WESTERN SYDNEY INTEGRATIVE HEALTHCARE CENTRE

Participant Information Sheet

Interventional Study - *Adult providing own consent*

Title	Feasibility study: Targeting post cancer fatigue among women with breast cancer using acupuncture.
Short Title	*Acupuncture to treat cancer related fatigue*
Protocol Number	*2*
Project Sponsor	Bankstown-Lidcombe Hospital
Coordinating Principal Investigator/ Principal Investigator	Dr Suzanne Grant Dr Kelly Mok
Associate Investigator(s)	Professor Caroline Smith
Location	NICM Health Research Institute, Western Sydney University, Westmead Campus

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you have *received treatment for breast cancer.* The research project is testing a new treatment for *cancer related fatigue.* The new treatment is called *acupuncture.*

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 Sheet to keep.

2 What is the purpose of this research?

The aim of this study is to provide important information for us to help us design a large well designed study of acupuncture to treat cancer related fatigue for women and men recovering from breast cancer.

Cancer related fatigue (CRF) effects 30% of women and interferes with normal functioning and quality of life. Multiple treatments have been tried; however, for many fatigue remains. Recent research suggests acupuncture may reduce cancer related fatigue following the completion of cancer treatment. This study will provide us with important information to examine how acceptable women find the study, how long it takes us to recruit women to the study, and the effect of acupuncture on reducing fatigue. This is an important study as it will inform the design of a new study that will be conducted in Western Sydney, and inter-state.

This research has been initiated by the study doctor Dr Kelly Mok and Dr Suzanne Grant.

3 What does participation in this research involve?

To be eligible for the study you need to be aged >18 years and above with a diagnosis of stage I, II, IIA, or III breast cancer, and completed surgery, radiotherapy or chemotherapy one month to 2 years prior to study enrolment. We will screen your level of fatigue using a questionnaire.

You will be asked to provide written informed consent before joining the study. This is a randomised controlled research project. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is 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 one in two chance of being given acupuncture plus treatment as usual or treatment as usual.

If you are in the acupuncture group you will be required to attend for 10 acupuncture sessions at NICM Health Research Institute in Westmead: commencing week one (one treatment), week two and three (twice weekly), week four to eight (once weekly). Each treatment session will last one hour.

If you are in the treatment as usual group, which will include advice on managing your fatigue. You will be given guidelines which will provide you with general strategies that help manage fatigue, and advice to initiate and maintain levels of exercise. We will also provide you with information from the Cancer Council and NBCF. You will be invited to participate hospital programmes such as Living Well after Breast Cancer offered by Westmead Hospital. Your participation in these programs is voluntary and not a necessary part of the trial.

In total the study will run for 8 weeks during this time we will ask you to complete questionnaires on two occasions, at the start and end of the study. The questionnaires will take you around 15 minutes to complete.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

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

It is desirable that your local doctor be advised of your decision to participate in this research project. If you have a local doctor, we strongly recommend that you inform them of your participation in this research project.

4 What do I have to do?

If you decide to participate in this research project, you will be able to continue with your usual lifestyle and diet. You will continue with all prescribed medication. Participants who are commenced on anticoagulant therapy during the study will be discontinued from the study.

If you have any of the following you may not be suitable for this study:

- Co-morbid medical conditions expected to cause ongoing fatigue, (e.g.co-morbidity significant anaemia (defined as Hb less than 100) or thyroid disease) as assessed by the investigator.
- Current use of acupuncture.
- Needle phobia.
- Concurrent treatment with medication interfering with blood clotting or bleeding time, including heparin and fractionated heparin, vitamin K antagonists, direct thrombin inhibiitors, factor Xa inhibitors, and antiplatelet agents.
- Life expectancy less than six months.
- Plan for major surgery during the time of the study e.g. breast reconstruction or re-excision.
- History of other malignany within 5 years of recruitment, other than CIN of cervix or non-melanomatous skin cancers.

5 Other relevant information about the research project

We will be enrolling 20 people in this study. Ten will receive acupuncture plus usual care and 10 will receive usual care. This is a pilot study which will be conducted at NICM Health Research Institute at Westmead. The study involves collaboration with researchers from the University of Western Sydney.

6 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.

If you do decide to take part, you will be given a Consent Form to sign and you will be given a copy of this sheet to keep.

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 Western Sydney University, South Western Sydney Local Health District, or NICM Health Research Institute.

7 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 usual care such as education sessions or psychological assistance. You can discuss the options with your local doctor or oncologist.

8 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 may include an improvement in your fatigue levels and general well-being. This study will primarily assist will developing the design of a future study.

9 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.

Acupuncture is generally considered safe when performed by an experienced, well-trained practitioner using sterile needles. Some people feel a brief stinging sensation, like a pinprick, during insertion of the needles. Others experience a dull ache around the needle after it goes in. Sometimes people report discomfort when needling certain acupuncture points or there may be a sharp sensation which lasts a second or two. Some people don't feel anything while the needles are in. The risk of minor side effects is small (a rate of 1.3 per 1000 treatments). These side effects may include nausea, dizziness, fainting, increased pain or bruising, any effects maybe mild, and if experienced are pass quickly. It is not expected that any of the possible mild or infrequent side effects will require treatment but in the unlikely event that they do, they will be treated directly by the clinician or you will be referred to your health care team.

Acupuncture needles are sterile prior to insertion, with only single-use, disposable, sterile needles used. All needles are disposed of after the treatment in a sharps-container. The area of needle insertion will be cleaned with an alcohol swab prior to insertion. Points used will be on the arms, lower abdomen and legs

If you become upset or distressed as a result of your participation in the research, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.

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.

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 should continue any medications or treatments as usual. 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.

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. There are no consequences to you for withdrawing from the study, and it will not affect the type of care you receive from either the clinician or your clinical team.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal 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.

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 as:

- Unacceptable side effects
- The treatment is shown not to be effective
- The treatment is shown to work and not need further testing.

14 What happens when the research project ends?

As this is the first phase of the research treatment will not be available after the study is completed. We will write to all study participants with details of the study findings.

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 the 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. 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.

Data will be stored for 15 years and kept securely at the Western Sydney University Campbelltown campus.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team 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 in a variety of forums, including scientific journals or meetings. In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

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

In accordance with relevant Australian and New South Wales 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 securely stored. It 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.

In the event of loss or injury, you may have a right to take legal action to obtain compensation if your injury or complication is sufficiently serious and is caused by unsafe equipment, of by the negligence of one of the parties involved in the study (for example, the clinician). If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies. You do not give up any legal rights to compensation by participating in this study.

If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for your 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 project is being conducted by Western Sydney University and Bankstown Hospital. No external sponsorship is involved and no member of the research team will receive any personal financial benefit from your involvement in this research project.

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 of South Western Sydney Local Health District (SWSLHD)

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 0413333010 or any of the following people:

Clinical contact person

Name	Dr Suzanne Grant
Position	Senior Research Fellow
Telephone	0419 126209
Email	s.grant@westernsydney.edu.au

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

Reviewing HREC approving this research and HREC Executive Officer details
This study has been approved by the South Western Sydney Local Health District Human Research Ethics Committee. Any person with concerns or complaints about the conduct

of this study should contact Ethics and Research Governance Office and quote ***HREC project number 15/124***:

Address	Locked Bag 7279 LIVERPOOL BC, NSW, 1871
Phone	02 8738 8304
Fax	02 8738 8310
Email	research.support@sswahs.nsw.gov.au
Website	http://www.sswahs.nsw.gov.au/swslhd/ethics/default.html

Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.