Effects of Relaxation on Wound Healing

PARTICIPANT INFORMATION SHEET

You are invited to take part in a study investigating the effects of different relaxation delivery methods on wound healing. This project is run by Isabella Pickering, a Master’s student in the Department of Psychological Medicine at the University of Auckland, supervised by Professor Elizabeth Broadbent from the Department of Psychological Medicine at the University of Auckland and co-supervised by Mikaela Law (PhD student) and Kate Loveys (PhD student) from the Department of Psychological Medicine at the University of Auckland.

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

Purpose of the study: This study aims to evaluate the effects of different relaxation delivery methods on wound healing, measured by skin barrier recovery.

Eligibility: To participate in this study, you must be over the age of 18, speak, read, and write in fluent English and be able to see and hear without difficulty. You will not be able to participate in this study if you are allergic to adhesive tape, have any inflammatory skin diseases/immunological-related health problems, are taking medication that affects immune functioning (e.g., prednisone), are pregnant, over the age of 60 or have hearing difficulties or vision loss.

Procedure: If you choose to participate in this research, you will be asked to complete one 90-minute session at the University of Auckland’s Clinical Research Centre in Grafton. You are encouraged to talk with whānau or support people before participating if appropriate. Following salivary procedures and to reduce interference in the TEWL measures, we ask you not to drink caffeine, juice or alcohol 18 hours before the study and not eat, shower, exercise or apply moisturiser in the hour before the study.

Relaxation. You will be randomly assigned to one of three types of relaxation delivery methods: magazines, audiotapes, or a digital human. Relaxation has shown to be effective at reducing stress and improving immune function. All relaxation sessions will take approximately 20 minutes. The relaxation session that is allocated to you will be completed after the tape-stripping procedure and during the recovery period to determine how it influences the rate at which your skin barrier recovers. During the 20-minute recovery period you will be video recorded using an external
webcam. The researcher will not be in the room during this recovery period but will be nearby if you need assistance.

**Tape stripping**: The study requires you to undergo a simple and non-invasive tape-stripping procedure on your forearm. During this procedure, tape will be applied to the skin on your forearm in three $1cm^2$ areas just below your elbow to remove the topmost layer of your skin. This will be repeated several times until your skin barrier function reaches below a certain threshold. To ensure the right level of skin disruption is achieved, a small probe will be pressed gently against your skin for a few minutes. After a 20-minute recovery period, your skin barrier function will again be tested using this probe to examine how much your skin has recovered.

**Biological measures.** Saliva samples will be collected at three time-points throughout the study: at baseline, after the tape stripping procedure and after the recovery period. These saliva samples will be analysed to examine levels of cortisol and alpha-amylase (hormones). The samples will be stored in salicap containers labelled only with your participant ID number in a secure lab in the University of Auckland at -20 degrees Celsius for up to 2 years. The samples will be sent overseas on dry ice to the University of Vienna (Austria) for analysis by a specialist laboratory. These samples will not be used for anything other than the purpose of this study. After the salivary samples have been analysed, they will be disposed of appropriately, and not used for any future research.

**Physiological measures.** During the experimental session you will be wearing a wrister sensor to continuously measure heart rate and skin conductance.

**Questionnaires.** During the experimental session you will be asked to complete a series of questionnaires related to your demographics, health behaviours, levels of stress, pain, anxiety and relaxation and opinions on relaxation delivery.

**Audiovisual Data.** There will be an external webcam set up to video record you during the 20 minute recovery period to see whether your wound was touched or interfered with (as this can effect how your wound heals). This recording will be stored on a single user, password protected computer and labelled with your participant number only to ensure confidentiality.

**Your rights as a participant:** Participation in this study is entirely voluntary. If you choose to participate, you can change your mind at any time, including during a session, without giving a reason and without any negative consequences. You may also withdraw your data up to two weeks after completing the study, in which case the data will be securely destroyed. You will be given a copy of this document to keep.

**Koha:** You will receive a $30 Westfield gift voucher at the end of the session as compensation for agreeing to participate in this research. You will receive this irrespective of whether you withdraw during the study.

**Risks and discomforts:** The procedures outlined in this protocol are minimally invasive and have been performed in other research settings. The tape-stripping procedure may cause slight discomfort and redness of the skin, but this should disappear within 24 hours. If you have an allergy to cello tape or adhesives, an inflammatory skin disease or are taking medication that affects immune functioning, you should not take part in this study. If skin irritation persists, you should contact University Health Services on 09 923 7681 (for University of Auckland students) or your GP (normal charges will apply) to make an appointment with a doctor or contact the researchers to organise to see the study dermatologist, Dr. Paul Jarrett.
Your researcher is not medically trained and therefore is unable to make any clinical observations about your physiological measures or mental states during the sessions. However, if any abnormal physiological or psychological recordings are made, you will be informed and encouraged to contact the appropriate experts.

**Cultural Support:** If you require Māori cultural support, talk to your whānau in the first instance. Alternatively, you may contact the administrator for He Kamaka Waiora (Māori Health Team) by telephoning 09 486 8324 ext 2324. If you have any questions or complaints about the study, you may contact the Auckland and Waitāmatā District Health Boards Māori Research Committee or Māori Research Advisor by phoning 09 486 8920 ext 3204.

**Data storage:** All data (including questionnaires, physiological, and wound healing measurements) and video recordings (from the 20 minute intervention period) will be stored on a single user, password protected computer in the University of Auckland, Department of Psychological Medicine for six years, after which all data will be disposed of by permanently deleting.

**Confidentiality:** All personal information will remain strictly confidential and no material that could personally identify you will be used in any report on this study. All questionnaire, wound healing, physiological measures and video recordings are labelled with a participant number only, so that your identity is kept confidential. Participant names and contact details will only be linked to the data via a master sheet that will be stored in a locked file, separately from the data. Only the researcher will have access to the password protected data files that contain participant data (including the protected folder for video recordings).

Research publications and presentations from the study will not contain any information that could personally identify you. We will publish the results but not the data itself. The purpose the data is collected is to investigate the research question and publish results in a journal paper and/or presentation.

**Results:** A summary of the results of this study in non-academic language will be sent to you if you wish. As it takes some time to analyse the results of studies, it may be more than a year after your participation that you receive this information.

**Technology confidentiality:** As this study involves the use of some technology by Soul Machines Limited, we do ask that you do not discuss your experiences during the Research with anyone. As this research forms part of Soul Machines’ world leading research program, we are insisting that you do not engage in media interviews or discussion, or blog or make any other form of account of your experience, including on your own social media. Accordingly, before you take part in the Research, we ask that you sign the acknowledgments related to technology confidentiality outlined in the consent form. It is a condition of your participation in the Research that you accept the acknowledgments outlined below. If you do not wish to sign the acknowledgments, you are free to withdraw from the Research. If you have any questions, please email privacy@soulmachines.com.

You will be asked to acknowledge and agree to the following:

a. I will not make any video and/or audio recordings or take any photographs of the Research or my participation in the Research.

b. I will not publish any articles (including any video and/or audio content) or make or authorize any public comments relating to or referring to the Research or my participation in the Research.

c. I do not work for or contribute to any media organization.
d. I have had the opportunity to ask questions and have them answered to my satisfaction.

**Contact details:** We appreciate the time you have taken to read this information. If you have any questions, please contact:

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**Head of Department:**

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For concerns of an ethical nature, you can contact the Chair of the Auckland Health Research Ethics Committee at ahrec@auckland.ac.nz or at 373 7599 x 83711, or at Auckland Health Research Ethics Committee, The University of Auckland, Private Bag 92019, Auckland 1142

Approved by the Auckland Health Research Ethics Committee on 3/3/2021 for three years.  
Reference number AH21981.