Patient Information sheet

Empowering People through Informed Choice in Rheumatoid Arthritis (EPIC-RA)

Developing a better understanding of people with Rheumatoid Arthritis' views on taking their RA medicines and about how they might feel about having novel test in the future that may predict whether those medicines will work before they start taking them.

Invitation paragraph
You are being invited to take part in a research study. This study is part of a bigger programme of work with academics, clinical consultants and industry groups working together to try and predict which patients might respond better to certain RA treatments. Before you decide it is important that you understand why the research is being done and what it will involve.

What is the purpose of the study?
Rheumatoid Arthritis (RA) is a long-term condition for which a group of drugs called biologic drugs are often prescribed. Different biologic drugs work very well for different people, however currently doctors cannot predict which ones will work for whom. This means that when treatments are recommended for someone, there may be only a 50/50 chance they will work for that particular person (like tossing a coin).

Researchers are now trying to find new simple tests that would give doctors a more accurate prediction of who might respond better to which treatment. This would reduce the number of attempts that doctors would need in order to match the right drug to the right person.

We would like to know what people with RA think about this approach to testing. For example, whether these tests would be acceptable and helpful to a person with RA if it meant selecting the right therapy and possibly getting a better outcome to treatment. We also want to understand any concerns people might have about the testing.

Why have I been chosen?
You have been chosen because you have RA and are having treatment for this.

Do I have to take part?
You do not have to take part in this study. However, if you do decide to take part, you may withdraw at any time without giving a reason. Your GP and Rheumatologist will continue to treat you regardless of the decision you make and any decision regarding participation will not affect the quality of care you receive.

If you decide to take part you will be given this information sheet to keep and will be asked to sign a consent form.

What will happen to me if I take part?
If you agree to take part in the study you will be invited for one focus group discussion with a researcher, Dr Kanta Kumar, and an assistant, who are interested in finding out about the experiences of people with RA, their thoughts about taking medicines and their ideas about undergoing tests to help get a treatment that may be more suited to them. The focus group will include approximately 4-6 other people with RA.

The discussion will last up 2 hours. During the discussion you will be asked questions by the researcher about how you feel about different tests to try and predict response to treatments. You will also be shown a scenario of how the tests might be used and asked to put yourself in that position and comment how you would think and feel should you be asked these types of questions or to undergo these types to test.

Please note, you will not be undergoing any of these tests. This focus group only involves finding out people with RAs' thoughts and ideas about the testing procedures and how doctors may use the result to help plan treatment.

The focus group discussion will be digitally recorded to allow us to find out about the range of views that different people hold. Information from the recordings will be typed up (with people's names removed) and then the recordings will be destroyed. The recordings themselves will not be used, but written quotations from the discussion will be. However, no names will be used in any reports or publications.

It is very important that the focus group discussions remain confidential, to protect members of the group, you will be asked to sign a confidentiality statement on the consent form.

Any travel expenses that you incur as part of the study will be reimbursed to you to a maximum of £30. We will arrange the interviews at a suitable local room, away from a clinical setting. Refreshments will be provided.

What are the possible benefits of taking part?
The benefit of you taking part is that it will allow the Rheumatology team to have a better understanding of people with RAs' beliefs and understanding about different tests to predict response to treatment. This initial focus group work will also lead on to a more extensive survey of people with RA to make sure our programme of research is meaningful and addressing the right questions.

What are the possible disadvantages and risks of taking part?
There are no risks involved in taking part in the study. The focus group session would take up to two hours of your time.

Will my taking part in this study be kept confidential?
All information collected about you during the course of the study will be kept strictly confidential. Any information collected for this study will not be discussed with your rheumatologist, specialist nurse or GP. All data will be completely anonymised for the purpose of publication. All data will be stored on secure databases within the Arthritis Research UK, Centre for Musculoskeletal Research at the University of Manchester. Professor Anne Barton will act as custodian of the data. The results of these discussions will be published and/or used by other bone fide researchers in the research field, however all identifiable information about you will be removed.

Who is organising the research?
The Arthritis Research UK Epidemiology Unit at the University of Manchester, the lead researcher Professor Anne Barton and Study Researcher Dr Kanta Kumar are organizing the research, who can be contacted for further details (see contact details below).

Who has reviewed the study?
Before any research goes ahead it has to be checked by an ethics committee. This project has been reviewed and approved by University of Manchester Ethics Committee.

Who is funding the study?
The MATURA consortium (**MA**ximising **T**herapeutic **U**tility in **R**heumatoid **A**rthritis) is funding the study at the University of Manchester.

What if something goes wrong?

If you would like to make a formal complaint about the conduct of the research, please contact the Research Governance and Integrity Manager, Research Office, Christie Building, University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 275 8093 or 275 2674.

Contact and Further information
If you have any concerns about this study and wish to conduct someone, you may telephone:

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Thank you for taking time to read the information sheet, which you should keep for future reference.

This Project Has Been Approved by the University of Manchester's Research Ethics Committee