Writing to patients from rheumatology

Participant Information Sheet (PIS) – Healthcare professionals - Workshops

You are being invited to take part in a research study. You may have been invited by another healthcare professional or member of the research team, or you may have seen an advert for this study in your department, a newsletter or online. This study is about the letters rheumatology healthcare professionals write after an outpatient appointment. These are called clinic letters. They include a summary of the outpatient appointment. Clinic letters are different from appointment letters and results letters.

We have studied current practice around writing clinic letters, and rheumatology patients' and healthcare professionals' views on who clinic letters are written to, including reasons for and against writing directly to patients, and the barriers to and facilitators of taking up this practice. We now want to run workshops with rheumatology patients and healthcare professionals. Our aim is to develop a set of resources to encourage and support rheumatology healthcare professionals to write directly to patients.

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 anything is not clear or if you would like more information. Thank you for taking the time to read this.

PART ONE - ABOUT THE RESEARCH

➢ What is the purpose of the research?

National guidance advises healthcare professionals to write clinic letters directly to patients, but not everyone does. Instead, some members of rheumatology teams write clinic letters to other healthcare professionals, for example, their patients' GPs. A copy may also be sent to the patients.

We want to develop resources to encourage and support members of rheumatology teams to write directly to patients. You can help us do this by joining our workshops and sharing your views on our study findings, what resources might be needed and draft versions. Resources could include, a best practice guide, example clinic letters and a glossary of terms with plain English explanations. We hope to hear from up to 20 healthcare professional participants, as well as 20 patient participants across a series of workshops.

Am I able to take part?

We want to hear from people who:

- Currently provide healthcare to adult patients (aged 18+) attending an NHS / HSC rheumatology outpatient department(s) in the UK
- As part of routine care, write letters summarising NHS / HSC rheumatology outpatient clinic consultations in the UK (either to the GP or to the patient)
- Can speak English
- Have capacity (the ability) to provide consent to take part

We would like to hear from a wide range of people, including people from each of the four countries in the UK, people of different ages, gender identities and ethnicities, and people who do and do not write clinic letters directly to patients. As such, everyone who expresses an interest in taking part will be asked to share some information about themselves.

- **Who will carry out the research?**

The research is being carried out by a team from the Division of Musculoskeletal and Dermatological Sciences at The University of Manchester. The team is led by Dr Charlotte Sharp, Honorary Senior Clinical Lecturer, and supported by Dr Rebecca Goulding, Research Associate. Charlotte has a clinical background and also works as a Consultant Rheumatologist. Rebecca has an academic background. Our contact details are at the end of this participant information sheet.

The idea for and design of the project were created in partnership with patients and healthcare professionals. Patients are being involved throughout the study. Input and advice are being sought from clinical and academic colleagues at The University of Manchester and healthcare organisations across the UK.

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

1) Contact us and/or visit the study website

If you are interested in taking part, the first step is to contact a member of the research team or visit the study website: https://sites.manchester.ac.uk/writing-to-rheumatology-patients/co-production-workshops-healthcare-professionals/

If you contact us, we will discuss the study with you and answer any questions you may have. We will then ask you to complete a screening survey (online, by email, phone or videocall).	
If you visit the study website, you will be able to complete the screening survey online.	

Completing the screening survey will take about 5 minutes. The first few questions make sure you meet the inclusion criteria (listed above) and can take part. The other questions help us ensure we invite a wide range of people to take part. Each question is optional but the answers will be used to help us select who to invite to take part. If you do not answer any of the questions you are unlikely to be selected. We will also ask you to share your contact details and contact preferences.

We will contact everyone who expresses an interest in taking part. However, we may not be able to invite everyone to join the workshops. We will let you know within four weeks if you have been selected to take part or not. After we have completed all the workshops for this study, the data collected through the screening survey will be deleted.

2) Take part in one or more online workshops

If we invite you and you decide to take part, this will be in one or more online workshops. The workshops will take place online via videocall (using the Zoom platform). With the permission of everyone taking part, these will be audio-recorded, and we may also take brief notes. The workshops will last between 90-120 minutes. At the end of the first workshop you take part in, you will be asked to complete a short demographics form to:

- help inform the analysis of the data collected through this study, and

- enable us to report summary information about the range of people who have taken part.

Audio-recordings will be made using Zoom. After each workshop, the audio-recording will be typed up (transcribed), checked and then destroyed.

There are not likely to be any direct benefits of taking part in this research. However, we will use what we learn to try to improve communication between healthcare professionals and patients. There are also no identified risks of taking part but the workshops will take you away from your normal responsibilities for a time.

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

You will not be offered any compensation for taking 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 decide not to take part you do not need to do anything further. If we have already been in contact with you, and you tell us you do not wish to take part, we will remove your details from our records.

If you do decide to take part you will be given this information sheet to keep, and you will be asked to initial and sign a consent form or provide verbal consent. As part of this, you will be asked to consent to audio-recordings of the workshops as this is essential for the study. It is important that you are comfortable throughout the workshops and the recording process. If you need a break, please mention it to the researcher. You can take a break at any time.

If you decide to take part you are still free to 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 as we will not be able to identify your specific data. This does not affect your data protection rights.

➢ **Will the outcomes of the research be shared?**

We will write up the findings for publication in a report to the research funder and in academic journals. We will also present the findings at seminars, conferences and events. Summaries of key study outputs, including the findings, will be shared online. Links to and/or copies of these summaries can be sent to you, if you agree to this when providing consent to take part.

➢ **Who has reviewed the research project?**

This study has been reviewed and approved by the Health and Social Care (HSC) Research Ethics Committee B (Ref: 24/NI/0063, 07/05/24).

➢ **Who is funding the research project?**

This project has been funded by the British Society for Rheumatology, as an Advanced Career Funding Award.

PART TWO - DATA PROTECTION, CONFIDENTIALITY AND COMPLAINTS

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

In order to take part in this research project we will need to collect information that could identify you, called “personal identifiable information”. Specifically, we will need to collect:

- Your contact details, including your name, email address and/or telephone number
- Your written consent, or an audio-recording of your verbal consent
- An audio-recording of your voice during the workshop(s)

We will also request the information listed below via the screening survey and demographics form. Questions will be multiple choice (tick box):

- Professional role
- Geographical location (country where you work)
- Age (in age groups)
- Ethnicity
- Gender identity

Collecting this information will help us ensure we involve a range of different people in our study and help us understand how things may differ for different people. All data will be stored on The University of Manchester's secure server.

➢ **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" and "a process necessary for research purposes".

➢ **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. Sometimes your rights may be limited if it would prevent or delay the research. If this happens you will be informed by the research team.

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 the Privacy Notice for Research Participants (https://bit.ly/UoMprivacy).

➢ **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 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. All researchers are trained with this in mind, and your data will be looked after in the following ways:

Data collection and transfer:

- Audio-recordings of consent will be made separately to audio-recordings of workshop(s).
- Workshops taking place via Zoom will be organised in line with The University of Manchester policy, and make use of passwords and waiting rooms.
- Workshops will be recorded via Zoom and your personal data will be processed by Zoom. This may mean your personal data is transferred to a country outside of the European Economic Area, some of which have not yet been determined by the United Kingdom to have an adequate level of data protection. Appropriate legal mechanisms to ensure these transfers are compliant with the Data Protection Act 2018 and the UK General Data Protection Regulation are in place. See further privacy information: https://zoom.us/privacy.

- Audio-recordings will be downloaded onto secure The University of Manchester servers as soon as possible following the end of each workshop and deleted from their original location.
- Workshops will be typed up (transcribed) by a The University of Manchester approved supplier who will follow the University's rules about keeping your information safe and confidential. Audio-recordings will be sent to the transcriber through a secure website. Transcripts will be sent to the research team through the same website. Once transcribed and checked, the audio-recordings will be deleted to preserve confidentiality.
- Transcripts will be pseudonymised as soon as possible. That is, the names of people and healthcare facilities, specific geographical locations and other potential identifiers will be removed, and the transcript will be given a unique ID code. Only members of the research team will be able to link this ID code to your personal information.
- The dataset will be fully anonymised at the end of the study, two weeks after the final workshop. After this time, it will not be possible to remove your data from the study.

Sharing and using anonymised data:

- To support data analysis, we may share extracts from fully anonymised transcripts with members of our formally appointed project working group and patient and public involvement and engagement group. Members of these groups will not have access to your personal information.
- Outputs from the research, including reports, journal articles and presentations, may include fully anonymised quotes or summaries of what you have said to demonstrate a research finding. You will not be identified but may be referred to by a number or fake name.
- The fully anonymised dataset, collected for this study, may be used to support other, future healthcare research carried out at The University of Manchester, in accordance with the UK Policy Framework for Health and Social Care Research (https://bit.ly/HSCRframework). You will be asked to provide your consent for this as and when you agree to take part in the study.

Data storage and retention:

- All data will be stored on secure The University of Manchester servers that can only be accessed by members of the research team.
- Contact details, consent forms and audio-recordings of consent will be stored separately to audio-recordings of workshops and all other research data. Contact details, consent forms and audio-recordings of consent will be kept for five years for audit purposes.
- With your consent, we would also like to keep your contact details for ten years to provide you with a summary of the findings for this study, inform you about future studies you may be interested in and/or send you information about becoming a writing to patients champion. If you provide consent for this, your details will be stored on a secure The University of Manchester server, only accessible to the research team and used only for the purposes you have consented to.

Your participation in the study will be kept confidential unless the research team become aware of a serious instance of bad practice or have serious concerns for your safety or the safety of someone connected to you. If this is the case, they will need to **break confidentiality** and inform the relevant services or authorities, such as your employers or the police.

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 research participant.

- **What if I have a complaint?**

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. If you have any worries or concerns, or if you have a complaint that you wish to direct to members of the research team, please contact **Rebecca Goulding, Research Associate** by email: **rebecca.goulding@manchester.ac.uk** or phone: **0161 275 0546 / 07823 456696**.

In the unlikely event that something does go wrong and you are harmed during the research you may have grounds for a legal action for compensation against The University of Manchester or the HSC / NHS Trust but you may have to pay your legal costs. The normal HSC / NHS complaints mechanisms will still be available to you.

- **How do I make a formal complaint?**

If you wish to make a formal complaint to someone independent of the research team or 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 email: **research.complaints@manchester.ac.uk**or phone: **0161 306 8089**.

If you wish to contact someone 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 and they will guide you through the process of exercising your rights.

You also have a right to complain to the **Information Commissioner's Office (ICO)** (https://ico.org.uk/make-a-complaint/) about complaints relating to your personal identifiable information. Tel: 0303 123 1113.

PART THREE - CONTACT DETAILS

If you have any questions or queries about the study, or if you are interested in taking part then please contact a member of the research team:

Rebecca Goulding, Research Associate **0161 275 0546 / 07823 456696** **rebecca.goulding@manchester.ac.uk**	**Charlotte Sharp** **Consultant Rheumatologist and Study Lead** **charlotte.sharp@manchester.ac.uk**
The University of Manchester | 5th Floor, Williamson Building Oxford Road | Manchester | M13 9PL	