An information booklet for young people aged 16-17 years

DIPSOC

Developing Diagnostic criteria
for Psoriasis in Children

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Contents

First, an introduction and a quick summary

Part A

1. Why is this study important?
2. What are the aims of the study?
3. Who is leading this research and has it been approved?
4. Why have I been invited to take part?
5. What will I have to do and how long will it take?

Part B

6. Are there possible disadvantages?
7. Are there possible benefits?
8. Will my information be kept confidential?
9. Will I find out the results of the study?
10. What if there is a problem?

NHS
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Contact details

Local contact details:

Central contact details:

Email address: dipsoc@nottingham.ac.uk

Postal address: Centre of Evidence Based Dermatology,
Kings Meadow Campus, University of Nottingham,
Nottingham, NG7 2NR

Lead researchers

Dr Esther Burden-Teh

Study Coordinator – the person managing the study day to day

Centre of Evidence Based Dermatology

Prof Kim Thomas

Chief Investigator – the person at the top who oversees the whole study

Centre of Evidence Based Dermatology

You are invited to take part in our research study

- It is important you understand why the research is being done, and what it will involve.
- If you have any questions about this information or this study, talk about it with others: your parents, the researcher or your doctor.
- It is up to you whether you want to take part. If you choose not to, this won't change anything about the quality of care you receive or will receive in the future for your skin disease.

A quick summary of what you need to know

- We want to improve the diagnosis of psoriasis.
- Our study will test how well a list of diagnostic criteria (skin changes to look for and questions to ask) work at diagnosing psoriasis.
- We only need to see you once and it will take about 30 minutes. We may want to contact you by post after the study. It is important you don't tell the researcher the name of the skin disease.
- There are no tests or medications in this study. If it is OK with you we may want to include some photos of your rash in our study.

PART A

1. Why is this study important?

Psoriasis (pronounced sor-aye-asis) can cause skin changes anywhere on the body. For many people it can be a long-term condition and have a significant impact on their quality of life.

Psoriasis can be associated with other diseases such as arthritis, which causes swelling and damage to the joints. It is therefore important that psoriasis is diagnosed early and accurately. This will help people receive specialist psoriasis treatment quickly.

Psoriasis in children and young people (17 years or younger) can be harder for non-specialist doctors and nurses to recognise. The development of diagnostic criteria will help non-specialist doctors and nurses recognise psoriasis.

2. What are the aims of the study?

Our study aims to test how well each item on the list of diagnostic criteria work at diagnosing psoriasis. This list has been created with experts in psoriasis from around the world. Using the results from the study we will create an improved list of diagnostic criteria.

We will test the criteria by inviting children/young people with psoriasis and those with other skin diseases to take part. We will investigate how well the diagnostic criteria separate the two groups.

9. Will I find out the results of the study?

The results from this study will be published in medical journals, presented at medical conferences and shared with patient groups/relevant charities. We will send you a newsletter with a summary of the study findings, unless you ask us not to.

10. What if there is a problem?

If you have a concern or questions about any part of this study, you can speak to your research nurse or dermatologist working on the trial (their contact details are on the front page of this leaflet).

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure by emailing england.contactus@nhs.net (ensuring you state 'For the attention of the complaints manager' in the subject line) or via the Local Patient Advisory and Liaison Service (PALS).

Thank you for reading this booklet

8. Will my information be kept confidential?

We will use ethical and legal guidelines to make sure we handle all information about you in confidence (not sharing it with anyone who isn't working on the study or who you haven't given us permission to share it with). If you join the study, some parts of your medical records and the data collected for the study will be looked at by the research team at the University of Nottingham. Anyone who sees your data will be required to keep everything they see confidential and respect your right to privacy.

All information which is collected about you during the course of the research will be kept strictly confidential, stored in a secure and locked office, and on a password protected database. Any data about you which leaves the hospital will have your name removed (anonymised) and a unique code will be used instead so that you cannot be recognised.

All research data will be kept securely for 7 years. After this time your data will be disposed of securely. During this time, everyone involved in the study will make sure that your right to privacy is protected. Anonymised data may be used to support research in the future and shared with other researchers.

If you agree to it on the consent form, your contact details will also be kept securely at the Centre of Evidence Based Dermatology after the end of the study so we are able to contact you about the results of the study, what has happened to your skin disease and future related studies. If you don't want your contact details to be kept and used in this way, or if in the future you decide you no longer want us to hold your personal details that is fine. You can let us know and we will remove your details from our database.

3. Who is leading this research and has it been approved?

The study is being led by a dermatology (skin) doctor, Dr Esther Burden-Teh, from the University of Nottingham. This is a combined project with doctors and nurses in the NHS, researchers from Universities of Nottingham and Rotterdam, and people with psoriasis.

This study has been reviewed and approved by the Research Ethics Committee (REC). The REC looks after the rights, wellbeing and dignity of people invited to take part in research studies. The study has also been reviewed by children, young people and adults with psoriasis.

4. Why have I been invited to take part?

To help us answer our research question we are inviting about 320 children/young people to take part. We will invite people with psoriasis and other skin diseases, like you, to help with the study.

5. What will I have to do and how long will it take?

If you decide to take part in the study you will see a member of the research team on one occasion. **It is very important that you don't tell us the name of your skin disease.**

At the visit we will ask you, and if needed your parent/carer, some questions. We will then look at your skin in many different places. Some of the places we will want to look are in your hair, on your stomach, in your belly-button and flexures (armpits and groin).

If you would like anyone else with you whilst you are being examined, for example a family member or a nurse/doctor, please ask. The examination will take place in a private space and you will have the option to wear a gown.

We will give you a quick questionnaire to complete about how your skin disease affects you. We may also like to include some photos of your rash (which have been taken as part of your usual care) in the study, but only if it is OK with you. Please ask if you would like to see the photos.

We will send some children and young people a questionnaire, after the main study has closed, to find out what has happened to their skin disease.

If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form.

For our study we only need to see you on this one occasion. The visit will take about 30 minutes.

Thank you for reading this far. Read on to Part B for more information about the study

PART B

6. Are there possible disadvantages?

The study does not involve any tests or medications. We will need to look at your skin in more private body sites such as the groin. The study does not change your individual medical treatment and will not improve your skin disease.

7. Are there possible benefits?

The results from the study will hopefully help children and young people in the future to be diagnosed with psoriasis earlier and more accurately. Everyone who takes part will receive a certificate and a gift voucher to say thank you.