University of East Anglia

Participant Information leaflet

Title: Patient and clinician perspectives on definitions and determinants of relapse and remission in polymyalgia rheumatica

Researchers: Dr Max Yates, Dr Marie McGee, Dr Janice Mooney, Ms Karly Graham

You have been invited to take part in a research study exploring your experiences of polymyalgia rheumatica (PMR). Before you decide if you would like to take part you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully and ask the researcher any questions that you may have or if you would like further information. Talk to others about the study if you wish.

What is the purpose of the study?

The purpose of this study is to understand your experiences of living with PMR, with a particular focus on how you view your illness and manage your symptoms. You may be familiar with words used by health care professionals with you around worsening symptoms (flare) or when your symptoms are controlled (remission), however we want to understand your perceptions of what these mean to you. This will help health care professionals better understand how they support and manage your symptoms and how best to evaluate the treatments they recommend, which are mainly steroids. Understanding your experiences will help develop measurements to identify the severity of disease and what works best in using steroids/treatments to manage your symptoms and to help you participate in decisions about your care.

Why have I been invited to take part?

You have been invited to take part as you identify as someone who has been diagnosed with PMR, is 50 yrs or older, and has previously or is currently prescribed Prednisolone.

Will this study benefit me?

The benefits of taking part in the study ~~will~~ is to provide you with an opportunity to share your experiences of living with PMR. This information may contribute to new understandings of how best to support health care professionals to make decisions about your care and treatment with you. This will aid understanding of which treatment outcomes are important and relevant to people with PMR. Participation in this study is unlikely to benefit you directly and there will be no incentives or payments offered in return for your participation in the study.

Are there any risks to the study?

There are no specific additional risks associated with taking part in this study. However, sometimes talking about your experiences of your illness may make you feel upset or uncomfortable. If this does happen, please let the researcher know ~~as~~ that you may not wish to continue discussing the area that caused you upset. We can take a break if you choose or stop the interview, at your discretion. If you need support the researcher can provide you with contact details of services that may be able to support you, (see page 3/4) or advise you to see your General Practitioner. You may prefer to contact services of your own choice.

How will I be involved?

If you consent to be involved in this research project, you will be invited to be interviewed either over the telephone or online through Microsoft Teams. The interview will be recorded, transcribed then analysed by the research team. There are still opportunities for you to contact the researcher to ask any further

questions about the study before you sign the consent form. This interview is expected to be no longer than 1 hour in duration. The interview format will involve a member of the research team asking you questions regarding your PMR, the symptoms you experience and how they affect you, as well as experiences related to treatment of your condition. The researcher will read you the questions prior to the interview.

What if I want to stop taking part in the study?

Participation in this study is entirely voluntary. You have the right to withdraw consent at any point however any information obtained to that point will be retained with your agreement, in accordance with the UEA Data Protection Policy; 2018.

Why are the interviews being recorded?

The researcher will need to audio record the interviews to ensure they record your experiences accurately and to help them to understand your view and perspective. During the interview they may need to ask you to give them more information about some of the areas you have discussed.

What will happen with my information collected during interview?

All participants will be given a unique identification number and this number will also be used when storing the information relating to each interviewee. The file linking the interviewee's personal details with an ID number will be stored separately, so as to anonymise the recorded data. The information you provide will be kept strictly confidential and your name or any identifiable information will not be included in the study in any circumstances. The recording will be deleted immediately following transcription. The information will be written up and all identifiable information removed. The information will be stored securely on the General Data Protection Regulation (GDPR) compliant Cloud Storage network and will be password protected and only members of the research team will have access. All members of the research team will preserve the confidentiality of participants taking part in the study and will abide by the UEA Research Data Management Policy; 2019 and the General Data Protection Regulations (2018). We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the analysis. Copies of the transcription of your interview may be provided on request.

Are there any exceptions that confidentiality can be broken?

All information is confidential unless you reveal something that would suggest harm or risk to yourself or others. If the researcher feels this is the case, they will need to talk about this with you first before passing on any information to the relevant people such as the research team. If deemed appropriate, the information may be shared in accordance with local and NHS Trust safeguarding policy.

How long is the information from the interviews held for?

The recorded interviews will be downloaded and imported into Microsoft Office, OneDrive (Microsoft Corp., Redmond, WA, USA). This will be securely stored password protected using the UEA OneDrive software, managed by the research team only, which is protected through the UEA password protection system. The information obtained from the research will be held securely and anonymously for 10 years in accordance with the Data Protection Act (1998) and the General Data Protection Regulation (GDPR) and the UEA Research Degrees' Code of Practice 2012. After ten years and the completion of the study and in accordance with the University Policy, the information will be deleted from the Cloud Storage network. All the researchers with access to the information you provide during your interviews are bound by the Data Protection Act (1998), local NHS Trust Confidentiality Code of Conduct and/or by a professional code of conduct.

Where can I find out more about how my information is stored?

You can find out more at the Health and Research Authority website at: Patient information and health and care research - Health Research Authority (hra.nhs.uk) (https://www.hra.nhs.uk/information-about-patients/)
For informal queries or information on the University's relevant policies or processes, please contact Research Integrity at ResearchIntegrity@uea.ac.uk. If you wish to discuss formally any other research integrity matters regarding how your information is stored, please contact the Pro-Vice-Chancellor for Research and Innovation, Professor Julian Blow: j.blow@uea.ac.uk or you can contact the research team for further information, details below.

What will happen to the results of the research study?

The information collected will be written up as an academic paper and submitted for publication in relevant journals or presented at conferences, so that health care professionals can learn from the views of people living with PMR. You will not be identified in any of these articles or at conference presentations. The final study will contain direct quotations from the people who participated in the study, but these will be anonymised and no identifiable information will be used in journal publications or professional conferences. If you are interested in finding out about the results from the study, you will be given a chance at the end of the study to leave your email or postal address. These details will be kept separate from your responses and will not be able to be linked in any way. After we have sent you information about what we have found your email/postal addresses will be destroyed.

Who is organising and funding this research?

The University of East Anglia is organising the research with funding secured for this work by Norfolk and Waveney Integrated Care Board. The University of East Anglia (UEA) is the sponsor for this study based in the United Kingdom. We will be using information gathered from your participation to undertake this study and we will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly.

Who has reviewed the study?

All research conducted by the University of East Anglia is looked at by an independent group of people, called a Research Ethics Committee, to protect your rights, dignity, and wellbeing. This study has been reviewed and given favourable opinion by a University of East Anglia Research Ethics Committee Reference ETH2324-2953:

Who can I contact about the study?

If you have any questions or concerns about this study, please do not hesitate to contact the relevant researcher who interviewed you and they will be happy to discuss any aspect of the study with you. If you have concerns about the study that you do not wish to raise with the researcher, you can discuss them with the following people:

- Dr Max Yates (M.Yates@uea.ac.uk), (01603 597348).

What if there is a problem?

It is very unlikely that this study would cause you any harm. If you have a concern or a complaint about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. The researchers contact details are given at the end of this information sheet.

Versus Arthritis Helpline: **0800 5200 520** (Monday–Friday, 9am–6pm). *The helpline is closed from 12.00 pm the last Friday of every month for training.* *helpline@versusarthritis.org.*

PMR GCA UK Helpline: 0300 111 5090 Volunteers with experience of PMR and/or GCA can talk with you and offer support. *Monday to Friday from 9am to 5pm*.

If you remain unhappy and wish to complain formally, you can make a formal complaint through the University complaints procedure or by contacting the Dean of Norwich Medical School, Professor Kristian Bowles k.bowles@uea.ac.uk.

Thank you for your time.

Chief Investigator Dr Max Yates
Clinical Associate Professor UEA
Email : M.Yates@uea.ac.uk