Information Sheet: Comparison of Mindfulness and Exercise During and After Cancer Treatment

**Study Title:** Comparison of Mindfulness and Exercise During and After Cancer Treatment

**Primary Investigator:** Ginny Eggleston, Clinical Psychologist | St Georges Cancer Care the Glasson Centre, 131 Leinster Road, Christchurch |Tel: 375 6100.

This Information Sheet will help you decide if you would like to take part in this study on exercise and mindfulness.

It describes why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends.

You do not have to decide today, and can take time to consider it. If you wish, talk with relatives or friends, before deciding whether or not to take part.

If you agree to take part in this study, you will be asked to sign the Consent Form attached to this document. You will be given a copy of the Information Sheet and the Consent Form to keep.

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

This study is to find out whether exercise or mindfulness can help improve physical and emotional well-being in people who have had or are having treatment for cancer.

This study is being conducted by the St Georges Cancer Care Centre Mindfulness and Exercise Research Team.

**Who can take part in this study?**

All patients attending St Georges Cancer Care Centre are invited to participate. Group sizes will be between 6-10 people. Your doctor will confirm whether you are able to participate. Patients with metastatic cancer will not be able to participate in this study.

**What will I be asked to do?**

* If you agree to take part in the study you will be randomized to an exercise group, a mindfulness group or a treatment as usual group. If you are in the treatment as usual group, after 6 weeks you will be then be randomized to either the mindfulness or exercise group.
* The exercise and mindfulness groups will run for an hour a week over 6 weeks. They will be held at St Georges Cancer Care Centre. Exercise or mindfulness practice in your own time between classes will be recommended.
* The **exercise group** will involve doing a range of different exercises that are at an appropriate level for you. Exercise during and after treatment for cancer can reduce symptoms and treatment side effects.
* The **mindfulness group** will involve discussions and practicing different mindfulness techniques. Mindfulness is the process of bringing one's attention to experiences occurring in the present moment. (John Kabat Zin 2013). For people with cancer mindfulness may help with symptom relief and improve quality of life.
* You will be asked to fill out self-report questionnaires (either electronically or on paper) before starting, at 3 and 6 weeks and again at 6 months. These forms will take about 15 minutes to fill out. You will also be asked to record any exercise or mindfulness practice you do in your own time during the six weeks. You will be asked to do some physical tests before starting, at 6 weeks and at 6 months. These tests include a six minute walk, a sit to stand test, and a body composition measurement (this measures the relative proportions of muscle mass and body fluid, and requires you to stand on footplates while holding onto hand grips, for approximately half a minute).

**What data or information will be collected and what use will be made of it?**

We will ask about your age, gender and ethnicity. With your permission information about your health and treatments will be accessed from your St Georges Cancer Care clinical file. Self-report questionnaires will ask for details about your symptoms, and exercise and mindfulness measures. The findings of the study will be published in scientific journals and presented at conferences or meetings.

A summary of the results will be provided to you if you wish to receive this.

**What about confidentiality?**

Anonymity and confidentiality will be protected in any publications. Questionnaires will be identified by study numbers, not personal names. Data will be stored either electronically or in a locked facility for a minimum of ten years. Only the researchers running this study will have access to the information you provide.

**What are the benefits and risks of taking part in this study?**

We expect that most people will experience positive personal benefit in taking part in the study. You are also taking part in research that has the potential to help future patients with cancer. Some of the questions may draw your attention to symptoms you are experiencing as a result of your cancer or its treatment. This may cause you some distress. If you feel distress at any stage during the study or after please let the researchers know. You may be referred to one of our clinical psychologists or another member of the team. You are free to withdraw at any time during this study.

If you were injured in this study, which is unlikely, you would be eligible **to** **apply** for compensation from ACC just as you would if you were injured in an accident at work or at home. This does not mean that your claim will be automatically beaccepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.

If travelling to St Georges Cancer Care Centre to attend the study is a problem for you please talk with one of the research team about getting help with travel.

**What will happen at the end of the study?**

You may wish to use the strategies learned in the groups after the group has finished.

Results of the study will be analyzed once the full study is complete. You may request a summary of the results of the study.

**What are participant’s rights?**

Your involvement in this study is entirely voluntary. You are free to withdraw from the project at any time without affecting your medical care.

**Who do I contact for more information or if I have concerns?**

At any stage of the study, please feel free to contact either:

Ginny Eggleston Julee Binns

St Georges Cancer Care Centre St Georges Cancer Care Centre

Email: ginny.eggleston@stgeorges.org.nz Email: julie.binns@stgeorges.org.nz

Phone: 03 375 6100 Phone: 03 375 6100

Sally Pitima

Palliative Kaiāwhina

Email: sally.pitima@xtra.co.nz

If you have any questions or concerns about the ethical conduct of the research, you may contact the Health and Disability Ethics Committees, telephone: 0800 4 ETHICS (0800 438 442) OR EMAIL: HDECS @MOH.GOVT.NZ. Any issues you raise will be treated in confidence and investigated and you will be informed of the outcome.

Telephone (NZ wide): 0800 555 050

Free Fax (NZ wide): 0800 278 7678 (0800 2 SUPPORT)

Email (NZ wide): advocacy@hdc.org.nz

This study has been reviewed and approved by the St Georges Clinical Advisory group. Ethical approval has been given by the Upper South A Regional Ethics Committee (#.........) To be completed