



Using Digital Humans to Deliver Stress Management to Women with Breast Cancer: Feasibility and Acceptability.

Participant Information Sheet

Supervisor: Professor Elizabeth Broadbent

Co-Supervisor: Dr. Geraldine Tennant

Co-Supervisor: Dr. Kate Loveys

Co-Investigator: Professor Michael Antoni

Co-Investigator: Associate Professor Mark Sagar

Researcher: Cerys Clayden (Masters in Health Psychology student)

You are invited to take part in a study that explores whether delivery of Cognitive-Behavioural Stress Management through digital humans is feasible and acceptable within adult women post-active treatment for breast cancer.

This therapeutic approach aims to educate individuals about the effects psychological processes, such as stress, may have on their body, and teach techniques to help manage these effects. This group-based therapy has been shown to be beneficial for women with breast cancer but is not available in New Zealand. A digital human is an engaging and social humanlike computer-based animation supported by Artificial Intelligence. Delivery through a digital human provide an avenue for individuals to receive this support anywhere there is an internet connection. Digital Human delivery of Cognitive-Behavioural Stress Management has not yet been assessed in those with breast cancer or in those following breast cancer treatment. This research hopes to fill this gap in the research.

This project is being carried out by Cerys Clayden, a master's candidate in the Department of Psychological Medicine at the University of Auckland, Professor Elizabeth Broadbent (Department of Psychological Medicine, University of Auckland), who is supervising the project, Dr. Geraldine Tennant (Department of Psychological Medicine, University of Auckland), and Dr. Kate Loveys (Department of Psychological Medicine, University of Auckland) who are co-supervising the project. Professor Mike Antoni is an expert in stress management for women with breast cancer, and A/P Mark Sagar is an expert in digital humans.

It is important that you read this document carefully so that you can make an informed decision about whether you wish to participate.

Purpose of the study: The aim of this study is to investigate whether it is feasible and acceptable to deliver Cognitive-Behavioural Stress Management (CBSM) therapy through an online digital human (DH) within breast cancer patient populations post-active treatment.

Your rights as a participant: Participation in the study is entirely voluntary. If you choose to participate, you can withdraw from this research project at any time during the session and up to two weeks after participation without giving reason and without negative consequences. If you withdraw from the study, your data will be removed. If you are a student of the researchers, we give our assurance that your participation or non-participation in this study will have no effect on

your grades or relationship with the University and that you may contact your academic head should you feel that this assurance has not been met. You may request a copy of this document to keep.

If you wish to withdraw for any reason, please email Cerys Clayden (ccla806@aucklanduni.ac.nz). You may withdraw from the study up to two weeks after completing the session.

Eligibility: We are recruiting two groups of participants;

- 1) Women who are aged 18 years or older, who have finished active treatment for breast cancer a minimum of two years prior to the study start date.
- 2) Healthcare professionals who work in psychology or cancer support spaces.

All participants must be comfortable using a computer and be able to come to the University of Auckland Grafton campus to complete the procedures below.

What would happen if you chose to participate?

If you choose to participate, we will ask you to complete a demographic questionnaire, and be asked your opinions of current psychological support services, and current stress levels. Then you will be asked to complete a 60-minute Cognitive-Behavioural Stress Management module delivered through the digital human. This session includes learning about the effects of stress on the body and learning a deep breathing stress management technique. We will ask you to complete a second questionnaire regarding how you felt about the module, the digital human, and your stress levels. Your answers will be used to investigate whether the digital human is feasible and acceptable to deliver a stress management programme to breast cancer patients' post-active treatment.

The total time commitment from you is approximately 90 minutes.

Compensation: As a thank you from us, for your much appreciated support and effort in completing the study, you will receive a \$50 Countdown shopping voucher as koha. You will receive this irrespective of whether you withdraw during the study.

Benefits: Many people who complete Cognitive-Behavioural Stress Management experience improvements in mood, stress, and relaxation after completion.

Risks and Discomforts: The procedures outlined in this study protocol are non-invasive and present risk that is comparable to the minimal risk and harm you would encounter in normal daily life. Interactions with the digital human are very unlikely to cause distress, however, if you wish to talk further about any issues that arise for you during this session, please contact your GP or reach out to support services provided to you.

Data Storage: When you have signed the consent form, the researcher will assign you a participant identification number. You and the researchers will use this number on all of the documents, forms, and questionnaires that you fill in. When you have completed the session for the day, your identification number will be used by the researchers to investigate results.

All of the data that we collect and store about you will be linked to your participant identification number and at no time will your name or other identification be linked to that number. In addition, all the data we collect will be stored in password protected files on secure servers. All data will be destroyed after 10 years.

Confidentiality: All your personal information will remain strictly confidential. Your data will only be stored with your participant number and not your name. Your de-identified responses to the questionnaires and interactions with the digital human will only be accessible by the researchers.

Results: A summary of the results of this study will be sent to you if you wish. As it takes some time to analyse the results of a study, it may be more than a year after you participate before you receive this information.

Incidental findings: This study asks you to rate how stressed you are currently feeling. This is not a formal assessment of stress. We will provide a list of possible avenues to seek support to any participant should you wish.

Soul Machines Ltd. Potential Conflict of Interest: Soul Machines provides the digital human software for this study. Professor Elizabeth Broadbent and Dr. Kate Loveys are paid consultants for research at Soul Machines Ltd. Soul Machines had no role in the design of this study and will not be involved in the analysis of data. They will not have access to the data.

We appreciate the time you have taken to read this invitation. If you have any further questions, please contact:

Cerys Clayden (Researcher)
Master of Health Psychology Student
Department of Psychological Medicine
The University of Auckland
Private Bag 92019
Auckland 1142
Email: ccla806@aucklanduni.ac.nz

Alternative contacts:

Professor Elizabeth Broadbent (Supervisor)
Department of Psychological Medicine
The University of Auckland
Private Bag 92019
Auckland 1142
Email: e.broadbent@aucklanduni.ac.nz
Phone: (09) 3737599 Ext. 86756

Dr. Geraldine Tennant (Co-Supervisor)
Department of Psychological Medicine
The University of Auckland
Private Bag 92019
Auckland 1142
Email: g.tennant@aucklanduni.ac.nz