Participant Information Sheet

Development of a questionnaire to assess polymyalgia rheumatica

What is this study about?

People with polymyalgia rheumatica (PMR) can have many different symptoms which can get better or worse at different times during the course of the illness. People with it often have to stay on medication (usually steroid tablets) for around 2 years and sometimes longer. It is important to be able to fully understand how PMR is affecting a person at any point in time to know if treatments are working and to help patients and their doctors make decisions about the best management.

We want to develop a questionnaire that assesses all aspects of how PMR is affecting someone. This questionnaire will be used in research studies about PMR and directly by people with the condition and their doctors. We have developed an initial questionnaire from information from interviews with people with PMR. This now needs to be tested to allow it to be shortened and improved.

Why have I been invited?

We asked your general practitioner to identify suitable patients who developed PMR in the last 2 years.

They have sent this information to you, but have not given us any information about you.

Do I have to take part?

No, you do not have to take part in the study if you do not want to.

If you decide not to take part, you don't have to give a reason and the service you receive will not be affected.

If you return the questionnaires, we will take it that you are agreeing for the information you provide to be used for our study. All the information will be anonymous.

What do I have to do if I decide to take part?

If you agree to take part, please complete 2 copies of the questionnaire:

- Fill in the blue one answering about how you feel at the moment.
- Fill in the yellow one answering about how you felt at the time your doctor told you you had PMR, before you started treatment. This may be some time ago now but try to remember how you felt then and answer the questions as well as you can.

Please put both questionnaires in the envelope provided and post it back to the study team.

How will the information from this study be used?

The answers to the questions will be analysed and used to make changes to the questionnaire to improve it.

Will there be any direct benefit from taking part in the study?

There is no direct benefit to your medical care to taking part in the study but you will be helping researchers and doctors to better understand experiences of people in your situation and this may improve care for others in the future.

Will there be any harm from taking part in the study?

It is very unlikely. If you find any of the questions upsetting you do not have to answer them.

Who will have access to my personal information?

No identifiable personal details will be collected. The questionnaire responses will be looked at by the research team.

Sometimes study information is checked by the NHS or Keele University to ensure that the research is being conducted properly.

Who has reviewed the study?

The North East - York Research Ethics Committee has reviewed this study (IRAS ID 241085).

Who is doing the research?

This study is being carried out by Dr Helen Twohig, Dr Sara Muller, Dr Caroline Mitchell and Professor Christian Mallen who are all GPs and / or researchers linked to Keele University. It is funded by a Wellcome Trust Doctoral Fellowship awarded to Helen Twohig.

Who can I contact for further information?

If you have any questions or would like more information about this study before deciding whether to take part, please contact the research team using the contact details below.

Who can I contact if I have any complaints about the study?

If you wish to voice concerns or complain about the research in any way please contact the research governance team at Keele University using the contact details below, or your local NHS complaints department.

RESEARCH TEAM CONTACT

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