**Participant Information Sheet/Consent Form**

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| **Title** | Living well with secondary breast cancer - the clinical outcomes and patient perceptions of a combined exercise and educational support group. |
| **Coordinating Principal Investigator/ Principal Investigator** | Danielle Feil, Lead Physiotherapist Oncology and Lymphoedema Clinic |
| **Associate Investigator(s)** | Dr Faye Jansen, Rehabilitation PhysicianDr Annemarie Lee, Senior Research Consultant, Allied HealthLouise Tilley, Senior Physiotherapist and Cancer Wellness Co-ordinator |
| **Location** | Cabrini Cancer Exercise and Wellness Centre, Malvern |

**Part 1 What does my participation involve?**

**1 Introduction**

You are invited to take part in this research project. This is because you have been referred into the secondary breast cancer program at Cabrini Rehabilitation. The research project will evaluate your perceptions to, and clinical outcomes after, the eight week program.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests 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 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 need to support and manage both the physical and psychological effects of treatment for secondary breast cancer is very well recognised. To date, Cabrini Health has been running a successful multidisciplinary program for patients with localised breast cancer. We have identified the need to develop a similar group for women with secondary breast cancer where we can attribute some differences in the goals, education needs and topics necessitating discussion in the peer support program. Consequently, a dedicated rehabilitation program incorporating exercise, education and peer support is proposed. The purpose of this research project is to (a) determine the outcomes of an 8-week exercise and educational support program for women with secondary breast cancer on functional exercise capacity, emotional well-being and quality of life and (b) to evaluate the participant perceptions of an exercise and educational support program for women with secondary breast cancer.

**3 What does participation in this research involve?**

Should you decide to participate in this research project, you will be assessed by our Rehabilitation Physician and Lead Physiotherapist (Principal Investigator) prior to commencing the exercise and education program. You will be invited to complete two surveys relating to quality of life measures, complete two self-related tools designed to measure for emotional states of depression, anxiety and distress and complete measurements of your exercise capacity, and the strength of your upper and lower limbs.

At completion of the 8 week course, you will repeat the same measurements and you will also be invited to participate in a detailed and anonymous interview with an independent staff member on a single occasion. In addition to this, you are encouraged to provide feedback at any time to your treating staff member or to a member of the research team

**4 What do I have to do?**

Should you decide to participate in the research project, you will take part in an exercise and education program. The program will consist of twice weekly sessions, 60 minutes of exercise and 60 minutes of educational support each. This equates to four hours a week for 8 weeks. The exercise program will be tailored to your individual needs by the lead physiotherapist and/or exercise physiologist. The educational support program will be delivered by a multidisciplinary team including exercise physiologists, physiotherapists, breast care nurse, psychologist, occupational therapist, dietician and social worker. Educational topics will include mindfulness, energy conservation, relationships, sleep, sexuality, nutrition and lymphoedema. You will also undertake measures of your exercise capacity, upper and lower limb strength and complete questionnaires asking about your symptoms and the impact of your condition on your well-being at the beginning and the end of the program.

**5 Other relevant information about the research project**

It is estimated that there will be 40 participants in total attending the group. Since it is a rolling program, there should be 4-8 participants at any given time in a group.

**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 this Participant Information and Consent Form to sign and you will be given a copy 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 Cabrini Health.

7 What are the alternatives to participation?

Yes, the alternative is not to participate in the ‘*Living well with secondary breast cancer’* program and it is important that you know that participation in this research is voluntary, it is not compulsory.

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 less fatigue, improved strength and exercise capacity, better quality of life and the peer support from participating in a group program.

9 What are the possible risks or disadvantages of taking part?

Possible risks, side effects and discomforts include the risk of becoming breathless or unwell during exercise training. An experienced physiotherapist and/or exercise physiologist will closely monitor your heart rate, oxygen levels and symptoms during exercise, to ensure that you are not exercising too hard and to minimise the risk of becoming unwell. Some questions asked in the interview or as part of the questionnaires may evoke sensitive issues but you are free not to answer a specific question. In the event of this occurring, support will be offered to you from the multidisciplinary team within this research project.

There may be additional risks that the researchers do not expect or do not know about. Tell a member of the research team immediately about any new or unusual symptoms that you get.

10 What if new information arises during this research project?

During the research project, although unlikely, new information about the risks and benefits of the project may become known to the researchers. If this occurs, you will be told about this new information and the researcher will discuss whether this new information affects you.

**11 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.

If you do withdraw your consent during the research project, the researchers 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 research team 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.

**Part 2 How is the research project being conducted?**

**12 What will happen to information about me?**

By signing the consent form you consent to the relevant research staff collecting and using personal information about you for the research project.

Hard (paper) and electronic copies of your data will be de-identified with an individual code assigned. Hard copies will be stored in a locked filing cabinet in the Allied Health Research Office at the Cabrini Institute. The code will be kept separate from the data files and will be accessible only by the principal investigator. Electronic copies of the data will be stored in a password protected file, only accessible to the principal investigator. Data will be stored for 7 years, after which it will be destroyed confidentially. 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.

Information about you may be obtained from your health records held at this health service 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.

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the institution relevant to this Participant Information Sheet, Cabrini Health, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

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 you cannot be identified. Only group findings will be reported for the purpose of the study.

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

In accordance with relevant Australian and/or Victorian 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.

**13 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 Cabrini Health.

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.

**14 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 any of the following people:

|  |  |
| --- | --- |
| Name | Danielle Feil  |
| Position | Lead Physiotherapist Oncology and Lymphoedema Clinic |
| Telephone | 0417 425 895 |
| Email | dfeil@cabrini.com.au |

**Clinical contact person**

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:

**Complaints contact person**

|  |  |
| --- | --- |
| Name | Cabrini Human Research Ethics Committee |
| Position | Manager, Cabrini HREC |
| Telephone | 03 95083494 |
| Email | hrec@cabrini.com.au |

**Reviewing HREC approving this research** **and HREC Executive Officer details**

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| --- | --- |
| Reviewing HREC name | Cabrini Human Research Ethics Committee |
| HREC Executive Officer | Manager, Cabrini HREC & Research Governance |
| Telephone | 03 95083494 |
| Email | hrec@cabrini.com.au |

**Consent Form**

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| **Location** | Cabrini Cancer Exercise and Wellness Centre, Malvern |

**Declaration by Participant**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

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

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 project without affecting my future care.

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

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| Name of Participant (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

**Declaration - for participants unable to read the information and consent form**

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| Witness to the informed consent processName (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \* Witness is not to the Investigator, a member of the study team or their delegate. Witness must be 18 years or older. |

**Declaration by 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.

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|  |
|  | Name of Study Doctor/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
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† An appropriately qualified 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.

**Form for Withdrawal of Participation**

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| --- | --- |
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| **Coordinating Principal Investigator/ Principal Investigator** | Danielle Feil, Lead Physiotherapist Oncology and Lymphoedema Clinic |
| **Associate Investigator(s)** | Dr Faye Jansen, Rehabilitation PhysicianDr Annemarie Lee, Senior Research Consultant, Allied HealthLouise Tilley, Senior Physiotherapist and Cancer Wellness Co-ordinator |
| **Location** | Cabrini Cancer Exercise and Wellness Centre, Malvern |

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, or my relationship with the researchers or Cabrini Health.

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|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
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In the event that the participant’s decision to withdraw is communicated verbally, the Senior Researcher must provide a description of the circumstances below.

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**Declaration by Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

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|  |
|  | Name of Study Doctor/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
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† An appropriately qualified member of the research team must provide information concerning withdrawal from the research project.

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