The Effect of Environmental Enrichment and Stress on Psoriasis

PARTICIPANT INFORMATION SHEET

You are invited to take part in a research project investigating the effect of environmental enrichment and stress on psoriasis. We are looking for 76 participants with chronic plaque psoriasis to participate in this study.

This project is being supervised by Professor Elizabeth Broadbent (Professor in Health Psychology), co-supervised by Dr. Paul Jarrett (Consultant dermatologist, Middlemore Hospital and the Department of Medicine) and carried out by Mikaela Law (PhD candidate in Health Psychology). The research is also supported by Dr. Michel Nieuwoudt (Senior Research Fellow in Chemical Sciences) and Hannah Holtkamp (Post-Doctoral Fellow in Chemical Sciences).

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

Eligibility: For this project you must fit a number of inclusion criteria. These include:

- Diagnosis of chronic stable plaque psoriasis
- Over the age of 16 years
- Fluent in English
- No other significant skin conditions
- Not currently taking any systemic (oral) therapy for psoriasis including cyclosporin, methotrexate, acitretin, or concurrent phototherapy or biologic agents. You must have been off all systemic psoriasis treatments for at least 3 months to be eligible to participate
- Not on any other immunosuppressive medications
- No recent or anticipated changes in anti-depressant or anxiolytic medications

If you are unsure if you fit these eligibility criteria, you can still attend the first screening session to be assessed by the study dermatologist and have a free skin-check.

Procedure: If you believe you are eligible for this intervention study and you would like to participate you will be asked to attend two sessions at the University of Auckland, Grafton Campus; a screening visit and an experimental session.
**Screening Visit:** the screening visit will take approximately 20 minutes of your time. During this visit, Dr. Paul Jarrett, a dermatologist, will conduct a free skin check to assess your psoriasis to see if you fit the inclusion criteria listed above. If eligible for the study, Dr. Jarrett will select a psoriatic plaque to be measured in the second session. This plaque will preferably be on your arm, leg or torso. The dermatologist will photograph and measure this plaque. You will be asked to refrain from treating this plaque with topical treatments until after your experimental session has been completed. The lead researcher will be in contact with you after this screening visit to arrange a time for the second, experimental session which will be held between 1 to 4 weeks after the screening visit, at a time that suits you best.

**Experimental Session:** The experimental session will last approximately 2 hours. During this session you will be exposed to a number of tasks and your selected psoriatic lesion will be measured to assess any changes across the session. You will need to turn off your phones and place all your belongings in a secure place during the experimental session.

**Psoriasis Measurements.** Your selected psoriatic plaque will be measured three times throughout the session. During these measurements, you will be asked to lie on a bed, with your selected plaque uncovered. A 1cm² site will be marked out on both your plaque, and on a control site of healthy skin nearby. The researcher will then measure each of these sites using two non-invasive devices: a Tewameter and a Raman spectroscopy device. The Tewameter measures the water content of your skin. It will be placed against your skin and will measure each site for up to 90 seconds. The Raman spectroscopy device focuses a laser of low power on your skin to measure the biomolecular composition of the skin. This device will measure each of the two sites for approximately 1 to 2 minutes. Both of these measurements are non-invasive and completely harmless. The laser light of the Raman device is approximately half the American National Standards Institute (ANSI) Z136 maximum permitted exposure for laser light on skin. You will also be issued with laser safety glasses as an added precaution; however, the chances are minimal that your eyes would be exposed to any laser radiation.

**Questionnaires.** During the experimental session you will be asked to complete a series of questionnaires pertaining to your general demographics, mood, health behaviours, stress levels and current pain. You will also be asked a series of questions about your psoriasis. You don’t have to answer a question if you feel uncomfortable doing so.

**Speech task.** During the procedure, you will be exposed to a speech task. During this task, you will be assigned a topic and given 3 minutes to prepare and 5 minutes to present a speech which will be recorded by a video camera. Your performance on this speech will be rated after the completion of the study by a panel of judges and you will have a chance to win a $100 Westfield voucher based on your performance.

**Recovery period.** After the speech task, you will have a 30 minute recovery period, before the final measures are completed, to assess your recovery from the stress task. During this 30 minutes, you will be randomised to one of two conditions which have differing amounts of enrichment. During this recovery period, you will be video-recorded to ensure compliance with instructions.

**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. If a student of the University of Auckland, your grades and your relationship to the University will not be affected by your participation or non-participation.

**Benefits:** You will be reimbursed a $40 Westfield voucher at the conclusion of the second experimental session as a koha for agreeing to participate in this research. You will receive this irrespective of whether you withdraw during the study. You will also receive a skin check by a trained dermatologist, free of charge, at the first screening visit, to assess your psoriasis. At this session, the dermatologist can answer any questions you may have about your psoriasis. During the skin check, the dermatologist may find lesions that may be suspicious. In this event the dermatologist will inform you and provide you with a referral letter for your GP.

**Risks and discomforts:** Participants are not expected to experience any adverse consequences or physical or psychological risks from this study. If your psoriasis does become more severe after the stress task, you should contact University Health Services on 09 923 7681 to make an appointment with a doctor or contact your own GP.

**Confidentiality:** Your data (questionnaire responses, video-recordings and skin measures) will be used to test the study’s hypotheses. Statistical analyses will be performed, the results of which will then be discussed in research reports. Research publications and presentations from the study will not contain any information that could personally identify you, only averages will be presented.

Any information that identifies you as a participant will be used confidentially and kept in a secure location. Your name will appear only on your Consent Form, which will be coded with a participation identification number. This identification number is used to de-identify all other data, ensuring your identity is kept confidential. Your data will only be referred to or labelled with this number. The Consent Form will only be seen by you and the researchers, and will be kept in a secure filing cabinet in the Department of Psychological Medicine at the University of Auckland for a period of 6 years to allow for publication and future analysis.

All data will be destroyed after a period of 6 years. This will be done by shredding physical data and deleting electronic data.

**Results:** A summary of the research’s findings can be emailed to you upon request. As it takes some time to analyse the results of the study, it may be more than one year after your participation that you receive this summary.

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

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For any queries regarding ethical concerns, contact the Chair, The University of Auckland Human Participants Ethics Committee, The University of Auckland, Office of the Vice Chancellor, Private Bag 92019, Auckland 1142. Telephone 09 373-7599 ext. 83711. Email: ro-ethics@auckland.ac.nz

APPROVED BY THE UNIVERSITY OF AUCKLAND HUMAN PARTICIPANTS ETHICS COMMITTEE ON
27/06/2019 for 3 years, Reference Number 023106