Participant Information Sheet

Evidencing Vibroacoustic Sensing for Inflammatory Skin Disease Monitoring

You are invited to take part in a research study. To help you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

Over 300 million people around the world struggle with skin conditions like eczema and psoriasis, which cause ongoing discomfort and emotional stress.

In the UK, these conditions are diagnosed by doctors looking at the skin to assess the severity of the disease, but delays in seeing specialists contribute to long waiting times in the NHS.

To tackle these problems, we have created a device that safely uses sound waves to measure skin properties, like stiffness and moisture. Unlike just looking, this device gives clear, data-based insights into skin health, which we hope will eventually enable us to accurately measure skin health in the community.

In our study, we want to explore the diversity of skin types and how they change over time. We are interested in comparing these to the same measurements but with people who have eczema and psoriasis.

We are looking for volunteers both with and without eczema or psoriasis to have measurements taken with our device as well as photographs of their skin (with no identifiable features collected), and measurements by Optical Coherence Tomography (similar to ultrasound but with higher resolution). This allows us to compare the structure of your skin to our sensor measurements. We'll gather some extra information through questionnaires which will give us information about your likely skin type, but no treatments or painful procedures are involved; it's all safe and painless.

By joining this research, you'll help us develop knowledge that could revolutionize care for these skin conditions, ensuring patients get the right treatment at the right time and reducing the stress of waiting and uncertainty.

Why have I been invited to take part?

We are recruiting individuals who might have an interest in contributing to research on skin health and/or new technology research at Heriot-Watt University.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare your legal rights.

What will happen if I take part?

GENERAL INFORMATION

We will give you this information about the study and let you consider it for at least 24 hours before any treatment starts. The research team will answer any questions and will ask you to sign the consent form to participate in this study.

The study is designed for the collection of skin details, with the following procedure followed:

1. You will be required to sign a participation consent form prior to any study procedures being completed.
2. You will be asked to answer a questionnaire about your personal details and skin health. This will help us to understand whether there are factors that contribute to your skin properties. This will include age, sex, heigh, weight, ethnicity, skin tone (Fitzpatrick scale) and any skin health/skincare details.
3. We will take 3 measurements from up to 4 different skin locations on each side of your body using our handheld acoustic sensor. These include the forearm, hand, inside of the elbow and neck.
4. Where practical (i.e. due to accessibility and positioning of the skin) we will take OCT measurements of each site.
5. We will photograph each site where a measurement is taken.
6. If you have any lesions from eczema or psoriasis then we will look to take measurements on these sites if you consent to us doing so (and if they are in an easily accessed location).

7. Photographs of lesions (anonymised and without identifiable features) will be provided to a dermatologist for independent scoring of lesion severity.

For the above, the data will be recorded against a participant number with only the research team having access to the names linked to these numbers. This ensures that any data held will not be attributable to you by others who are not part of the study. The study time is likely to be around 20-30 minutes per measurement session. As we are interested in how skin changes over time, you will be invited to participate in the following procedures and may choose which you wish to participate in:

- A single timepoint measurement via a single session
- 6 sessions over the period of two weeks to assess how skin properties vary over that time
- Hourly measurements over the period of 8 hours on a single day.

Other than inflammatory skin conditions, subjects must be healthy, with no conditions that could have an effect on the measurements.

FURTHER DETAILS ON MEASUREMENT TECHNIQUES

(1) Use Optical Coherence Tomography to measure skin thickness in each area. This technique doesn't require contact with your skin. It uses near-infrared light, and it has been widely and safely used in patients with and without skin conditions alongside their treatments.

(2) Measure your skin mechanical properties with our handheld acoustic sensor. The measurement takes 4-5 seconds per region and its painless (it is the equivalent of placing a headphone on your skin). There is contact with skin, but the device uses disposable tips (we will use one per patient) and the materials are dermatologically tested and deemed safe to use in most people. Please do let us know if you have any known allergies to any materials and if there is a conflict, we will look for potential alternatives.

(3) Photograph the area so that the visual aspect of the patches can be tracked throughout the treatment (optional). This is to document whether there is information invisible to the eye that can be measured with our acoustic sensing technology, and also to assess your condition's severity by means of teledermatology (with the help of a dermatologist independent to the study). To avoid showing any identifiable parts of your body, we will offer to place a protective drape with a small opening that only shows the area of interest. You may opt out of having the photographs taken if you feel uncomfortable, and we will use verbal descriptors instead.

After the session we will perform a short questionnaire to gather your expectations and views regarding the service we are seeking to deploy with our technology.

DATA ANONYMITY

The data will not be identifiable as having come from you and your name and personally identifiable details will not be attached to the data. The data will be stored on Heriot-Watt University servers for 10 years and anonymised data will be made available to researchers within Heriot-Watt University and on request to researchers outside the university, but no personal data will be shared. Heriot-Watt University is the Data Controller. The University of Edinburgh will act as a data processor for anonymised data only, through our collaborative project agreement.

Is there anything I need to do or avoid?

We ask that subjects carry on with their normal way of life.

What are the possible benefits of taking part?

Participants will receive £5 per study session attended, provided they complete the full number of sessions agreed to. The findings from this research may directly contribute to improving healthcare services for patients in the future, helping to shape better care pathways for skin conditions.

What are the possible disadvantages of taking part?

Most measurements are fast, and we will aim to carry them in under 20 minutes. For initial sessions this could be longer, depending on what further information may be needed to allow you to make an informed consent.

Please note, there is no risk of incidental findings as we are only measuring superficial parameters and exploring their meaning knowing the a priori information of your condition. Thus, this is not equivalent to a medical evaluation and there will be nothing to report to your GP from our tests.

What if there are any problems?

Whilst all procedures to extract data have been tested and are safe, if you have any concerns after one of your visits and you think could be related to the measurements, please contact Dr Sara Medina-Lombardero (0774 614 1621). If you have any other concern about any aspect of this study please get in touch too, and the research team will do their best to answer your questions.

What will happen if I don't want to carry on with the study?

If you decide to withdraw from the study at any time, you are free to do so without any negative impact on your care. However, as we would need to recruit another participant to ensure the study's success, the compensation for participation would no longer be available once you withdraw.

Any anonymised data collected prior to your withdrawal may still contribute to the study's analysis, as this ensures the research remains scientifically meaningful. Rest assured, you will not be personally identifiable in any findings or published results.

We will completely respect your decision and appreciate your consideration of participating in this research.

What happens when the study is finished?

After the study finishes there is no need to follow you up. Your anonymised data will be stored for 10 years in a Heriot-Watt University data repository but cannot be linked to you. We anticipate researchers in the future making use of this data in future ethically approved studies.

Will my taking part be kept confidential?

All the information we collect during the course of the research will be kept confidential and there are strict laws which safeguard your privacy at every stage.

How will we use information about you?

We will need to use information from you for this research project.

Personal identifiable information collected will include name / date of birth / ethnicity / sex / address / post code/ e-mail address. Only authorised people will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number assigned instead.

Heriot-Watt University is responsible for looking after your information and is the Data Controller. We will keep all information about you safe and secure by keeping your personal details offline (in a look up book) separate from the study evaluations and results.

We will not share your data outside of the UK.

Once the study is finished, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

All data collected will be kept in a secure place (data will be stored on protected cloud server to which only the research team have access). All data that could identify you will be deleted upon completion of the project. All other research data (non-identifiable) will be deleted 10 years after project completion. Data is collected, processed, stored and destroyed in line with Heriot-Watt University's data protection policy (https://www.hw.ac.uk/uk/about/policies/data-protection.htm) and GDPR regulations.

You may also obtain more information by contacting the Data Protection Officer at: dataprotection@hw.ac.uk

You can also find more details of our privacy notices for academic research participants here: https://www.hw.ac.uk/uk/services/information-governance/protect/gdpr-what-it-means-for-researchers.htm

https://www.hw.ac.uk/about/professional-services/governance-and-legal-services/information-governance/protect-information/data-protection-overview/privacy-notice-for-academic-research-participants

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we have already collected.

You have the right to ask us to remove, change or delete data we hold about you for the purposes of the study. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

If you agree to take part in this study, you will also have the option to allow the research team to securely store your contact details and agree to be contacted about other ethically approved research studies. You will only be contacted by a member of this research team to determine if you are interested in taking part in another research study.

Where can you find out more about how your information is used?

You can find out more about Heriot-Watt University's Data Protection Policy here: https://www.hw.ac.uk/about/professional-services/governance-and-legal-services/information-governance/protect-information/data-protection-overview/data-protection-legislation/data-protection-policy

What will happen to the results of the study?

This study will be written up in scientific journals.
You will not be identifiable from any published results.
We will send you a lay summary of the results of the study.

Who is organising and funding the research?

This study has been organised by Prof Michael Crichton, Professor at Heriot Watt University. The study is funded by the Medical Research Council.

Who has reviewed the study?

All research is looked at by an independent group of people called a Research Ethics Committee. The study is not permitted to be conducted unless approved by this committee.

Researcher Contact Details

If you have any further questions about the study please contact Prof Michael Crichton m.crichton@hw.ac.uk or Dr Sara Medina-Lombardero (sm2113@hw.ac.uk).

Complaints

If you wish to make a complaint about the study, please contact either the study lead, Prof Michael Crichton (m.crichton@hw.ac.uk), the data protection officer at Heriot-Watt University (dataprotection@hw.ac.uk) or follow this link to access details of HWU's complaint procedures https://www.hw.ac.uk/about/our-policies/complaints.

Participant ID:

CONSENT FORM

Evidencing Vibroacoustic Sensing for Inflammatory Skin Disease Monitoring

Please **initial** box

1. I confirm that I have read and understand the information sheet for the above study.

*Date (DD MMM YYYY)	*Version Number

**complete during consent process*

2. I have had the opportunity to consider the information, ask questions and have had these questions answered satisfactorily. ☐
3. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care and/or legal rights being affected. ☐
4. I give permission for my personal information (including age, sex, heigh, weight, ethnicity, skin tone (Fitzpatrick scale) and any skin health/skincare details) to be retained on the Heriot-Watt University servers for administration of the study. ☐
5. I understand that data collected about me during the study may be converted to anonymised data. ☐
6. I agree to my anonymised data being used for future ethically approved studies. Yes ☐ No ☐
7. I agree to be contacted about ethically approved research studies for which I may be suitable. I understand that agreeing to be contacted does not oblige me to participate in any further studies. Yes ☐ No ☐
8. I agree to the use of anonymised quotes from my interview in research reports and publications. Yes ☐ No ☐
9. I understand that the data generated during this study may be used for future commercial development of products/tests/treatments/ biomarkers and I will not benefit financially from this. ☐
10. I agree to take part in the above study. ☐

Name of Person Giving Consent	Date	Signature
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