Participant Information Leaflet

STUDY TITLE: Acne App - Referral

We would like to invite you to participate in a research project about the assessment of acne and acne treatment using a mobile phone app.
Before you decide whether or not you wish to take part, it is important for you to understand why the research is being done and what it will involve. Please take your time to read the following information.

Purpose of the research

Mild acne is extremely well managed by GPs with various creams and antibiotics. However, in more severe cases, patients are referred for a specialist Dermatologist's opinion. Unfortunately, current waiting times to see consultants are extremely long. We are therefore interested to see whether we can assess acne, using a mobile phone app and online questionnaires. We are interested to see if we can improve acne treatment before the patient comes to clinic.

By joining the study you will

1. Help us to evaluate the mobile phone app for assessing acne
2. Help us to evaluate whether we can assess acne using mobile phone images and online questionnaires.
3. We may be able to offer further advice on how to treat you acne
4. In some cases if the acne is very severe we may organise an earlier clinic appointment.

The primary aim of our research is to determine if such an app is desirable and practical for patients, but additionally whether such a system may improve acne management for patients

Why have I been chosen?

You have been identified as a patient who has seen a GP for acne treatment and has been referred to the RVI for an opinion from a Consultant Dermatologist.

Do I have to take part?

No, taking part is entirely voluntary and your decision will have no consequences. You clinical care will not be affected by your decision to participate or not to participate.

What will I have to do?

If you are happy to take part, once you have completed and returned a Research Consent Form, just sit back and relax!

We will subsequently send out to you further instructions and acne questionnaires. Please find below a summarised timeline of the further actions that will be required as part of the study:

START	WEEK 4	WEEK 8	WEEK 12
1) Complete and return Consent Form 2) We will send out further instructions and acne questionnaires 3) Submit acne selfies and completed questionnaires	1) Submit further acne selfies	1) Submit further acne selfies	1) Submit final acne selfies 2) Submit final questionnaire
At every time point (Start, Week 4, 8 & 12), a dermatologist will review your selfies +/- questionnaires and optimise your current treatment if necessary (e.g. change your treatment or expedite your appointment)			

Am I eligible to take part?

5 Essential Criteria for Inclusion:

- Aged 16 – 35
- Currently receiving treatment for acne from your GP
- Owns a smartphone with a camera and enough memory to operate the MySkinSelfie mobile phone app
- Can operate a smart phone independently
- Has home WiFi and/or adequate mobile data allowance

Criteria (any 1) excluding patients from participation:

- Previously diagnosed with depression or any other mental health disorder
- Currently under the care of a hospital dermatologist
- Currently involved in another dermatology research study

Participant Information Leaflet – Additional Information

Will my taking part in the study be kept confidential?

Yes, when you consent to take part in the study you will be assigned an anonymised study number.

What will happen to my data?

All your data will be stored in accordance with the General Data Protection Regulation. All imaging data will be encrypted and stored securely in the cloud (Newcastle University Microsoft azure cloud storage). Access to the stored images and decryption keys will be limited to the study team members only. Participant's usage will be monitored during the study and for 12 months after the study has ended to see whether patients find it helpful to continue with self-monitoring. Your data will be held on a secure password protected NHS database in the dermatology research office at the Royal Victoria Infirmary. If the study results are published, the published report will not include identifiable data, and no content in the publication will be traceable to you.

The Newcastle upon Tyne Hospitals NHS Foundation Trust is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The Newcastle upon Tyne Hospitals NHS Foundation Trust will keep identifiable information about you for 5 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information by contacting the Research team on 0191 2823568.

The Newcastle upon Tyne Hospitals NHS Foundation Trust will collect information from you for this research study in accordance with our instructions.

The Newcastle upon Tyne Hospitals NHS Foundation Trust will use your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from The Newcastle upon Tyne Hospitals NHS Foundation Trust *and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The RVI research team will pass these details to The Newcastle upon Tyne Hospitals NHS Foundation Trust along with the information collected from you. The only people in The Newcastle upon Tyne Hospitals NHS Foundation Trust who will have access to information that identifies you will be people who need to contact you to send you further instructions or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or contact details.*

What will happen if I wish to withdraw from the study?

You can withdraw from the study at any time. I you wish to do so, you only need to notify the research team. Any data collected about you will not be used in the study and will be discarded

safely.

What do I do if I feel distressed, anxious or depressed?

If during your study participation you become depressed, anxious or distressed, you should contact the research team via telephone or email and you will be given an urgent appointment to meet with the clinical team or referred to your GP if necessary.

How do I complain if I wish to do so?

If you have a complaint about the study you can speak to the research staff or the Principle Investigator of the study. The telephone number is 0191 2829167. If you are still unhappy you can contact the Patient Advice and Liaison Service (PALS) office. PALS is open on all weekdays except Bank Holidays on a drop-in basis. A messaging service is available out of hours. Tel: 0800 0320202, email: northoftynepals@nhct.nhs.uk, Text/SMS: 01670511098.

Who is organising and coordinating the research?

This research is being funded by Engineering and Physical Sciences Research Council. The research is being coordinated by Computing Science at Newcastle University and Dermatology at Newcastle Hospitals and sponsored by the Dermatology Department at the Royal Victoria Infirmary. This study has been reviewed by the Dulwich Research Ethics Committee.

Principal Investigator

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End of leaflet