

The Development of a Rapid Access Clinic for Patients with Psoriasis

Have you been diagnosed with psoriasis in the last 2 years?

You are being invited to take part in a research study about the best ways to manage psoriasis in people who have recently been diagnosed with it.

The study is being conducted by researchers at the University of Manchester.

Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please ask 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. Thank you for taking the time to read this.

Who will conduct this research?

Dr Claire Reid is a consultant dermatologist and will conduct this research, supervised by the Principal Investigator: Professor Christopher Griffiths from the *Centre for Dermatology Research, The Dermatology Centre, Barnes Building, Salford Royal Hospital, Manchester, M6 8HD*

The research is being coordinated and sponsored by the University of Manchester and some of the research will be part of Dr Reid's further degree (Doctor of Medicine or MD).

What is the purpose of this research?

We recognise that psoriasis is a complex skin disease. This study is intended to investigate the usefulness and costs of a Psoriasis Rapid Access Clinic (P-RAC) for people who have recently developed psoriasis. This research study is being set up at the same time as developing this new clinic. The overall aim is to improve access to specialist care for patients with psoriasis and to investigate how effective this new rapid access care pathway is.

Why have I been chosen?

Information from your GP suggests that you have got a diagnosis of psoriasis and are suitable for this clinic if you:

- have been diagnosed with psoriasis in the last 2 years (*you may also be able to take part if you were diagnosed over 2 years ago as long as you meet the other inclusion and exclusion criteria below, please contact the team using the details below*)
- are 16 years or older
- are registered with a Salford GP

This clinic is **not** available to the following people:

- those with a psychiatric or other disorder which may affect their capacity to provide informed consent
- Ever had systemic therapy for psoriasis i.e. Biologics (injections), tablets or phototherapy.

Please take as much time as you need to consider the information and decide if you think you meet the criteria and if you want to attend. Members of the research team are happy to discuss the study and answer any questions you may have.

What will I be asked to do if I agree to take part?

If you agree to take part you will be invited to attend a specialist clinic designed for patients with psoriasis. At the clinic, you will have consultations with a dermatologist (a specialist skin doctor), a nurse and a health psychologist or health coach. You will have a thorough assessment of your psoriasis which will involve examining your skin, and checking for other conditions which sometimes occur in people with psoriasis such as psoriatic arthritis.

You will be involved in creating your own management plan, with an emphasis on getting the best understanding of psoriasis, skin treatments and focusing on your treatment goals.

We will be collecting data related to your psoriasis during these consultations by examining you and asking you some questions. We will also ask you to complete some questionnaires. These will consist of general questions about you and your health, your family history of disease, your psoriasis and how this affects you.

Our nurse will take some measurements including blood pressure, weight, height and waist measurement.

You will be asked to attend our clinic again 4 weeks and 24 weeks later (approximately 6 months) so that we can repeat our assessments including questionnaires, and ensure you are on the right treatment for your psoriasis. You will also have the opportunity to ask more about your condition and review your treatment plans.

The clinic will take place at:

The Willows Centre for Healthcare,
Lord's Avenue, Salford, M5 5JR

Optional Blood sample collection at first visit

With your permission, we would also like to take blood samples (at the first visit only). You can decide if you want to give these blood samples or prefer not to. It will not affect your participation in other aspects of the clinic.

Blood samples will be collected for two reasons:

1. We will test your blood sample for cardiovascular disease risk factors by testing for evidence of high cholesterol, diabetes and kidney disease.
2. In addition, we ask you to donate blood samples to help us to understand the processes involved in people who have been diagnosed with psoriasis. This would involve the processing and storing of blood samples for genetic research. This means that your genetic code will be interpreted from tiny particles in your blood to enable us to understand more about psoriasis and find better treatments for patients. A total of 51 mls of blood (around three and a half tablespoons) will be requested at the first visit only.

What happens if I attend this clinic – but the dermatology consultant examines me and says my rash is not psoriasis?

The dermatology consultant will refer you back to your GP. Equally, if the dermatologist decides your psoriasis is particularly serious, or has other concerns, then you may be referred to hospital.

How much time will it take to attend this clinic?

Will I be paid for taking part?

You will be asked to attend this clinic three times over a 6-month period. Each visit will take approximately 1 hour to 2 hours. You will not be paid or reimbursed for taking part in this research.

What are the possible benefits of taking part?

There are several benefits of taking part. People who have recently developed psoriasis will have access to a specialist team much more quickly than is normal in the NHS at present. You will have an opportunity to learn about psoriasis, understand how it can affect various aspects of your health and wellbeing, make a plan to treat your psoriasis and stay healthy.

What are the possible disadvantages or risks of taking part?

One disadvantage may be the time taken to attend clinic and complete the questionnaires. Some questions about how you feel may be personal and sensitive for you. The healthcare professionals at the clinic will provide a supportive environment for you and sign-post appropriate help and support that you may need. There may be some brief discomfort associated with having a blood test.

What if I become distressed when my psoriasis is being assessed or my questionnaire responses indicate that I may be depressed or anxious?

The dermatology consultant, health coach and nurse will be there to support you during your clinic visit. If there are concerns about your mood, these will be addressed by first discussing with you in the clinic. Depending on the situation, we may inform your GP or a psychiatrist.

Will my participation in the study be confidential?

Your participation in the study will be kept confidential to the study team and your GP (and the service you were referred from, where applicable). We will inform your GP (or the service you were referred from) of your participation in the study and the result of cardiovascular risk screening bloods and any other relevant results by sending a letter. Your NHS (National Health Service) electronic patient record will be updated accordingly. Any results from the blood samples donated for research will not be fed back to you or your GP (or other referring service). This is because the nature of this research is to examine patterns in large numbers of individuals so we will not be able to report back on individual results.

If the dermatologist determines that you require an onward referral to another specialist doctor, perhaps at a hospital, then we will ask for your agreement to make these arrangements. We will also inform your GP of this.

What will happen to my personal information?

In order to undertake the research project, we will need to collect some personal information about you. This information will be obtained from your visit to the psoriasis rapid access clinic, as detailed above, and from your medical records. This information will include:

- your name,
- your contact details
- health information from medical records or patient notes.

This information is regarded as a special category of information. We will use this information to carry out psoriasis research, make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from The University of Manchester and regulatory organisations may look at your medical and research records to check the accuracy of the research study.

The data which we collect during the consultation will initially be held at The Willows Centre for Healthcare. Then it will be transferred securely to the University of Manchester offices at Salford Royal Hospital or the main campus on Oxford Road. The study team at the University of Manchester will have access to your personal identifiable information, that is data which could identify you, but they will anonymise it as soon as practical.

Participant Information Sheet

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The University of Manchester will keep identifiable information about you for 5 years after the publication of results. Please see the last sheet of this information sheet for more details on the guidelines we follow when looking after your personal information.

How will you keep my data secure?

For this study, the University of Manchester is called **the data controller and sponsor**. This means that the University of Manchester takes responsibility for the protection of the personal information that this study is collecting about you. In order to comply with the legal obligations to protect your personal data the University of Manchester has safeguards in place such as policies and procedures. All researchers are appropriately trained.

Once we have collected the data it will be hard for us to change or move your information and your rights to change anything will be limited. This is because 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 have a number of rights under data protection law regarding your personal information. For example you can request a copy of the information we hold about you. This is known as a Subject Access Request. If you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, University of Manchester, Oxford Road, M13 9PL. at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the [Information Commissioner's Office](https://ico.org.uk/make-a-complaint/) (<https://ico.org.uk/make-a-complaint/>), Tel 0303 123 1113

You can find out more about how we use your information on the last page of this document. You can also ask one of the research team or look online at the University of Manchester privacy pages which can be found using this website address

<http://documents.manchester.ac.uk/display.aspx?DocID=37095>

Will the outcomes of research be published?

The results of the research study may be discussed at scientific meetings and published in national and international scientific journals *but your name and other identifying information will be separated from your data and you will not be able to be identified.*

If you would like to receive information about the anonymous results of this study we can contact you if you provide us with a contact address and/or e-mail address for this purpose.

Who has reviewed the study?

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All research which involves NHS patients has to be reviewed by the National Health Service Research Ethics Committee (REC). This study has been reviewed and approved by the North West - Liverpool Central Research Ethics Committee (18/NW/0596).

Do I have to take part? What happens if I do not want to take part or if I change my mind?

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. Even if you decide to take part you are still free to change your mind and withdraw at any time without giving a reason and without detriment to yourself.

However, it will not be possible to remove your data from the project once it has been anonymised and forms part of the dataset as we will not be able to identify your specific data. This does not affect your data protection rights.

What if I want to make a complaint?

Minor complaints

If you have a minor complaint then you need to contact the Psoriasis Rapid Access Clinic team in the first instance.

Email: PRAC@srft.nhs.uk

Phone: 0161 206 0891

Address: The Dermatology Centre, Barnes Building, Manchester, M6 8HD

Formal Complaints

If you wish to make a formal complaint or if you are not satisfied with the response you have gained from the Psoriasis Rapid Access Clinic team in the first instance then please contact:

Research Governance and Integrity Manager, Research Office, Christie Building, University of Manchester, Oxford Road, Manchester, M13 9PL research.complaints@manchester.ac.uk or 0161 275 2674 or 275 2046.

I want to take part in the research and attend the Psoriasis Rapid Access Clinic. Or I would like to find out more about it.

What should I do next?

Please contact the Psoriasis Rapid Access Clinic team using the phone number **0161 206 0891** or email address PRAC@srft.nhs.uk

MY DATA

How will my data be looked after if I take part?

Information about how your data are looked after can be found in a document called the University of Manchester Privacy notice. It can be found at the following address.

<http://documents.manchester.ac.uk/display.aspx?DocID=37095>

General Data Protection Regulation

We are collecting and storing this personal information in accordance with the General Data Protection Regulation (GDPR) and Data Protection Act 2018 which legislate to protect your personal information. The legal basis upon which we are using your personal information is “public interest task” and “for research purposes” if sensitive information is collected. For more information about the way we process your personal information and comply with data protection law please see our [Privacy Notice for Research Participants](http://documents.manchester.ac.uk/display.aspx?DocID=37095) (<http://documents.manchester.ac.uk/display.aspx?DocID=37095>).

Will my data be used for future research?

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies at the University of Manchester or the NHS. If this happens, the research will have similar aims and will be about psoriasis. Your information will only be used by organisations and researchers to conduct research in accordance to strict guidelines based on something called the **UK Policy Framework for Health and Social Care Research** More details can be found at this website address:

www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/

If this information was used **it will not identify you and will not be combined with other information in a way that could identify you.** The information will only be used for the purpose of health and care research, and cannot be used to contact you regarding any other matter or to affect your care. It will not be used to make decisions about future services available to you.

If you have any other questions or would like to speak to someone about how your research data may be used please contact

Research Governance and Integrity Manager,

Research Office, Christie Building,

University of Manchester, Oxford Road, Manchester, M13 9PL

Or Telephone 0161 275 2674 or 0161 275 2046.