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

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**Introduction**

Psychological stress is commonly experienced by women following diagnosis and treatment of breast cancer (Jassim et al., 2023). Acute and chronic stress both preceding cancer diagnosis and succeeding the life changes associated with cancer can cause psychophysiological changes within human systems, potentially resulting in detrimental health outcomes (Antoni, Moreno & Penedo, 2023). Within cancer patients, psychological stress has documented negative health impacts on the neuro-endocrine and immune system (Denaro, Tomasello & Russi, 2014). Perceived stress, stressful life events, and post-traumatic stress can contribute to an increased likelihood of cancer re-occurrence and metastasis alongside lower quality of life (Soung & Kim, 2015). Reducing psychological stress within patients’ post-cancer treatment may improve the etiology or cancer progression and bolster quality of life.

Cognitive Behavioural Stress Management (CBSM) is a 10-week cognitive, interpersonal, and behavioural skills training program that has shown efficacious outcomes in breast cancer populations (Antoni & Dhabhar, 2019; Groarke, Curtis, & Kerin, 2013). This group-based stress management program conducted within breast cancer patient populations has been shown to improve stress (Carpenter et al., 2014), stress management skills (Gudenkauf et al., 2015), quality of life (Stagl et al., 2015b), mood (Tang et al., 2020), and immune function (McGregor et al., 2004; Antoni et al., 2009).

Women with high cancer-specific distress after active treatment may benefit more from CBSM than those with low cancer-specific distress (Wang et al., 2018). Furthermore, CBSM within breast cancer populations post-active treatment may improve survival and reoccurrence prognoses (Stagl et al., 2015c). Early intervention aimed at harboring stress management techniques may produce long-lasting beneficial psychophysiological outcomes in breast cancer patients after active treatment (Stagl et al., 2015a). Although effective in breast cancer populations, CBSM delivered face-to-face is not available to most women due to limited resources and time. Delivery of CBSM through other means may open an avenue to reach breast cancer patients in New Zealand to enhance access to wellbeing support.

Technology can advance the reach of stress management interventions to wider populations, especially within patient populations experiencing distress post-treatment (Singleton et al., 2022; Chen et al., 2023). Online delivery of CBSM has been shown to promote quality of life, cortisol rhythm, and improve anxiety and depressive symptoms within cancer patients (Penedo et al., 2020; Penedo et al., 2021; Zion et al., 2023). Self-directed online delivery may result in lower engagement and adherence to psychological therapies due to the lack of social accountability and human engagement (Rathbone & Prescott, 2017; Christensen, Griffiths, & Farrer, 2009). A relatively novel avenue for delivering CBSM with greater engagement, more scalable features, and cost-effective implementation is digital human therapy. A digital human is an embodied conversational agent with artificial intelligence. Given their humanlike social cues and features, digital humans present the opportunity to be just as engaging as human therapists whilst learning from iterative social data and social input from users (Loveys et al., 2022b).

Digital human delivery of CBSM has been shown to be feasible and acceptable within stressed adult women samples (Loveys et al., 2022). Adult women found digital humans to be interactive, non-judgmental, low in social pressure, easy to use, and just as relaxing as interacting with a human tele therapist (Loveys et al., 2023a). CBSM delivered through digital humans enabled adequate reductions in stress, learning of stress management techniques, and a high willingness to utilise the service again in the future (Loveys et al., 2023a). Overall, adult women liked how the digital human held eye gaze and was factual, providing a basis for delivery of CBSM through relatable means. Established as acceptable within stressed adult women populations, the question now turns to how digital humans may provide support to patients with breast cancer.

Although studies have established the efficacy of CBSM in 10 weekly sessions within breast cancer populations (Antoni et al., 2023), and established the acceptability of digital humans for delivering this programme (Loveys et al., 2023a), research is yet to investigate the acceptability of digital humans in breast cancer populations. Both the online intervention and the digital human have been tailored to women with breast cancer using the CBSM manual (Carpenter et al., 2014; Antoni et al., 2023).

Research is now needed to investigate the acceptability and feasibility of delivering this evidence-based stress management intervention through the digital human for women with breast cancer.

**Aims**

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. This research would involve both patients and healthcare professionals to gather both perspectives.

**Hypotheses**

We hypothesize that CBSM delivered by a digital human therapist will be feasible and acceptable for adult women post-cancer diagnosis and active treatment.

**Study design**

This study will evaluate the feasibility, and acceptability, of a digital human therapist at delivering one module of CBSM therapy to adult women post-breast cancer diagnosis and active treatment. The primary outcomes are feasibility and acceptability, and secondary outcomes are stress and relaxation, as well as rapport and trust with the digital human. Data will be collected during one in-person session using questionnaires.

**Study Setting**

This study will take place at the Clinical Research Centre at the University of Auckland Grafton Campus. The Clinical Research Centre is located in central Auckland, adjacent to Auckland City Hospital and regular public transport. Participants will be provided a private room with a stable internet connection to participate in one module of CBSM therapy and fill in two questionnaires. A researcher will be available on standby during the session to provide technical support if needed.

**Study Population**

This study will recruit 15 women who have experienced breast cancer and 15 healthcare providers in the greater Auckland area who are fluent in English, recruiting 30 participants total. Group one (BCp) will consist of females aged 18 years or older who have finished active treatment for breast cancer a minimum of two years prior to the study start date. Participant group two (HCp) will consist of healthcare providers aged 18 years or older working within cancer-related and/or CBT spaces. A minimum of 30 participants is recommended for a feasibility and acceptability study (Teresi et al., 2022). We aim to recruit a representative sample of 17.3% Māori participants (i.e., 5 of 30 participants).

**Outcomes**

The primary outcomes will be feasibility and acceptability of the digital human therapist named “Rosie” in delivering one CBSM module. Secondary outcomes include stress and relaxation, and rapport/trust with the digital human therapist Rosie. These outcomes are described here, and the study questionnaires are included in Appendix A.

**Measures**

*Interviews at baseline to assess current stress management.*

* A series of open-ended questions will be asked to post-active treatment patient participants on their current stress management techniques and beliefs about current psychosocial therapeutic services:
	+ Do you currently use any psychological support services to manage stress? If ‘yes’, what do you use?
	+ Were psychological support options offered to you during or after your active treatment finished? If ‘yes’, what were they?
	+ How do you feel about the psychological support services you use?
	+ Would you be interested in a digital support programme? If so, is there anything specific you would like it to do?
	+ Have you ever used Google to ask questions about your health, wellbeing, or about cancer? If ‘yes’, how much did you trust the answers it gave you? If ‘no’, is there any reason why not?
	+ Have you ever used a Large Language Model or Artificial Intelligence programme (E.g., ChatGPT) to ask questions about your health, wellbeing, or cancer? If ‘yes’, how much did you trust the answers it gave you? If ‘no’, is there any reason why not?
* A series of open-ended questions will be asked to healthcare clinician participants on their current views regarding psychosocial therapeutic services in cancer care:
	+ Do you currently recommend any stress management techniques? If ‘yes’, what do you recommend?
	+ What psychological support options are currently offered after active treatment for cancer patients?
	+ What do you think about the psychological support options offered to cancer patients?
	+ What kinds of digital psychological support do you think might benefit women with breast cancer?

*Demographic information will also be collected at baseline (age, ethnicity, education, occupation)*

*Feasibility*

*Recruitment Process:*

* Number of participants collected from different groups and recruitment methods.
* Number of people who attend the in-person session.

*Measurement Tools:*

* Time taken to fill in questionnaires.
* Missing data from questionnaires.

*Technical Difficulties:*

* Frequency of different program errors identified.
* Number of times the researcher provided technical support during in-person session.

*Acceptability*

*Delivery Method:*

* A series of open-ended questions will be asked to post-active treatment patient participants on the acceptability of the intervention delivery through the digital human, including:
	+ What did you like about Rosie?
	+ How do you think Rosie could be improved?
* A series of open-ended questions will be asked to healthcare clinician participants on the acceptability of the intervention delivery through the digital human, including:
	+ What did you like about Rosie?
	+ How do you think Rosie could be improved?
* Acceptability of the digital human delivery of the session (100mm Visual Analogue Scale).

*Intervention Acceptability:*

* A series of open-ended questions will be asked to post-treatment patient participants on the acceptability of the intervention content, including:
	+ What did you learn from this therapy session?
	+ Would you recommend this therapy session to someone you care about? Why or why not?
	+ What was the aspect of the therapy session you liked the most?
	+ What did you like least about the therapy session?
	+ What do you think could be improved about the therapy session?
	+ Were there any difficulties in taking part? If yes, what were the difficulties?
	+ How easy was it to use the session?
	+ Did you understand Rosie’s instructions and responses? If ‘no’, what did you not understand?
	+ Are there any changes in your perspective on how to cope with stress? If ‘yes’, what are they?
* A series of open-ended questions will be asked to healthcare professionals on the acceptability of the intervention content, including:
	+ Would you recommend this therapy session to a patient? Why or why not?
	+ What was the aspect of the therapy session you liked the most?
	+ What did you like least about the therapy session?
	+ What do you think could be improved about the therapy session?
	+ Were there any difficulties in taking part? If yes, what were the difficulties?
	+ How easy was it to use the session?
	+ Did you understand Rosie’s instructions and responses? If ‘no’, what did you not understand?
	+ As this intervention was a preliminary single-session intervention, do you think this would be useful as 5 or 10 sessions in the future? Why or why not?
* Satisfaction with using the resource for improving stress management (1-item, 7-point Likert scale).
* Likelihood of using the resource to cope with stress in the future (1-item, 7-point Likert scale).
* Comfort with completing the therapy independently at home (100mm Visual Analogue Scale).

*Intervention Engagement:*

* Session completion.
* Desire to continue with more Cognitive-Behavioural Stress Management sessions (100mm Visual Analogue Scale).
* Perceived engagement in the therapy session (100mm Visual Analogue Scale).
* One open-ended question will be asked to all participants on difficulties in engaging with the intervention:
	+ Did you experience any difficulties in engaging with the intervention? If ‘yes’, what difficulties did you experience?
* Retention rate measured with study drop-out.

*Treatment Fidelity*

* Satisfaction with digital human (Rosie) responses (100mm visual analogue scale).

*Stress and Relaxation:*

Visual analogue scales (VAS) will be used to measure current feelings of stress and relaxation. VAS items will be modelled from Loveys et al. (2023a). Current feelings of stress and relaxation will be measured at baseline and post-intervention for intervention effect descriptive purposes.

Responses to ‘How stressed are you currently feeling?’ will be marked with an X along a 100mm line. Higher scores will indicate greater stress at the time of measurement.

Responses to ‘How relaxed are you currently feeling?’ will be marked with an X along a 100mm line. Higher scores will indicate greater relaxation at the time of measurement.

*Digital Human Therapist Rapport and Trust: Visual Analogue Scale.*

Rapport and trust will be assessed using visual analogue scales. Previous research has expressed low trust and rapport experiences with digital humans, potentially due to rapport measurement methods (Loveys et al., 2023a). Visual Analogue Scales provide adequate sensitivity measurement of perceived trust and quality of interactions within cancer patient samples (Hauser & Walsh, 2008).

Responses to ‘How much did you feel a sense of rapport with Rosie?’ will be marked with an X along a 100mm line. Higher scores will indicate greater perceived rapport with the digital human.

Responses to “How much did you trust Rosie?’ will be marked with an X along a 100mm line. Higher scores indicate greater perceived trust in the digital human therapist.

**Procedures**

*Recruitment of participants*

Participants will be recruited via flyers and information posters placed around the University of Auckland, research platforms, and social media. Flyers will be posted online to the University of Auckland Faculty of Medical and Health Sciences (FMHS) Research Recruitment website as well as posted in the community targeted to females aged 18 years or older and healthcare clinicians in the greater Auckland area. The Breast Cancer Foundation New Zealand and the New Zealand Cancer Society will also be approached to promote the study.

Healthcare clinicians working within the cancer space or related areas will also be approached via email. A QR code and contact email will be provided on the flyers for anyone who is interested in participating. All those who display interest in the study will be screened for eligibility over an emailed questionnaire. After the recruitment target has been met, people who contact the researchers will be informed that the recruitment quota has been filled and will be given the option to be contacted by the researchers for further information on other studies for which they are eligible.

*Study procedure*

Participants will attend one 90 minute session at the University of Auckland Clinical Research Centre. To begin the session, participants will provide written informed consent. Next, participants will fill out a baseline questionnaire that collects information on demographic characteristics. All participants will also fill out respective questionnaires regarding what stress management techniques they/their patients currently use, are aware of, and are provided to them/their patients.

The researcher will then set up the intervention by opening the digital human therapist on a secure computer, providing an in-depth description of the intervention and digital human delivery method, and then will leave the room for the duration of the session to provide privacy. Participants will complete one module of Cognitive-Behavioural Stress Management (CBSM) therapy for approximately 60 minutes. The therapy session involves psychoeducation about the effects of stress on the body and learning a stress management technique: deep breathing. After the therapy session is finished, the researcher will return to the room. The participant will then complete follow-up questionnaires on the intervention acceptability, engagement, perceptions of the digital human therapist, and further improvements. To conclude the session, participants will be compensated with one $50 voucher for their time. In total it is expected that study participation will take 90.

*Facilitators*

A student researcher will provide participants with instructions for interacting with the digital human therapist as well as provide technical support to participants during the session where needed. The researcher will be on standby in a neighboring room to give participants privacy while completing the therapy session.

*Measurement*

Participants will be asked to complete a questionnaire at baseline and post-intervention. Questionnaires will be different dependent whether they are post-breast cancer patients or healthcare clinicians.

**Data analysis**

Feasibility will be assessed on practicality of recruitment methods, acceptability of the digital human therapist, and technical difficulties experienced, as well as the coverage of the measures. Descriptive statistics will be produced to evaluate stress, relaxation, perceived rapport and trust with the digital human. Answers to interview questions will be coded by researchers using methods of conventional content analysis. The qualitative acceptability data will be compared between Māori and non-Māori by assessing convergence and divergence in the themes. The results will be used to inform future Māori-focused research.

**Ethical considerations**

Approval was granted from the Auckland Health Research Ethics Committee on 12/04/2024 for three years (Ref. AH27228). Participants will be informed about ethical considerations for the study, including confidentiality, data storage, right to withdraw, risks and discomforts, compensation, and results, in written and oral form during the informed consent procedure.

*Confidentiality*

All personal information will remain strictly confidential and no material that could personally identify participants will be used in any study reporting. Participant names will only appear on the consent form, which will be coded with a participant identification number to keep identities confidential on all data files. After completion of the study, all confidential data, including securely stored computer files, will be kept for a minimum of six years to allow for publication and re-analysis, after which time it will be confidentially disposed of. Research publications from the study will not contain any information that could personally identify participants.

*Data storage*

All data will be securely stored electronically by the researcher at the University of Auckland. Consent forms will be temporarily stored in a locked filing cabinet in the Clinical Research Centre at the University of Auckland and will be kept for a period of six years in the PI’s cabinet in her office.

*Right to Withdraw*

Participants will be informed that their participation in the study is entirely voluntary. Participants have a right to withdraw without giving a reason up to two weeks after taking part in the study by contacting the researchers.

*Safety, Risks, and Discomforts*

The procedures outlined in this protocol are non-invasive and have been performed in other similar research settings. Cognitive-Behavioural Stress Management (CBSM) therapy and similar psychosocial interventions have been used extensively with adult women post-breast cancer and has been shown to be effective when delivered online and in virtual forms (Carpenter et al., 2014). Furthermore, digital human delivery of CBSM has been shown as accepted and feasible within distressed women samples (Loveys et al., 2023).

*Compensation*

Participants will receive a $50 countdown voucher at the end of the in-person session as compensation for their participation in the research. Participants will receive this voucher irrespective of whether they withdraw during the study or provide incomplete data.

*Results*

Participants will be offered the opportunity during informed consent stages to be sent a summary of the results and findings in non-academic language. The researchers are also happy to be contacted to korero about the results further with Māori participants, whānau and iwi.

*Relationship With Soul Machines*

Professor Elizabeth Broadbent and Dr. Kate Loveys are paid consultants for research at Soul Machines Ltd. Soul Machines Ltd had no role in the design of the study and will not be involved in the analysis of the data. They will not have access to the data. Soul Machines has provided the researchers access to their software for this research.

**Expected Outcomes**

This study will evaluate whether digital humans as a delivery method for Cognitive-Behavioural Stress Management (CBSM) are feasible and acceptable for use in breast cancer patient populations. Results will indicate whether participants feel a sense of rapport and trust with the digital human, and whether participants feel that the digital human could be capable of supplying psychosocial therapies on a wider scale. Results will also indicate whether participants feel as though digital human delivery of Cognitive-Behavioural Stress Management could be utilized within cancer-related healthcare services, and what improvements can be made. Outcomes will be measured using questionnaires during one in-person session. Findings will inform any changes to intervention delivery for larger studies aiming to develop digital humans further within this population, including in investigating the efficacy of effects of Cognitive-Behavioural Stress Management intervention programmes delivered by digital humans.

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