

British Society for Rheumatology Psoriatic Arthritis Register (BSR-PsA)

PARTICIPANT INFORMATION SHEET

We would like to invite you to take part in the above study. Before you decide, please read this information sheet to understand why this research is being done and what it will involve.

Please read the information carefully and discuss it with others, such as family members or your GP, if you wish. Please contact us if there is anything that is not clear or if you would like more information – our contact details are on the back.

Please take as much time as you need to decide.

1. What is the purpose of the study?

The BSR-PsA is a long-term study, which has been set up to investigate the impact of psoriatic arthritis (PsA) on quality of life, and to monitor the effectiveness and safety of treatments. We also want to find out more about how these treatments affect the lives of PsA patients in areas like work, and quality of life, and why some people respond well to certain drugs and others do not.

The study has been set up by the British Society of Rheumatology, but is coordinated by the Epidemiology Group (www.abdn.ac.uk/epidemiology) at the University of Aberdeen.

2. Why have I been invited?

We aim to recruit over 1000 patients from rheumatology departments across the UK and your rheumatology consultant thinks you may be eligible for the study.

3. Do I have to take part?

No. It is up to you whether you take part or not. And if you do decide to take part, you are free to withdraw at any time, without giving us a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

4. What will happen if I decide to take part?

If you decide to take part, we will ask you to complete some questionnaires and for your permission to collect clinical data about you.

You will continue to be treated as usual by your rheumatology team. This is not a clinical trial, and the treatment you are given will be based upon the decision of your consultant, as per usual.

Some patients from some participating hospitals may be asked to donate some blood and urine samples for storage in a biobank. If this is happening at your hospital you will be given a separate Participant Information Sheet, and you can choose not to participate.

5. What will I have to do if I join the study?

If you do decide to take part, you will be asked to sign a consent form. You will also be asked to complete a questionnaire about your disease, and a member of the local research team will measure your height, weight and blood pressure. You will also be asked to complete some annual follow up questionnaires.

We are particularly interested in certain medicines: 'biologics' and other targeted therapies. The BSR-PsA is not a clinical trial (sometimes referred to as a drug trial) and if you are starting one of these medicines, it is because your consultant thinks it is appropriate for you, and will discuss this with you. However, if you are starting one of these medicines, we would also like you to complete a questionnaire three months and six months after starting.

The questionnaires will take about 30 minutes to complete. This will allow us to collect data about your disease activity, medication use, quality of life and general health. We also collect basic personal information such as age, gender, education and employment, to allow us to describe the study population and to allow us to compare it with other studies around the world.

If we do not hear back from you after we have sent you a follow-up questionnaire, we will send you up to three reminders by post, email or text. If you do not wish to receive a reminder – or if you wish to withdraw from the study altogether – you can contact the researchers at the University of Aberdeen. The contact details are on the back of this Participant Information Sheet, and will be printed on all questionnaires you receive from us.

We also ask that you keep a record of any time you may spend in hospital, any new medications or hospital referrals. You will be given a diary to record these events.

Currently, very little is known about the effect of PsA, and the effect (if any) of PsA medications, on pregnancy. If you tell us that you are pregnant, we will send you a short additional questionnaire specifically about this. Alternatively, if you tell us that your partner is pregnant, we will send you the questionnaire to pass on to her. As with all our questionnaires, you do not have to fill it in, or pass it to your partner, if you do not wish to do so.

To summarise, if you choose to participate in the study, you will be asked to:

- (a) Complete an initial questionnaire about you and your disease;
- (b) Consent to your medical records being accessed to collect clinical data;
- (c) Complete follow-up questionnaires; and
- (d) Keep a record of any time you spend in hospital, any new medications or referrals;

In addition, if you tell us that you or your partner becomes pregnant, you will be asked to:

- (e) Complete a short pregnancy questionnaire, or pass it on to your partner.

6. Medical records and your personal information

The BSR-PsA needs your permission to be able to access information contained in your medical records and from future clinic visits that are relevant to the study. This will include information about treatments or illnesses you may have. Much of the clinical information is collected anyway, as part of your normal clinical care by the rheumatology team, but we need your consent for us to have access to this information.

We also require your consent to link the information you give us, such as your name and date of birth, to other information held by the NHS. There are various different health databases across the UK – such as the Hospital Episode Statistics (England), the Scottish Morbidity Records, eDRIS (Scotland), and the Patient Episode Database for Wales. Linking your study data to these NHS datasets will allow us to gain additional information – for example, about any hospital admissions, or if you are diagnosed with cancer, or even in the event of your death. This data will provide the BSR-PsA with a more complete profile of your health, which will give us more accurate information about the long-term safety of treatments for PsA.

7. Can I take part in the study if I am already taking part in another study?

Yes, perhaps, but it may increase the burden placed upon yourself to do so. If you have any questions regarding this, please talk to your rheumatology team or a local research nurse to discuss this further.

8. What are the possible disadvantages or risks of taking part?

Apart from the time it takes you to complete the questionnaires, you will not be disadvantaged in any way by joining this study. You will continue to be treated as usual by your rheumatology care team.

The questionnaires ask about various aspects of your PsA, and about your life living with PsA. Some of the questions may be considered sensitive. If you find them upsetting, the details of the study coordinator are printed at the end of this leaflet, along with those of an independent contact person – somebody not associated with the study – in case you would prefer to talk to someone outside the study. Alternatively, you can discuss the issues with the research nurse or your consultant.

9. What are the possible benefits of taking part?

The information obtained from this study will help inform doctors to treat patients with PsA more effectively in the future.

Being in the BSR-PsA does not require your rheumatology care team to change your treatment in any way. However, your consultant may have access to your questionnaire responses which may tell him or her things about your disease that they didn't already know, and this may help them to help you manage your PsA better.

10. What if something goes wrong?

If you have any concerns with any aspect of this study please ask to speak to the researchers who will do their best to answer your questions – contact details are on the back of this Participant Information Sheet, and will be printed on all questionnaires you receive from us.

If you remain unhappy and wish to make a formal complaint, you can do this through the NHS complaints procedure. Further information about this can be obtained from:

- England: www.nhs.uk/nhsengland/complaints-and-feedback/pages/nhs-complaints.aspx
- Scotland: <https://nhsns.org/contact-us/>
- Wales: www.wales.nhs.uk/ourservices/contactus/nhscomplaints

11. What will happen if I do not want to continue with the study?

You can withdraw from the study at any time, without having to give a reason. No new data will be collected, but any data obtained prior to your withdrawal will remain part of the study.

You can withdraw by contacting the researchers at the University of Aberdeen – contact details are on the back of this Participant Information Sheet, and will be printed on all questionnaires you receive from us.

12. Will my data be confidential?

Yes. All documents you complete will be given a unique ID number to identify you. Your name and contact details will remain separate and all data storage (paper and electronic) will be kept secure at all times. Only a small number of study staff will have access to your personal data and we will follow relevant legislation in determining who on the study team will have access to it.

Please read the privacy notice you have received along with this Patient Information Sheet. If you have not received one, please contact the Coordinating Centre (contact details are below).

13. Who is organising and funding the research?

The study is funded by the British Society for Rheumatology, but organised and run from the University of Aberdeen, in collaboration with hospitals all over the UK. At the University of Aberdeen, the study is based in the Epidemiology Group, part of the Aberdeen Centre for Arthritis and Musculoskeletal Health, under the direction of the Chief Investigator: Dr Gareth Jones.

14. What will happen to the results of the research study?

The results from the study will be published in scientific journals and presented at academic conferences. All participants and hospitals taking part in the study will be sent regular study updates letting you know how the study is progressing and, in time, giving a summary of the research findings. You will not be identifiable in any of the study results.

15. Will my data be shared with anyone?

The data we collect is principally for research purposes but also for monitoring the safety of medicines that people take to help manage their condition.

Anonymised data (i.e. data without any information that might identify you as an individual) may be shared with the funder: the British Society for Rheumatology. Other researchers, from within the UK or abroad, who are undertaking research into PsA, may apply to the British Society for Rheumatology for access to study data. The society has a committee (including rheumatologists, researchers, and representatives from patient organisations) that decides whether any proposed research is justified. If the application is approved, the researchers will sign a contract that covers how data may be stored and used. None of the analysis will need you to do anything, but we do require your consent to be able to do so. Study participants will not be identifiable in any of the study results, and no-one analysing the data will have access to your name or contact details.

In the unlikely event of a serious or significant medical problem that might be associated with some of the medication you are taking, we may need to share some of the information we have collected about you with the company that manufactures that medicine. Companies collect this information to help ensure the safety of medicines they produce. You will not be identifiable from this information, and the company will not have access to your name or contact details.

16. Who has reviewed the study?

This study has been reviewed and approved by the NHS West of Scotland Research Ethics Committee 3.

For further information, or if you have any questions, please contact Dr Karen Forrest Keenan, the study coordinator:

**BSR-PsA study team
Epidemiology Group
University of Aberdeen
1st floor, Health Sciences Building
Foresterhill, Aberdeen, AB25 2ZD**

E-mail: bsr-psa@abdn.ac.uk
Tel: 01224 437562
Web: www.abdn.ac.uk/bsr-psa

The NHS Health Research Authority offer independent and impartial advice on whether or not to take part in clinical research, see: www.hra.nhs.uk/about-us/what-we-do/taking-part-or-getting-involved-research.

Alternatively, if you would like to speak to another health professional who is not directly involved in the study, please contact: Ann Tierney

Centre for Rheumatic Diseases, Ward 15, Royal Infirmary
84 Castle Street, Glasgow, G4 0SF
Email: ann.tierney@ggc.scot.nhs.uk
Tel: 0141 221 4258

17. Updates to this document

If you agree to take part in the BSR-PsA, you will be given a copy of this Patient Information Sheet. However, from time to time it may require to be updated. The most up-to-date version will be available on the study website: via www.abdn.ac.uk/bsr-psa.

Thank you for taking the time to read this Participant Information Sheet.

Please keep it for future reference.