

National Rheumatoid Arthritis Society (NRAS) Right Start Service Evaluation

Participant Information Sheet (PIS) – Survey and interview

You are being invited to take part in a service evaluation project which aims to understand how the NRAS Right Start Service has been implemented. The aim of Right Start is to improve outcomes of the newly diagnosed with RA through a provision of emotional support, normalisation of fears and anxiety and a range of supported self-management resources tailored to individual need. NRAS Right Start is already available across the UK, and this project aims to understand how it is being implemented, and to explore how it might benefit patients.

Specifically, we aim to:

- a) understand barriers, challenges and enablers to implementation
- b) compare expectations of the service with practice
- c) explore the perceived impact of the service.

Before you decide whether to take part, it is important for you to understand why the project is being conducted and what it will involve for you. Please take time to read the following information carefully before deciding whether or not to take part 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. If you would like, one of our team can go through the information sheet with you and answer any questions you have. Thank you for taking the time to read this. We understand you may need some time to think about your decision before deciding whether to take part.

About the study

➤ Who will conduct the project?

We are a collaboration formed between NRAS and staff working at the Centre for Epidemiology Versus Arthritis, University of Manchester. The study is led by Dr Suzanne Verstappen (Reader) and Dr Charlotte Sharp (NIHR Clinical Lecturer) in collaboration with NRAS.

➤ What is the purpose of the project?

The aim of Right Start is to improve outcomes of the newly diagnosed with RA through a provision of emotional support, normalisation of fears and anxiety and a range of supported self-management resources tailored to individual need. Referral to Right Start enables health professionals to meet their responsibilities against NICE Quality Standard 33, Statement 3, on which they are audited through National Early Inflammatory Arthritis Audit (NEIAA), and improve the patient's experience of care at the same time.

Through the Enhanced Right Start pilots, our intention is to demonstrate that in providing the right kind of evidence-based support to people with RA at the right time, in line with NICE NG100 and QS33, we can improve patients' self-efficacy and outcomes and reduce feelings of anxiety and isolation, enhancing the normal care pathway provided by rheumatology units in the UK.

We are recruiting a single staff member from each of the five participating NHS sites, in order to understand how Right Start is implemented at each site, including barriers and enablers, to compare initial expectations of the service with practice, and to explore the perceived impact of the service. Each staff member will be invited to complete an online survey at baseline and 6 months into the pilot, with an interview conducted at 12 months. You have been asked to take part because you are a staff member with a key role in implementing the service at one of the participating sites.

➤ **Will the outcomes of the study be published?**

Our findings will be published in a final report, which will be shared with all participants. We will also publish in academic journals and present at conferences. Any quotations from survey responses and interviews used in any publications will be anonymised.

➤ **Who has reviewed the project?**

The project has been reviewed by The University of Manchester Research Ethics Committee 2022-13072-21696.

➤ **Who is funding the project?**

Costs for this social responsibility project have been covered by the National Rheumatoid Arthritis Society.

What would my involvement be?

➤ **What would I be asked to do if I took part?**

If you would like to take part, you will be invited to complete an online survey at 0 and 6 months, and to participate in an interview at 12 months.

If we invite you to take part and you decide to do so, you will be asked to complete an online survey at 0 and 6 months, and to participate in an interview at 12 months. You will be given a unique, anonymous identifier to enter into your survey data, which would enable us to link the answers you give in the baseline and 6 month survey, and the 12 month interview. This will make it possible for us to compare expectations of Right Start with implementation in practice.

Due to social distancing measures the interview will take place either over a video platform such as Zoom or the telephone (whichever is best for you). We will ask you to agree to be interviewed, and for that interview to be recorded. If you prefer not to be recorded, the researcher will instead take notes of the interview. If you give permission for the interview to be audio-recorded, it will be recorded on a digital audio-recorder, and we may also take brief notes. After the interview the audio recording will be typed up (transcribed), and then destroyed. The interviews will last for around 1 hour. If you need to have a break, please just mention it to the researcher and the conversation can be paused at any time.

➤ **Will I be compensated for taking part?**

We are very grateful to you for your time. There will be no compensation offered for taking part.

➤ **What happens if I do not want to take part or if I change my mind?**

The study is voluntary and it is up to you to decide whether or not to take part. Please just let a member of the team know by email or telephone. If you do decide to take part you will be given this information sheet to keep and will be asked to provide written consent, which will be stored for 5 years in line with The University of Manchester's research governance policy. If you decide to take part you are still free to withdraw up to two weeks after completing the first online survey. After this point the data will be analysed and it will not be possible to withdraw your individual responses. Likewise, if you decide to take part, you are still free to withdraw up to two weeks after completing the second online survey, following which the data will be analysed and not possible to remove from the data set. If you do decide to take part in an interview, you are free to withdraw the interview data at any time during the interview without giving a reason and without detriment to yourself. The interview will be audio recorded with your permission, but if you prefer it not to be audio recorded, we can take notes instead. If you change your mind after the interview, you can ask for your data to be withdrawn from the project for up to two weeks after the interview date. However, it will not be possible to remove your data from the project once it has been anonymised as we will not be able to identify your specific data. This does not affect your data protection rights. If you decide not to take part you do not need to do anything further.

Data Protection and Confidentiality

➤ **What information will you collect about me?**

In order to participate in this project we will need to collect information that could identify you, called "personal identifiable information". This information will help us to ensure that we have a good understanding of each of the sites involved. Specifically we will need to collect:

- Your name
- Your job title
- Clinical setting
- Whether the clinical setting is urban / rural
- Whether the clinical setting is secondary / tertiary care

➤ **Under what legal basis are you collecting this information?**

We are collecting and storing this personal identifiable information in accordance with UK data protection law which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is "a public interest task".

➤ **What are my rights in relation to the information you will collect about me?**

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, including transcripts of audio recordings.

If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our [Privacy Notice for Research](#).

➤ **Will my participation in the study be confidential and my personal identifiable information be protected?**

In accordance with data protection law, The University of Manchester is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept secure, confidential and used only in the way you have been told it will be used. The study team at The University of Manchester will have access to your personal information and they will anonymise it as soon as possible. Your name and any other identifying information will be removed and replaced with a random ID number. The team will have access to the key that links this ID number to your personal information.

All researchers are trained with this in mind, and your data will be looked after in the following way:

- You will be invited to email your completed written consent form to a secure University of Manchester email address.
- The written consent will be stored on University of Manchester secure research drives
- Your online surveys will be conducted using University of Manchester approved software, Qualtrics.
- We will give you a unique identifier to enter along with you survey responses. This will enable us to collate your responses to the two surveys (baseline and 6 months) and the interview. Once we are in receipt of your survey responses, these responses will be assigned a further unique identifier, to which only the University of Manchester team will have access.
- You will be given the option to have your interview conducted by telephone, or via the online platform Zoom.
- All interviews taking place via Zoom will take place in accordance with University policy, including the use of password protected meetings.
- All audio-recordings of telephone interviews will be recorded on a password protected and encrypted audio recorder.
- Interviews taking place via Zoom will be recorded in Zoom and your personal data will be processed by Zoom. This may mean that your personal data is transferred to a country outside of the European Economic Area, some of which have not yet been determined by the European Commission to have an adequate level of data protection. Appropriate legal mechanisms to ensure these transfers are compliant with the UK General Data Protection Regulation are in place. The recordings will be removed from the above third party platform and stored on University of Manchester managed file storage as soon as possible following the completion of data collection. See Further privacy information: <https://zoom.us/privacy>
- All audio-recordings will be downloaded onto secure University of Manchester research drives immediately following the interview, and deleted.
- All interviews will be transcribed by a University of Manchester approved supplier, 1st class Secretarial Services.
- All audio-recordings of interviews will be deleted once transcribed to preserve confidentiality.
- All transcriptions will be pseudonymised (all personal names and identifying information will be removed and your interview will be given a unique ID code, which is linked to your

personal data if needed). Any information relating to locations / healthcare facilities / other potential identifiers will be removed. Only the team will have access to the key that links your contact data and ID code.

- All data will be held on secure research drives at the University of Manchester. A summary of anonymised data will be shared with NRAS.
- The team at The University of Manchester will keep your information private and only accessible to the team and NRAS according to the data sharing agreement.
- In writing up reports and scientific papers we may use anonymous quotes or summaries of what you have said to demonstrate a finding; this would only be done linked to an ID number.
- The audio-recorded consent, written contact details and transcripts of interviews will be retained for 5 years.
- Please also note that individuals from The University of Manchester or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a study participant.

What if I have a complaint?

➤ Contact details for complaints

We do not anticipate that taking part in the study will cause you any problems and it is very unlikely that anything will go wrong, but if you have any worries, concerns or minor complaints you can inform a member of the team first:

DR SUZANNE VERSTAPPEN Suzanne.Verstappen@manchester.ac.uk

DR CHARLOTTE A SHARP Charlotte.sharp@manchester.ac.uk

- **Telephone: NB** there is currently no access to University landline, due to remote-working

If you wish to make a formal complaint to someone independent of the team or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact

The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 306 8089.

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, The 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 about complaints relating to your personal identifiable information](#) Tel 0303 123 1113

Contact Details

If you have any queries about the study or if you are interested in taking part then please contact the team:

DR SUZANNE VERSTAPPEN Suzanne.Verstappen@manchester.ac.uk

DR CHARLOTTE A SHARP Charlotte.sharp@manchester.ac.uk

Are there any additional considerations that I need to know about before deciding whether I should take part?

No.