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# Participant Information statement for the research project: Multi-health: Co-creating a technology-based multiple behaviour intervention for colorectal cancer survivors at increased risk of cardiovascular disease

Version 5; 8/7/2024

You're invited to participate in the research project noted above which is being conducted by the following researchers:

Professor Mitch Duncan, University of Newcastle

Dr Sasha Fenton, University of Newcastle

Professor Aaron Sverdlov, University of Newcastle

Professor Annie Anderson, University of Dundee

Professor Bogda Koczwara, Flinders University

Dr Camille Short, University of Melbourne

Professor Gary Wittert, University of Adelaide

Dr Stina Oftedal, University of Queensland

Dr James Lynam, Calvary Mater Newcastle, University of Newcastle

Dr Kiranjit Kaur, University of Newcastle

This project is funded by Cancer Australia and the World Cancer Research Fund.

The information below details the project and how you can participate, if you choose to do so.

## What is the research about?

Survivors of colorectal cancer are at greater risk of developing cardiovascular disease due to side effects of cancer treatment. Also, many colorectal cancer survivors report being physically inactive, having an unhealthy diet, and having poor sleep quality, which can increase the risk of developing cardiovascular disease. Despite this knowledge, existing health interventions are not specifically designed to help colorectal cancer survivors improve their physical activity, dietary quality and sleep behaviour. As such, the purpose of this research is to work collaboratively with colorectal cancer survivors who are at high risk of cardiovascular disease, and healthcare professionals, researchers, and cancer organisations to design a lifestyle intervention to improve the physical activity, diet and sleep quality of colorectal survivors and reduce their risk of developing cardiovascular disease. The research team are seeking input from colorectal cancer survivors, healthcare professionals and cancer organisations to design the intervention that specifically meets the needs and expectations of colorectal cancer survivors and may be used by many colorectal cancer survivors in the future.

#### Who can participate in the research?

This research project is recruiting adults ≥18 years with Stage I, II or III colorectal cancer who have <u>completed</u> treatment in the last five years, and who

 Have low physical activity levels, and/or consume a poor quality diet, and/or have poor quality sleep, or

- Have been diagnosed by a doctor with high blood pressure, and/or high cholesterol, and/or type 2 diabetes,
- Have a smartphone or tablet (e.g. iPhone, Samsung, Oppo, Nokia, iPad) with internet access,
- And have an email address

## What does participation involve?

If you agree to participate, you will have the choice to attend up to four group workshops (2-3 hours each), OR up to four one-one interviews (1-1 ½ hours each) over the course of approx. two months. The workshops/interviews will be held at Newcastle, NSW and online via Zoom. You can choose to attend in-person or online. The in-person workshops will be conducted in a Covid-safe manner, e.g., common surfaces will be disinfected, participants will be socially distanced, face masks and hand sanitiser will be available.

At the workshops, participants will be provided with educational information and be asked to participate in group discussions with the researchers. The discussions will mainly be about lifestyle behaviours such as physical activity, diet/food intake, and sleep, and participants will be asked to share their thoughts and opinions. Participants will also be asked to complete questionnaires and do some tasks in between the workshops such as use an app that is provided to log their lifestyle behaviours. This will take approximately 15 minutes each day. The workshops will be recorded by the research team, and data logged on the app during the study period will also be collected. Only members of the research team will access the recordings and data. The interviews (if participants choose this option) will include the same topics, but the discussion will be one-on-one with Professor Mitch Duncan or a member of the team. The workshops/interviews will be recorded by the research team. Only members of the research team will access the recordings and data collected.

As a gesture of appreciation by the researchers, participants will each receive a **\$100 Woolworths gift card** at the completion of each workshop. Food and drinks will also be provided during the workshops.

## Do you have to take part in this research study?

No. Participation in this research study is voluntary. If you do not want to take part, you do not have to. And, if you do agree to participate, you can withdraw from the research study at any time without giving a reason. You also have the option of withdrawing information collected from you up until data has been permanently deidentified. The research team will not disclose your participation or non-participation to anyone else in the health service.

## What is the benefit of participating in this research study?

Participants will have the opportunity to gain knowledge about how to improve their physical activity, diet and sleep behaviours and reduce their risk of developing cardiovascular disease. They will have access to an evidence-based app which has been proven to be effective in previous research studies. It is not anticipated that there will be commercial benefits from the app. Involvement will also help the researchers create a new lifestyle intervention to help other colorectal cancer survivors reduce their risk of developing cardiovascular disease.

#### Are there any risks associated with your participation in this research?

Participants in this study will be involved in group discussions about their lifestyle behaviours such as their physical activity, diet/food intake, and sleep habits. This will involve reflection on previous and current lifestyle behaviours and may evoke emotional discomfort or distress. Participation in the discussions will be entirely by choice, and those who feel uncomfortable with any discussion will not be required to take part. In the case of feeling emotional discomfort help is available by reaching out to the following organisations

Lifeline: Phone: 13 11 14; Website: https://www.lifeline.org.au

Cancer Council: Phone: 13 11 20; Website: https://www.cancercouncil.com.au/get-support/cancer-survivors

## How will your privacy be protected?

All participant data will be stored on a password-protected University of Newcastle electronic storage system. Survey data will be collected and stored using REDCap which is a secure, web-based software platform approved for use by the University of Newcastle Human Research Ethics Committee. REDCap uses 256-bit Advanced Encryption Standard (AES) to convert data to random text and is housed securely on Hunter Medical Research Institute servers. The workshops will be recorded and transcribed via Zoom, a video conferencing platform which uses 256-bit AES. The workshops will be password protected meaning only invited participants will be able to take part. The Zoom privacy statement is available at <a href="https://explore.zoom.us/en/privacy/">https://explore.zoom.us/en/privacy/</a>. Workshop discussions might explore personal details and participants must maintain confidentiality by not divulging information to outside parties.

Except as required by law, only members of the research team will have access to the data, including the Zoom recordings. Survey data that identifies participants will be removed and replaced with numerical codes. No identifying data will be reported. Data will be retained securely for a minimum period of five years from the completion of the research project. Information will be managed and stored in accordance with the University's Research Data and Materials Management Guideline or any successor Guideline as well as any other applicable University of Newcastle policy provisions.

## How will information collected by the research team be used?

The results of the research will be reported via national and international conferences and peer reviewed publications, and in research student theses supervised by the Chief Investigator. These research students will have access to the data collected in this study. Individual participants will not be identified in any reports arising from this research, but individual anonymous responses may be quoted. Non-identifiable data may be shared with other parties as part of a peer-review process, or to contribute to further research and public knowledge.

Participants will have the opportunity to have a summary of the research findings provided to them after completion by indicating this on the Participant consent form, or by emailing the research team at multihealthstudy@newcastle.edu.au

# What you need to do to participate?

Please read this Information Statement in its entirety and be sure you understand all the information provided before agreeing to participate.

If there is anything you don't understand, or if you have questions, please contact Professor Mitch Duncan by emailing mitch.duncan@newcastle.edu.au, or by calling (02) 4921 7805.

If you would like to participate, please do one of the following:

- Visit <a href="https://redcap.link/multihealth">https://redcap.link/multihealth</a> or scan the QR code, and complete the consent form questionnaire, and the research team will contact you shortly after
- Email the research team at multihealthstudy@newcastle.edu.au and provide your full name and daytime telephone number
- Call the research team on (02) 4921 7805
   (If the phone is unattended please leave a message with your contact details)



## What if you want to withdraw from the research project?

You may withdraw from the project at any time, without providing a reason by contacting Professor Mitch Duncan via email or phone, as shown above.

Your decision not to participate or to withdraw from the project will not affect your relationship with the University of Newcastle or any of the other organisations involved in this research.

# Do you need more information?

If you would like more information about this research project and your potential involvement, please contact Professor Mitch Duncan/Dr Sasha Fenton via email or phone.

Thank you for your time and consideration of this information,

#### Professor Mitch Duncan (Chief Investigator)

Professor, University of Newcastle

## Concerns or complaints about this research

This project has been approved by the University of Newcastle's Human Research Ethics Committee, Reference No. H-2022-0238.

If you have concerns about your rights as a participant in this research, or if you have a complaint about the manner in which the research is conducted, please contact the Chief Investigator, Professor Mitch Duncan. If you would prefer to contact someone independent of the research project, you can forward your concerns to:

Human Research Ethics Officer Research and Innovation Services University of Newcastle University Drive Callaghan NSW 2308, Australia

Phone: (02) 4921 6333

Email: Human-Ethics@newcastle.edu.au