program combining exercise and mindfulness for CRF. Mindfulness is a form of meditation suggested to be helpful in relieving CRF. This is because you have indicated you have CRF.

This Participant Information Sheet tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the research project
- Consent to have the tests and treatments that are described
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

The purpose of this study is to investigate whether it combining mindfulness with routine exercise impacts fatigue caused by cancer or its treatment ('cancer-related fatigue').

It is recommended that cancer-related fatigue is treated in an individualised way. Physical exercise is one routine form of effective treatment. Although we know mindfulness works in some patients for fatigue, we do not know if combining it to exercise is beneficial.

This means that mindfulness must be tested in combination with routine exercise (new treatment), and compared against routine exercise alone.

Approximately 65 participants will be enrolled in the study, based at the Sydney Cancer Survivorship Centre, Concord Hospital.

3 What does participation in this research involve?

You will be participating in a randomized trial.

Sometimes we need to compare different treatments. We put people into groups and give each group a different treatment. The results will be studied to see if one treatment may be better. To try to make sure the groups are the same, each participant is put into a group by chance (random). You will have a two in three chance of receiving the new treatment.

At first visit, you will be asked to consider participation in this trial. If you are happy to participate, you may sign this consent form. The doctor will then check whether or not you are suitable to join the study. This will involve a medical history, physical examination and if necessary, a blood test (about two tubes / 12 millilitres). You will also have assessments with our clinical psychologist and exercise physiologist, to understand a little more about any existing conditions that we need to be aware of.

If you are suitable for the study, you will have some baseline questionnaires and some light activity tests (such as a walking test) to complete. These will take about 20-30 minutes each to complete and will assess your current energy levels, mood and function, for us to understand a little more about how to help you.

You will then receive either the combination of exercise and mindfulness, or exercise alone.

If you are in the **'Exercise alone' group**:

This will involve coming to the Sydney Cancer Survivorship Centre at Concord Hospital ***, **once a week, regularly for 12 weeks**. The **exercise** will involve aerobic exercise (walking, cycling in the gym ***) or resistance training (weights). Sessions will be in a small group format and guided face to face by our Exercise Physiologist. You may share the gym with other patients who are not participating in this study.

The schedule for the 'Exercise alone' arm is shown in the table below.

Week	Exercise	Phone call from Exercise Physiologist
1	1 x 1 hour session [b]	1 x 15-30 mins
2	1 x 1 hour session [b]	1 x 15-30 mins
3	1 x 1 hour session [b]	1 x 15-30 mins
4	1 x 1 hour session [b]	1 x 15-30 mins
5	1 x 1 hour session [b]	1 x 15-30 mins
6	1 x 1 hour session [b]	1 x 15-30 mins
7	1 x 1 hour session [b]	
8	1 x 1 hour session [b]	
9	1 x 1 hour session [b]	

10	1 x 1 hour session [b]	
11	1 x 1 hour session [b]	
12	1 x 1 hour session [b]	

[b] The 1-hour Exercise session may be held on a different day of the week

If you are in the **combination group**:

You will have a combined exercise and mindfulness session, from Weeks 1 to 8.

This will involve coming to the Sydney Cancer Survivorship Centre at Concord Hospital ***, **once a week, regularly for 12 weeks**. You may choose which Exercise sessions are most convenient for you to attend. If you choose to do both Exercise and Mindfulness sessions on the one day, the Mindfulness session will be scheduled to occur after one of the Exercise sessions. In addition, each participant will receive a brief scheduled phone call from the Exercise Physiologist for Weeks 1-6, to provide ongoing support.

The **exercise** will involve aerobic exercise (walking, cycling in the gym ***) or resistance training (weights). Sessions will be in a small group format and guided face to face by our Exercise Physiologist. You may share the gym with other patients who are not participating in this study.

The **mindfulness** will involve group discussion, mindfulness practice, meditation and gentle yoga. Sessions will be in a group format in a separate room within hospital grounds ***, and will be guided face to face by our Clinical Psychologist. **There will also be a full one-day, mindfulness retreat held towards the end of the course,** most likely located within hospital grounds* (depending on COVID-19 status) and scheduled according to group convenience. This retreat day will be scheduled well in advance, for group convenience.

All sessions will be a group activity. You will be given resources to take home, to help you practice. These resources **may** include:

- handouts / guides relating to mindfulness technique and practice (which you may keep)

- wearable technology, such as a fitbit (which may be on loan from Concord Cancer Centre), elastic bands or dumbbells.

- activity log for you to record your home practice.

- accredited smartphone 'apps' to help remote monitoring of fitness levels

The schedule for the combination arm is shown in the table below.

Week	Mindfulness	Exercise	Phone call from Exercise Physiologist
1	1 x 2 hour session [a]	1 x 1 hour session [b]	1 x 15-30 mins
2	1 x 2 hour session [a]	1 x 1 hour session [b]	1 x 15-30 mins
3	1 x 2 hour session [a]	1 x 1 hour session [b]	1 x 15-30 mins
4	1 x 2 hour session [a]	1 x 1 hour session [b]	1 x 15-30 mins

5	1 x 2 hour session [a]	1 x 1 hour session [b]	1 x 15-30 mins
6	1 x 2 hour session [a]	1 x 1 hour session [b]	1 x 15-30 mins
7	1 x 2 hour session [a]	1 x 1 hour session [b]	
8	1 x 2 hour session [a]	1 x 1 hour session [b]	
9	-	1 x 1 hour session [b]	
10	-	1 x 1 hour session [b]	
11	-	1 x 1 hour session [b]	
12		1 x 1 hour session [b]	

[a] Each Mindfulness session will occur about 30 minutes after the Exercise session
[b] The 1-hour Exercise session may be held on a different day of the week
NB: The one-day Mindfulness retreat will be scheduled in advance for a date between Weeks 6-8

For either group:

At the end of the program, and at two (2) and six (6) months after program completion, we will ask you to undergo a clinical assessment, and to complete the same set of questionnaires and tests you did at the first visit.

Six (6) months after you finish the program, we will also invite you for a 30 minute interview and additional questionnaire about your experience.

****** COVID-19 modifications:***

In the event of the COVID-19 pandemic social distancing regulations, both mindfulness and exercise components may be delivered 'virtually' through a secure, free videoconferencing platform. You may require data usage to install the platform 'app' on your personal device if required. Sessions will continue to be in live and supervised, and in group format wherever possible. The content will be adapted to allow safe, optimal supervision while you remain at home. Sessions may be recorded for quality and training purposes only. Individual support sessions from the therapists or clinical trial staff will also be available to you if required.

Where hospital visits are necessary for clinical assessments / tests, we will arrange individual visits as appropriate, while adhering to relevant hospital policies.

There are no additional costs associated with participating in this research project, nor will you be paid. Study tests and medical care required as part of the research project will be provided to you free of charge.

4 What do I have to do?

It is important to tell your doctor and the study staff about any treatments or medications you may be taking, including non-prescription medicines, vitamins or herbal remedies and any changes to these during the study.

5 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Sydney Survivorship Centre or Concord Cancer Centre, or Concord Hospital.

6 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital. Other options are available; these include individual, tailored physical activity and or mindfulness or cognitive behavior counselling with our Survivorship Centre health professionals. Your study doctor will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your local doctor.

7 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research, however, possible benefits from any of the interventions may include improved energy levels, mood and wellbeing.

8 What are the possible risks and disadvantages of taking part?

Medical treatments often cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe. If you have any of these side effects, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects.

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study doctor immediately about any new or unusual symptoms that you get.

Possible risks, side effects and discomforts include the following:

- Risks with exercise
  - joint, muscle or bone injury. The risk is uncommon – between 1 in 100 and 1 in 1000. In the event of this occurring, you would be medically assessed and managed as appropriate.
  - Problems with your heart or lungs, such as undiagnosed / uncontrolled heart disease or asthma. The risk depends on your underlying health, but is uncommon – between 1 in 100 and 1 in 1000. In the event of this occurring, you would be medically assessed and managed as appropriate.

- Risks with mindfulness – triggers for anxiety, distress or depression. In the event of this occurring, your doctor will assess the situation and refer to support services as appropriate.

- Depending on the severity of any adverse event, ongoing participation in the trial is a shared decision between you and your treating medical team.

- If you happen to be pregnant or breast-feeding, please advise your doctor before engaging in any physical activity as part of this study. If you do become pregnant whilst participating in the research project, you should advise your study doctor immediately. Your study doctor will withdraw you from the research project and advise on further medical attention should this be necessary. You must not continue in the research if you become pregnant.

- Risks and inconveniences of routine care given for your illness (for example, the time and travel commitment to participate in the combined intervention) will be discussed with you by your study doctor or members of the study team as needed.

- Having a blood test taken may cause some discomfort, bruising, minor infection or bleeding. If this happens, it can be easily treated. The risk is uncommon – between 1 in 100 and 1 in 1000. In the event of this occurring, you would be medically assessed and managed as appropriate.

9 What will happen to my test samples?

Any blood samples taken before and during your treatment will be used for your routine care.

10 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form confirming that you have been made aware of the new information.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

11 Can I have other treatments during this research project?

Whilst you are participating in this research project, you may not be able to take some or all of the medications or treatments you have been taking for your condition or for other reasons. It is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project. Your study doctor should also explain to you which treatments or medications need to be stopped for the time you are involved in the research project.

12 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you decide to discontinue the study treatment, you will be asked to attend follow-up visits to allow collection of personal information regarding your health status. If you do not wish to attend follow-up visits, your study doctor/sponsor will request permission to collect health status information from your medical records.

If you do withdraw your consent for collection of any future personal information, information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

If you wish to withdraw from this research project you will be asked to complete and sign a "Withdrawal of Consent" form. This will be provided to you by the study team. You will be required to return any wearable technology which is the property of the investigational site.

13 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such the treatment being shown to not be beneficial.

14 What happens when the research project ends?

If the intervention is not shown to be beneficial, the study will close. If it is shown to be beneficial, you will be eligible to enroll in the next phase of the study. Further information will be provided and the decision will be made in consultation with you and your consulting doctor about the most appropriate treatment for you at that time.

You will be required to return any wearable technology which is the property of the investigational site.

Your study doctor will inform you about your own results where relevant. Your study doctor will inform you of result of the study after it has been analysed and reported.

Part 2 How is the research project being conducted?

15 What will happen to information about me?

By signing the Consent Form you consent to your study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. The information collected in this study will be identified by a code number. Only your study doctor and the research team will be able to link the code number to you personally. Your information will be included in the research project database for analysis. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Your personal details will be held by the Sydney Cancer Survivorship Centre. This includes storage on an electronic RedCap research database held on a platform hosted by the study sponsor (The University of Sydney). This information will be held securely and confidentially. Authorised representatives of the relevant study personnel may contact you to obtain follow-up information.

Information about you may be obtained from your health records records (paper files and electronic medical information systems) held at this service for the purpose of this research, such as demographic data, other illnesses and cancer treatment. By signing the consent form you agree to the relevant study personnel accessing health records if they are relevant to your participation in this research project.

It is anticipated that the results of this research project will be published and/or presented at professional meetings. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

Information about your participation in this research project will be recorded in your health records.

In accordance with relevant Australian and State privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and stored securely. This includes storage on a secure, validated RedCap research database stored on The University of Sydney server. Any information will be disclosed only with your permission, or as required by law.

16 Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication free-of-charge, as a public patient in any Australian public hospital.

17 Who is organising and funding the research?

This research has been initiated by the study doctor, Dr A. Malalasekera.

The study Sponsor is the University of Sydney. The study is funded by a Concord Cancer Centre Research grant and International Lung Cancer Foundation (ICLF) Young Investigator grant. An annual progress report is sent to ICLF in return for funding. This progress report does not contain any identifiable patient information.

The ICLF grant will be paid out from the Sponsor via staged payments over the course of the trial for:

1. Research Assistant (to be employed through the Sponsor / University)
2. Accredited Exercise Physiologist (AEP) for the study: will be employed as a Non-Medical Contingency Worker at SLHD (Concord).
3. Statistician
4. Incidentals

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

18 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC and Research Governance Office of Concord Repatriation General Hospital.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

19 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor on or any of the following people:

Clinical contact person

Name	Dr Ashanya Malalasekera or Sr Kim Kerin-Ayres
Position	Survivorship Clinic team
Telephone	9767 8031
Email	Ashanya.Malalasekera@health.nsw.gov.au

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Complaints contact person

Name	Concord Research Governance Officer
Position	Concord Research Governance Officer

Telephone	02 97675622
Email	SLHD-ConcordEthics@health.nsw.gov.au

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 name	Sydney Local Health District
HREC Executive Officer	Kate Flinders
Telephone	02 9767 5622
Email	SLHD-ConcordEthics@health.nsw.gov.au

Consent Form

Coordinating Centre: Sydney Cancer Survivorship Centre
Concord Cancer Centre

Coordinating Centre Staff

Clinical Lead Ashanya Malalasekera
Co-Investigators Sue Butler, Jane Turner, Eliza Mc Donald, Kim Kerin-Ayres, Janette Vardy

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Concord Hospital concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

I understand that I will be given a signed copy of this document to keep.

Name of patient_____

Signature:_____Date:_____

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher†_____

Signature:_____Date:_____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature