



The Activity and Technology (ACTIVATE) Trial

This information is provided to help you decide if you would like to take part in the ACTIVATE Trial.

What is the trial about?

Increasing physical activity after a breast cancer diagnosis has been shown to improve survival and other health outcomes, yet many women who have had breast cancer find it difficult to make changes without some help. The ACTIVATE Trial will test whether using fitness bands (Garmin Vivofit 2®) can increase physical activity and reduce the amount of time spent sitting for women who have undergone treatment for breast cancer.

Who will be taking part in the trial?

Those invited to take part in the ACTIVATE Trial are post-menopausal Australian women who have been diagnosed with stage I - III breast cancer within the past five years, and have completed primary treatment at least six months ago (surgery, chemotherapy, radiation therapy). Having ongoing endocrine therapy does not exclude women from taking part in the trial.

Participants also need to: have a relatively inactive lifestyle (do less than 75 minutes a week of moderate-vigorous physical activity); usually sit for at least six hours a day; be able to speak/write fluently in English; have daily access to a smart phone, mobile device or personal computer.

What does the trial involve?

Part 1 – Preparation for the trial

Before the trial begins, we need collect a range of information about your usual activity and lifestyle. This will allow us to compare measurements before the trial with those after the trial so that we can see whether the trial has had any effects on your activity levels or lifestyle.

(a) 7-day measure of activity patterns

Before you begin the trial, we need to measure your usual activity patterns using two types of activity monitor: one measures how much you move, the other measures whether you are sitting, standing or lying down. These need to be worn for seven days in a row. Written instructions are provided to help with their correct placement and use. You will also be asked to keep a diary, recording the times that the monitors are worn.

Midway through the trial (in about three months) and at the end of the trial (in about six months) you will be asked to wear the monitors again to see if there are any changes in your activity patterns.

(b) Questionnaire

We will ask you to complete a questionnaire about you, your health and lifestyle, and details of your breast cancer diagnosis and treatment. The questionnaire will take approximately 15 minutes to complete, depending on your answers. We understand there may be some questions that could cause distress (e.g. questions relating to your treatment and side-

effects). Should you need it, you will have access to free face-to-face or telephone counselling with a cancer nurse from the Cancer Information and Support Service. You can call 13 11 20, Monday to Friday between 9:00 am and 5:00 pm.

You will also be asked to complete a reduced version of the questionnaire midway through the trial (in about three months) and at the end of the trial (in about six months).

(c) Physical measurements and memory tasks

The Trial Coordinator will schedule two appointments with you (one in a couple of weeks, the other in about three months) to undertake measurements. These appointments will be scheduled at a time and place convenient to you (such as the Cancer Council Victoria offices or your home).

During the appointment, the Trial Coordinator will measure your height, weight and waist size. Your waist can be measured over light clothing, such as a t-shirt. Physical functions will also be measured, including walking speed and rising from a seated position. These measurements will take approximately 15 – 20 minutes.

You will also be asked to complete some computerised tasks. These measure memory, learning and attention. These will take approximately 15 – 20 minutes.

Part 2 – The fitness band trial

The ACTIVATE Trial tests whether the use of a fitness band can increase your physical activity and reduce the amount of time you spend sitting.

Therefore, we will ask you to wear a Garmin Vivofit 2® fitness band continuously for a period of 12 weeks.

The fitness band will be given to you at your first appointment with the Trial Coordinator. It will be yours to keep once the trial has been completed.

The Garmin Vivofit 2® is a 'smart' device that sends information about your activity patterns to devices such as a smartphone, tablet or personal computer. This allows you to keep track of your activity levels. The Trial Coordinator will help you to set up your device so that it can be used with the fitness band.

We ask that you regularly check your activity levels to help you track your progress towards increasing physical activity and reducing sitting time.

Who runs the trial?

The ACTIVATE Trial is run by Cancer Council Victoria and has been approved by the Human Research Ethics Committee of Cancer Council Victoria.

The chief investigators are: Dr Brigid Lynch (Senior Research Fellow, Cancer Epidemiology Centre, Cancer Council Victoria), A/Prof Marina Reeves (Principal Research Fellow, Cancer Prevention Research Centre, The University of Queensland), Dr Melissa Moore (Medical Oncologist, St Vincent's Hospital), Dr Dori Rosenberg (Assistant Investigator, Group Health Research Centre), Prof Dallas English, (Senior Principal Research Fellow, Cancer Epidemiology Centre, Cancer Council Victoria), Prof Christine Friedenreich (Scientific Leader, Cancer Epidemiology and Prevention Research, Alberta Health Services).

If you have any questions, please contact Brigid Lynch, Principal Investigator, on 03 9514 6209 or email brigid.lynch@cancervic.org.au