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Warwick
Medical School
CLINICAL TRIALS UNIT

Strengthening and Stretching for Rheumatoid Arthritis of the Hand

Patient Information Leaflet

THE UNIVERSITY OF
WARWICK

ISRCTN89936343,

We would like to invite you to take part in this research being carried out at your local hospital. However, before you decide if you would like to be part of the Strengthening and Stretching for Rheumatoid Arthritis of the Hand (SARAH) Trial, please take time to read the following

information carefully and discuss it with friends, relatives and your GP if you wish. Ask us if there is anything that is not clear or if you would like more information.

Thank you for reading this.

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1. What is the purpose of the study?

The SARAH trial is looking at two approaches to treatment for Rheumatoid Arthritis (RA), affecting the hands. We are comparing the provision of joint protection advice with joint protection advice in addition to an exercise programme for the hands and arms. All people who enter the trial will receive joint protection advice, with half of all people in the study also undertaking the additional exercise programme.

2. Why have I been invited?

You have been chosen because you are an adult with RA affecting your hands. We wish to recruit 480 people with RA affecting their hands, across the country.

3. Do I have to take part?

It is up to you to decide whether or not to take part. If you decide not to take part, the care you receive from the hospital or GP will not be affected. You are free to withdraw from the study at any time.

4. What will happen if I do take part?

People will be allocated to one of two treatment programmes and then the effects of these treatments will be compared. The reason we need to do this is that sometimes we do not know the best way to treat patients for certain conditions and we need to compare the different treatments that are available. A computer is used to decide randomly which treatment programme you would receive, similar to tossing a coin. In this trial you have an equal chance of receiving either of the two treatments. This is called a randomised controlled trial.

You will be offered one of the following options:

- Advice session(s), covering methods to protect your joints during every day function. You will attend for a maximum of one and a half hours with a specially trained physiotherapist or occupational therapist, who will advise and discuss how best to protect your hand joints from day to day.

- Advice session(s) on joint protection, identical to the above, followed by a further five sessions of supervised exercise. These sessions will be spread over 12 weeks and will encourage you to strengthen and stretch your hands and arms. A specially trained physiotherapist or occupational therapist will provide treatments, and advise on how best to manage your condition. The exercise sessions will last 30-45 minutes and be on a one to one basis with the therapist.

5. Expenses and Payments

So that you will not be out of pocket by participating in this research, we will pay for your transport costs (taxi / public transport) to attend for the research assessments. Transport costs will be reimbursed on the submission of your travel receipts.

6. What do I have to do?

As well as attending your allocated treatment, you will be asked to attend three assessments and asked to fill in some questionnaires about your condition and how it has affected you. We will arrange for you to attend an assessment of your hand and arm function before you receive either treatment and again at four and twelve months after you have joined the study. These assessments will enable us to measure your hand and arm strength, flexibility and dexterity. If you do not participate, this will not affect the standard of care you receive from the hospital or GP.

7. What is the procedure that is being tested?

We are testing the effectiveness of gently stretching the hand joints and strengthening the hand muscles on the painful and disabling effects of RA. Whilst all participants will be advised on how to protect their joints in every day life, we are investigating whether it is possible to make the hand stronger and more mobile.

8. What are the alternative treatments?

The alternative to exercise is often to rest the hands, although we do not know if this is the correct advice. Traditionally, the treatment of RA of the hands has either involved encouraging exercise or not

encouraging it. Whilst there is some evidence that exercise might be beneficial, not all people with RA of the hands are encouraged to exercise.

9. What are the possible disadvantages of taking part?

Occasionally people experience a short-term increase in pain after beginning an exercise programme. This is a normal response to treatment and is not usually long lasting.

10. What are the possible side-effects of the treatment, when taking part?

There are very few risks associated with exercising with RA. Exercise has not been shown to be detrimental to RA and is likely to be of benefit. We are not testing drugs or surgery and will not change your current medication.

11. What are the possible benefits of taking part?

We hope that the treatments will help you. However, this cannot be guaranteed. The information we get from this study may help us to treat future patients with RA of the hands.

12. What happens when the research project stops?

After you have completed your allocated treatment as part of the trial, your hospital will continue to treat you, if necessary, or, when appropriate, will refer you on to other health professionals.

10. What if there is a problem?

It is unlikely that you will be caused problems by taking part in this study. If you are concerned about the treatment you should contact your hospital straight away. If you are harmed by taking part in this study, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action, but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available to you.

11. Will my taking part in this project be kept confidential?

All information that is collected about you during the course of the research will be kept strictly confidential. This information will be kept in a secure place and only people involved in the study will have access to it. Any information which leaves the hospital will have your name and address removed so you cannot be recognised from it.

12. What if relevant new information becomes available?

Sometimes, during the course of a research study, new information becomes available about the treatment that is being studied. If this happens, the hospital or researchers will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw from the research they will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form. Also, on receiving new information the hospital or researchers might consider it to be in your best interests to withdraw you from the study. He/she will explain the reasons and arrange for your care to continue.

13. What will happen if I don't want to carry on with the study?

You can withdraw your participation in the study at any point. If you withdraw it will have no bearing on any further treatment you would receive at your hospital or with your GP.

14. Will my GP be informed of my decision to participate in the study?

If you consent, your GP will, with your permission, be notified of your participation in the study. We will write to your GP, to inform them that you have agreed to participate in the trial. We have asked them to contact us if they have concerns about your participation in the study.

15. What will happen to the results of the research study?

The data collected will be analysed and the results will be used to write a research report and journal articles for doctors and other health professionals. In any report or publication we will not use your real name, and will not give any details that could identify you. We will post a regular report of the trial progress on our web-site: www.warwick.ac.uk/go/sarahtrial

16. Who is organising and funding the research?

The person responsible for the research is Professor Sallie Lamb from the University of Warwick. It is being paid for by the National Health Service's Health Technology Assessment Programme. The study has

received a favourable ethical opinion by Oxfordshire Multi-Centre Research Ethics Committee.

17. Who is being paid for this research?

The researchers involved in this study will not be paid for including you in the study. No participants will receive a payment for inclusion either.

18. Who has reviewed this Study?

This study was reviewed by independent experts involved in the awarding of the funding for the study. Independent scientists and doctors working on behalf of the NHS Health Technology Assessment Agency reviewed this study and agreed that it was an important clinical question to investigate.

19. What if I have any concerns?

If you have any concerns or other questions about this study or the way it is being carried out, you should contact:

Mr Mark Williams
SARAH Trial Lead
[redacted]

Tel: [redacted]
Fax: [redacted]
E-Mail: [redacted]

Or you may contact the hospital complaints department.

Thank you for taking the time to read this leaflet.