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**Participant Information Sheet**

**Health Behaviour Change:** **A behavioural intervention to improve physical activity in cancer survivors**

**Investigators:**  **Chloe Maxwell-Smith1, Dr Sarah Hardcastle1, Dr Paul Cohen2, Dr Cameron Platell2, Dr Raj Mohan3**

(1 Curtin University; 2 St John of God Hospital, Subiaco; 3 Hollywood Private Hosptial)

This project is being conducted by a collaborative team from Curtin University and the Departments of Colorectal & Gynaecologic Oncology at St John of God Subiaco Hospital (SJGSH), WOMEN centre in Subiaco, and Hollywood Private Hospital in Nedlands.

Please take time to read the following information carefully and to discuss it with others if you so wish. If any part of the information is not clear to you, or if you would like more information do not hesitate to ask us to explain it more clearly. Make certain you do this before you consent to participate in this study.

**Introduction**

You are invited to take part in this research project. The purpose of this study is to improve physical activity in cancer survivors. In keeping with the Catholic foundations of St John of God Health Care, this research aims to reach out to people to improve health and wellbeing. The results of the project will be used to inform the development of future physical activity programs for cancer survivors.

In this study, individuals will be invited to participate in a physical activity intervention, where some participants may have the opportunity to attend group sessions to assist with goal-setting and receive assistance to improve physical activity. Other participants will receive information about the government recommendations for physical activity and tips about how to achieve them. We will be monitoring physical activity in participants for approximately 6 months. Your participation will help us to better understand the needs of cancer survivors and inform strategies to improve lifestyle change post-cancer.

This Participant Information and Consent Form explain the study and include details such as:

* possible benefits and risks of the study
* what you will be asked to do if you choose to participate
* what your rights and responsibilities are if you agree to participate

**Contact persons:**

If you have any questions about the study you can contact:

Investigators:

Chloe Maxwell-Smith 0449 768 269

 chloe.maxwell-smith@curtin.edu.au

Dr Sarah Hardcastle 0439 226 015 sarah.hardcastle@curtin.edu.au

**Decision to Participate**

Participation in this research is voluntary, that is, you may decide to be in this study or not take part in it at all. If you do decide to participate, you are able to change your mind at any time during the study. However, before you make any decision, it is important that you understand why this study is being done and what it will involve, including your rights and responsibilities.

**What is the purpose of the study?**

We plan to assist individuals to increase their physical activity levels. Our previous research in this field has indicated that cancer survivors have support needs and barriers that may prevent them from being sufficiently physically active. This study will aim to improve physical activity by addressing support needs, and providing methods for participants to monitor their physical activity.

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

If you agree to participate in the study, we will ask you to return the consent form using the reply paid envelope by the 1st March 2017. You will then be contacted to organise baseline assessment of your health and physical activity. You will be required to wear an accelerometer (small electronic device worn on wrist or around waist to measure physical activity) for 7 days at the beginning of the trial, after 12 weeks of the trial, and after 24 weeks of the trial commencement. At these three time points, you will also be required to attend a brief assessment at St. John of God Subiaco Hospital. At these assessments you will be asked to complete some questionnaires about your activity, and your blood pressure, height and weight will be recorded. These assessments will take approximately 15 minutes. You may also be invited to participate in group sessions to assist with goal-setting.

**How long will I be in this study?**

If you agree to participate in this study, we will ask you to monitor your physical activity over a 6-month period. Your activity will be measured on the first week of the study, after 12 weeks of the study, and again after 24 weeks.

**What are the costs to me?**

There are no direct financial costs to you from taking part in this study.

**Will I be paid to participate in this study?**

You will not be paid to participate in this study.

**What are the possible benefits?**

You will receive printed information on the government guidelines for physical activity. You may receive printed worksheets to assist with action planning and goal setting. You may also be given the opportunity to use tools to monitor your own physical activity levels.

**What are the possible risks?**

There are no foreseeable risks to your participation in this study. This research study employs a client-centred approach to assist in improving the health of cancer survivors. You do not have to participate in this study. If you do choose to participate in this study, you are welcome to withdraw at any time. If you experience distress from your participation in this study, you will be offered counselling opportunities.

**What are my alternatives if I do not want to participate in this study?**

If you decide that you do not wish to participate in this study, you do not need to do anything. Your decision to not participate will not disadvantage you in any way.

**What if I withdraw from this research project?**

You may withdraw from the interview at any time. If you decide to leave the project, the researchers would like to keep any data that has been collected. This is to help them make sure that the results of the research can be captured properly. If you do not want them to do this, you must tell them before you join the research project.

**How can I find out the results of this study?**

The results of this study will be published in peer-reviewed journals and presented at national and international conferences. You may find out about the study results by reading these articles or by contacting the lead investigators for the results after the study is complete.

**Will my taking part in this study be kept confidential?**

All of your data (activity levels, blood pressure, BMI & questionnaire responses) will be treated confidentially and the raw survey data will only be accessed by the research team at Curtin University for the purpose of this research project. Any information which would identify you will never be disclosed to your employer/s, or to any other source. It will only be disclosed with your permission, except as required by law.

Once entered into our statistical software, all the information you provide will be coded so you cannot be identified by name. All print information will be stored securely in a locked filing cabinet at Curtin University during the study and in a locked archive for 5 years from the time study is closed and may be destroyed at any time thereafter. The data will be examined for group trends, and will not be considered individually. In any publication, information will be provided in such a way that you cannot be identified.

**Who has reviewed the study?**

The St John of God Health Care Ethics Committee and the Hollywood Private Hospital Ethics Committee have given ethical approval for the conduct of this study. If you have any concerns or complaints regarding this study, you can contact the Executive Officer of the Committee (telephone number (08) 9382 6940 on a confidential basis. Your concerns will be drawn to the attention of the Committee that is monitoring the study.

If you have any question about the study, please contact Chloe Maxwell-Smith on 0449 768 269 or the Executive Officer of Human Rights and Ethics Committee on 08 9346 2999.

**CONSENT**

**NOTE: If you are still unclear about anything you have read in the Participant Information Sheet, please speak to the researcher before signing this Consent.**

Name of Participant Signature of Participant Date

Name of Researcher Signature of Researcher Date

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|  | Please check this box if you would like to receive a copy of published findings from this trial. |
|  | If you have checked the above box, please provide your email address: |
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