Participant Information sheet

Study title: Perceptions about predictive testing in those at risk of developing rheumatoid arthritis: participants' views about an information leaflet-ONLINE EVALUATION

Name of Lead Researchers: Prof Karim Raza, Dr Gwenda Simons, and Dr Marie Falahee

We would like to invite you to take part in our research study to see what people think about an information leaflet that we have developed. Before you decide whether you would like to take part it is important for you to understand why the research is being done and what it would involve for you.

What is the purpose of the study?

The purpose of this study is to ask people what they think of a leaflet that we have developed to give people information about rheumatoid arthritis (RA), including why some people are more likely to develop RA in the future, and about tests that doctors can use to help predict someone's risk of developing RA.

Who can take part?

You have been invited to take part in this research study because you, as a close relative of a person diagnosed with RA, may be more likely to develop RA in the future than a member of the general public and we are interested in your views. To put this into context, the risk of someone without a history of RA in their family developing RA themselves at some point in their lives is about 1 in 100 (or 1%). If you have a first degree relative (e.g. a parent, brother or sister) with RA your risk increases to about 4 in 100 (or 4%) – in other words having a history of RA in your family increases you chances of developing RA but you still remain much more likely to **not get** it than to get it.

Please note that in order to take part in the research, you need to be 18 years or older and be the biological relative of someone with RA (sibling or offspring) but should not yourself have this diagnosis.

Do I have to take part?

No. It is up to you to decide if you want to take part. If you do decide to take part you will be free to withdraw from the study at any time, without giving a reason. If you do take part, you can withdraw at any time prior to or during completion of the form. However, as we only record anonymous data through the online evaluation form (i.e. you are not asked for your personal details or given a participant number) you cannot withdraw your data once submitted.

What will happen to me if I take part?

If you agree to take part in the study you will be invited to read the leaflet (which will probably take you around 30 minutes) before completing a short anonymous online evaluation form (which will probably take you around 15 minutes depending on your feedback).

A number of the questions are open ended and direct quotations from these answers may be used in our research reports, but no confidential information will be used.

What are the possible disadvantages and risks of taking part?

We do not believe that there are risks involved in taking part in the study. The disadvantage is that you will have to spend some time reading the leaflet and completing the form. We think this should take about 45 minutes in total (30 minutes reading and 15 minute form completion). It is possible that you may be concerned about some of the issues raised in the leaflet. Please discuss any concerns with a member of the research team in the first instance. However, please note that the research team cannot advise you about your personal situation. Please contact your GP if you have such concerns.

What are the possible benefits of taking part?

There are no direct benefits to you, though we hope you will find the information in the leaflet useful. By taking part you will allow the researchers to have a better understanding of the information needs of those who are at risk of developing RA and how the information leaflet meets these needs. It will also allow them to make changes to the leaflet before it is circulated more widely.

What if there is a problem or if I have concerns?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. In the first instance please contact Professor Karim Raza, Dr Gwenda Simons or Dr Marie Falahee on 0121 3713235. You might also consider talking to someone at NRAS about the issues raised in this research (contact details on the next page).

In the event that something does go wrong and you are harmed during the research, and this is due to someone‘s negligence, then you may have grounds for a legal action for compensation against the Sponsor of the study (University of Birmingham).

Will my taking part in this study be kept confidential?

You will complete the online evaluation form anonymously. The data recorded cannot be traced back to you as an individual and we do not ask you for personal information such as your name, date of birth or address.

What will happen to the results of the research?

We intend that the results of this study will be published. If you take part and are interested in understanding how your contribution to this study has been used, you can request a participant version of the final study report by contacting Dr Gwenda Simons by writing to her at: Rheumatology Research Group, Institute of Inflammation and Ageing (IIA), University of Birmingham, Queen Elizabeth Hospital, Birmingham, B15 2WB or via email: g.simons@bham.ac.uk.

Who is organising and funding the research?

The Research is being organised by the Rheumatology team at the University of Birmingham. This research has been funded by the European Union.

Who has reviewed the study?

This study has been reviewed and given favourable opinion by the Ethics committee from the University of Birmingham.

Contact and Further information

If you want any further information about this particular study, you can contact Dr Gwenda Simons or Dr Marie Falahee on 0121 3713235 or 07505626368 or email g.simons@bham.ac.uk

If you want any more information about arthritis you can contact Arthritis Research UK (01246 558033;www.arthritisresearchuk.org), or the National Rheumatoid Arthritis Society (Freephone Helpline: 0800 298 7650; http://www.nras.org.uk/).

You can print this participant information sheet or keep a copy on your computer