**Participant Information Sheet/Consent Form**

**Interventional Study** -*Adult providing own consent*

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| --- | --- |
| **Title** | I-Move: A randomised controlled pilot trial of a personalised, semi-supervised exercise intervention to reduce fatigue for patients receiving immunotherapy for stage IV Melanoma |
| **Protocol Number** | 18\_248 |
| **Project Sponsor** | Peter MacCallum Cancer Centre |
| **Principal Investigator** | Dr Donna Milne |
| **Location**  | Peter MacCallum Cancer Centre |

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

**1 Introduction**

This information sheet is 9 pages long. Please make sure you have all of the pages.

You are invited to take part in a research project called iMove, which involves testing a new exercise program for patients with cancer to help reduce side-effects of immunotherapy.

You have been invited to take part because you:

- have been diagnosed with stage IV Melanoma and

- have been prescribed immunotherapy to treat your melanoma

- are aged 18 years our over

- have access to a smartphone

This Participant Information Sheet/Consent Form 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 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?**

Immunotherapy is a new drug used to treat melanoma, and can cause side-effects. At the moment, we don’t know whether exercise will help people receiving immunotherapy by reducing their experience of side-effects in the same way that exercise helps people receiving other cancer treatments like chemotherapy or radiotherapy.

The iMove project involves testing a prescribed, individual exercise program developed by an exercise physiologist, and comparing it with care as usual for people diagnosed with Melanoma who are receiving immunotherapy.

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

If you choose to take part in this study, you will be participating in a randomised controlled research project. Participation will be for 24 weeks, and will involve completing:

* a safety assessment which involves answering questions about your health
* one or more physical assessments which involve 4 short exercise activities, timed by an exercise physiologist
* a questionnaire booklet 5 times over three months
* having your usual bloods reviewed by the research team
* 10ml additional bloods collected at the same time as your usual bloods for review by the research team

As mentioned above, we assign everyone to either the exercise group or the usual care group using a computer program which does this randomly (similar to tossing a coin).If you are randomly assigned to the group with the exercise intervention, you will be prescribed an exercise program which will last for 12 weeks.

The diagram on the next page explains what is involved if you decide to participate in this research project



The diagram shows the research process.

You will have given in person or posted a pack including the following documents:

1. This Participant Information Sheet which has a consent form at the end;
2. A questionnaire; and
3. A study information brochure;

Please make sure you have all of the documents.

A researcher will make a time to tell you about the study either face to face or over the telephone. When they do, they will go through this information sheet with you, and answer any questions you have.

**If you decide that you would like to participate in this research:**

1. You will be asked to sign the consent section at the end of this form. (The researcher will give you another copy of the consent form for your records when you come into the hospital for your appointment.)

You will be asked to fill in the first questionnaire. This will take approximately 30 minutes. We will ask you to bring your signed consent form and completed questionnaire into the hospital with you when you come in to receive your first immunotherapy transfusion. You will not be able to take part in the research project without these documents completed.

1. When you come into the hospital for your first infusion, we will ask you to arrive 1 hour earlier to meet with both the study research assistant, and the exercise physiologist. Please wear clothing and shoes which are comfortable to exercise in.
2. The exercise physiologist will ask you to do some short, simple and easy exercise activities, and will ask you some questions about your general health, and if you have any other illnesses or health concerns. These are called your physical assessment and safety assessment.
3. Your details will then be put into a computer which will allocate you at random to one of two groups: **Group A** or **Group B**. The study researcher will tell you which group you have been allocated to.

**Group A:** if you are in group A, you will be given a prescribed exercise program which will run for 12 weeks. You will be asked to download an app called “physitrack” on your smartphone which will allow the exercise physiologist to send you information about exercises you can complete as part of the program. Your participation in the study will be for 24 weeks.

The exercise physiologist will arrange to meet you every time you come into the hospital to receive your immunotherapy transfusion, to talk to you about your exercise program. They will also telephone you between infusions to check how you are going with your exercise program. After you have finished your 12-week exercise program, the study research assistant will arrange a telephone interview to talk about your experiences with the exercise program.

**Group B:** if you are in group B, you will be given a booklet developed by the Cancer Council called “Exercise for people living with cancer”. This book has detailed information about the benefits of exercise during and after treatment, plus some examples of exercise techniques which can be done at home. At the end of your participation in the research project, the exercise physiologist will arrange to meet with you to help you start an exercise program close to your home, if you are interested in doing so. Your participation in the study will be for 24 weeks.

**Both groups**:

Whether you are in group A or group B, we will ask you to take part in the following:

1. Complete questionnaires every few weeks. We will send via email or post questionnaires for you to fill out. They will be the same each time, and will ask you about your symptoms and side-effects of your cancer treatment, any regular exercises you are doing, your general health, and how you are coping with day to day life. There will be 5 questionnaires in total.

1. Allow us to review some of the bloods you have taken as part of your usual care at Peter Mac. We will ask for a copy of some of your results as currently it is not well understood how exercise can help people receiving immunotherapy treatment. We will be looking at inflammatory markers and haemoglobin in these tests.
2. Allow us to take additional bloods. When you have your routine blood draw, the nurse will take a small amount (10ml) extra for us to run some additional tests. These tests will also be used for us to understand how exercise might help people receiving immunotherapy treatment. We will be looking at additional inflammatory markers in these tests.
3. Complete regular physical assessments. The exercise physiologist will ask you to complete the same short, simple exercises you did at the start of the project two more times. This means you will have three physical assessments in total. They will be scheduled for when you are coming in to receive your infusions. This will take approximately 30 minutes.
4. We will also be collecting clinical information about your diagnosis and treatment from your medical record. We will also check this to make sure that you are feeling well enough to be taking part in exercise activities. If we see that your situation has changed, we will telephone you to check that you still want to/are able to take part in this research project.
5. Future research projects can apply to get access to your data collected as part of this study, provided that they have the approval of Peter MacCallum Cancer Centre Human Research Ethics Committee (HREC), their own institutional approval, and the iMove project committee.

If you have any questions about the research project while you are taking part, you can call a member of the research team any time.

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

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

We will be inviting a total of 30 people to take part in this project. If we find that the exercise program (in comparison with receiving care as usual) and project design is safe, acceptable, and looks like it may help reduce some side-effects people may experience from receiving immunotherapy, we will apply for funding to run this study in more hospitals around Australia.

**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.

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 Peter MacCallum Cancer Centre.

**6 What will happen to my blood test samples?**

Blood samples taken before you receive each infusion will be analysed to see how exercising or not exercising affects inflammation in the body. While we know that exercising can lead to people with cancer having fewer side-effects of treatment, at the moment we don’t really understand how this works. While we think that exercising will help people receiving immunotherapy, by looking at different blood samples, we may be able to see changes in people while they are exercising or not, to help us understand this further.

If you give consent for blood specimens to be collected, they will be kept securely in the Translational Research Laboratory at the Peter MacCallum Cancer Centre for an indefinite period. You are asked to give permission for possible future research using these samples. The confidential nature of the tissue and associated data will be fully protected, and any other research using your tissue will first be reviewed and approved by an ethics committee.

The type of tests that will be done on your blood will not relate to either your treatment or your cancer. Therefore you will not be told about your individual results as they will not change your care in any way. If you are interested in finding out the results of the study, we can provide you with the results when it has finished. This will be in a summary form with everyone’s results combined.

**7 What are the possible benefits of taking part?**

We cannot guarantee or promise that you will benefit from this research; however, possible benefits may include a reduction in some of the side-effects caused by immunotherapy (such as fatigue or tiredness) if you are enrolled in the group who receive the exercise intervention.

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

If you are allocated to the exercise intervention group, there is a small risk that you will experience some *discomfort* when exercising if you are not used to the activities/exercises prescribed to you. This may take the form of sore muscles, or feeling fatigued. If you experience any discomfort, we ask that you contact either the exercise physiologist or your treating team.

It is very unlikely that you will suffer any *injuries* as a result of participation in this study. However, if you suffer any injuries, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you have a Medicare number, 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.

Whether you experience discomfort, injuries or side-effects from your cancer or treatment, the exercise physiologist can also work with you to modify, reduce or stop the exercise program, or you can withdraw from the study at any time.

For both groups: Part of the research project will also involve answering questions about yourself, including how you are feeling. If you become upset or distressed as a result of your participation in the research, the study team 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.

Having a blood sample taken may cause some discomfort, bruising, minor infection or bleeding. If this happens, it can be easily treated.

**9 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. Withdrawing from this project will have no impact on your treatment or you care at Peter Mac.

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. 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 when you withdraw.

If you decide to leave the project, the researchers would like to keep the blood samples that have been collected. This is to help them make sure that the results of the research can be measured properly. If you do not want to allow your data or blood samples still in storage to be used please indicate this to a member of the research team and we will destroy your samples.

**10 What happens when the research project ends?**

Once you have finished your participation in the research project, the exercise physiologist will meet with you to discuss community based exercise programs. You can access this consultation whether you received the exercise intervention or received care as usual. During this consultation they will help you find local exercise programs or supports near your home so you can start, or continue exercising.

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

**11 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. All the information collected from you for this research project will be treated confidentially, and only the researchers directly involved in this project and your treating doctor will be aware of your participation and have access to your identifiable information. All data will be stored in a potentially identifiable format but each participant will be assigned a unique Project Identification number that will be used where identifiable information is not required. Hard copy consent forms will be filed in a locked project filing cabinet.

Your blood test results will be stored in a password protected database in the research department at the Peter MacCallum Cancer Centre. If you give your consent, your bloods and related data will be kept and stored indefinitely.

The personal information that the research team collect and use will be information from your questionnaires and telephone interviews. 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.

The information collected about you as part of this study will be kept in locked filing cabinets and on computer files that are password protected. Data will be kept at Peter MacCallum Cancer Centre throughout the study and then securely transferred for archived storage at study completion. Data will be retained for a minimum of 15 years from the date of publication of the results. Your coded data may also be used in other future studies and research.

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, except with your permission.

Information about your participation in this research project may also be recorded in your health records, so that your doctors know about your participation in this study.

In accordance with relevant Australian and 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.

**12 Who is organising and funding the research?**

This research project is being conducted by Dr Donna Milne, a nurse consultant at Peter MacCallum Cancer Centre, and has been also funded by the Peter MacCallum Cancer Centre Foundation.

**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 Peter MacCallum Cancer Centre.

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, you can contact the clinical contact person below, who is also the principal investigator on the study.

 **Clinical contact person**

|  |  |
| --- | --- |
| Name | Dr Donna Milne |
| Position | Principal Investigator  |
| Telephone | 03 8559 7837 |
| Email | donna.milne@petermac.org |

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 | Consumer Liaison  |
| Position | 03 8559 7517 |
| Telephone | consumerliaison@petermac.org |
| Email | Consumer Liaison  |

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 | Peter MacCallum Cancer Centre Ethics Committee |
| HREC Executive Officer | Ethics Coordinator |
| Telephone | 03 8559 7540 |
| Email | ethics@petermac.org |

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

**Consent Form -** *Adult providing own consent*

|  |  |
| --- | --- |
| **Title** | I-Move: A randomised controlled pilot trial of a personalised, semi-supervised exercise intervention to reduce fatigue for patients receiving immunotherapy for stage IV Melanoma |
| **Protocol Number** | 18\_248 |
| **Project Sponsor** | Peter MacCallum Cancer Centre |
| **Principal Investigator** | Dr Donna Milne |
| **Location**  | Peter MacCallum Cancer Centre |

**Consent Agreement**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand, and 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 Peter MacCallum Cancer Centreconcerning 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 I will be given a signed copy of this document to keep.

I consent to the storage and use of blood and tissue samples taken from me for use, as described in the relevant section of the Participant Information Sheet, for:

* This specific research project
* Other research that is closely related to this research project
* Any future research.

**Declaration by Participant – for participants who have read the information**

|  |
| --- |
|  |
|  | Name of Participant (please print) |  |  |
|  |
|  | Signature |  |  Date |  |  |
|  |

**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.

|  |
| --- |
|  |
|  | Name of Researcher (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
|  |

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

**Form for Withdrawal of Participation -** *Adult providing own consent*

|  |  |
| --- | --- |
| **Title** | I-Move: A randomised controlled pilot trial of a personalised, semi-supervised exercise intervention to reduce fatigue for patients receiving immunotherapy for stage IV Melanoma |
| **Protocol Number** | 18\_248 |
| **Project Sponsor** | Peter MacCallum Cancer Centre |
| **Principal Investigator** | Dr Donna Milne |
| **Location**  | Peter MacCallum Cancer Centre |
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**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, my relationship with those treating me or my relationship with Peter MacCallum Cancer Centre

* I am happy for any samples/data collected to date to be retained for analysis
* I request that my samples/data be removed (where possible) and destroyed.

|  |
| --- |
|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
|  |

In the event that the participant’s decision to withdraw is communicated verbally, the Study Researcher will need to provide a description of the circumstances below.

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**Declaration by Study 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 StudyResearcher (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
|  |

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