

# SARAH: Stretching and Strengthening for Rheumatoid Arthritis of the Hand

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<b>Registration date</b> 13/02/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/04/2017	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

<http://www2.warwick.ac.uk/fac/med/research/ctu/trials/ecr/sarah>

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

HTA 07/32/05

## Study information

### Scientific Title

SARAH: Stretching and Strengthening for Rheumatoid Arthritis of the Hand: the clinical and cost effectiveness of an exercise programme over and above usual care

## **Acronym**

SARAH

## **Study objectives**

1. To estimate the clinical effectiveness of adding an optimised exercise programme for hands and upper limbs in addition to standard care, joint protection, in the reduction of hand dysfunction and pain for patients with rheumatoid arthritis
2. To estimate the cost-effectiveness of adding this programme to usual care
3. To describe, qualitatively, the experience on participants in the trial with a particular emphasis on patient expectation, exercise behaviours, and reasons for adherence/non-adherence

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Oxfordshire Research Ethics Committee C, 10/06/2008, ref: 08/H060/47

## **Study design**

Pragmatic randomised controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Rheumatoid arthritis affecting the hands and wrists

## **Interventions**

Participants will be randomly allocated to the intervention and control groups.

Intervention group: Standard care (joint protection advice and functional splinting) supplemented with an optimised exercise programme

In addition to the participants receiving conventional care we are proposing to implement a programme of exercise therapy to increase hand function using functional exercises to stretch and strengthen the muscles and tendons, also to mobilise the joints of the hand and wrist and improve dexterity. The programme will entail six half-hour appointments spread over 12 weeks. This number of contacts, spread over this epoch, will allow sufficient progression of the intensity of exercise and physiological response in the neuromuscular system to significantly improve function. The exercise programme was developed following a professional consensus of UK physiotherapists/occupational therapists and has some evidence of short-term effectiveness. We are proposing a number of additional elements designed to increase long-term effectiveness. The intervention will use a standardised protocol of progression and reduction of exercise intensity.

1. Specific Functional Exercise: Our exercise programme will use sound exercise principles to improve strength, mobility and dexterity whilst performing functional tasks.
2. Progressive Resistance Training: Participants will be provided with elastic resistance bands (Theratube, Akron, USA) that provide this resistance and can progressively increase demand.
3. Mobility Exercise: The tendon sheaths of patients with RA hands are known to suffer from adhesions and consequently specific 'tendon sliding' exercises have been developed that target movements of the wrist and fingers in combination to maintain full mobility of the flexor and extensor tendons and will be incorporated into the programme. People with hand RA frequently have deformity of the hands and wrists that make the placement of their hands into positions for efficient function difficult. Additionally, people with RA can develop restriction of movement of the elbows and shoulders as well as the hands. Thus, as the function of the hand is associated with the ability to position and maintain the hand in space, the exercise programme will also include mobility exercise of all the upper limbs joints.
4. Dexterity Exercise: Functional tasks demanding increasing dexterity will be introduced in stages and the performance of tasks timed and critiqued.
5. Home Exercise: The number of home exercises and the demand of dexterity tasks will be progressively increased to ensure the intensity of home exercise is adequate to overload the muscular system and challenge sensori-motor control. Targets for home exercise will be based on individual assessment of performance and progressed at four, eight and twelve weeks.
6. Adherence with Home Exercise: We aim to maximise adherence to the prescribed exercise regimen through a two-stage mechanism that distinguishes between motivational and volitional phases of behaviour.

The programme will entail six half-hour appointments spread over 12 weeks. Exercise will be provided individually by a physiotherapist.

Control group: Standard care only

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome(s)**

Current primary outcome measure as of 18/08/2011:

The Michigan Hand Outcomes Questionnaire (MHQ) Overall hand function score over 12 months

Previous primary outcome measure:

The Arthritis Impact Measurement Scales (AIMS) 2, Finger and Hand function subscale at 0, 3 and 12 months.

### **Key secondary outcome(s)**

Current secondary outcome measures as of 14/08/2009:

1. Michigan Hand Outcomes Questionnaire (MHQ) at 0, 4 and 12 months
2. MHQ pain subscale and Pain 'Troublesomeness' at 0, 4 and 12 months
3. Grip and pinch strength at 0, 4 and 12 months
4. Dexterity at 0, 4 and 12 months
5. Hand and wrist Range of motion at 0, 4 and 12 months
6. MCPJ Joint alignment at 0, 4 and 12 months
7. Joint tenderness and swelling at 0, 4 and 12 months

8. Disease activity at 0, 4 and 12 months
9. SF-12 at 0, 4 and 12 months
10. Self-efficacy at 0, 4 and 12 months
11. Treatment satisfaction at 4 and 12 months
12. Global change question 7 point Likert scale at 4 and 12 months
13. Adherence to home exercise questionnaire at 0, 4 and 12 months
14. Resource use questionnaire at 0, 4 and 12 months
15. EuroQol EQ-5D: Health Utility at 0, 4 and 12 months

The above changes are in line with protocol V2 14/08/2009

Previous secondary outcome measures:

1. AIMS 2 Upper Limb function subscale at 0, 3 and 12 months
2. AIMS 2 Arthritis Pain Scale at 0, 3 and 12 months
3. Grip and pinch strength at 0, 3 and 12 months
4. Dexterity at 0, 3 and 12 months
5. Range of motion at 0, 3 and 12 months
6. Joint alignment at 0, 3 and 12 months
7. Joint tenderness and swelling at 0, 3 and 12 months
8. Disease activity at 0, 3 and 12 months
9. EuroQol EQ-5D at 0, 3 and 12 months
10. Adapted Michigan Hand Outcomes Questionnaire at 3 and 12 months
11. Global change question 7 point Likert scale at 3 and 12 months
12. Resource use questionnaire at 0, 3 and 12 months
13. EuroQol EQ-5D: Health Utility at 0, 3 and 12 months

The following secondary outcome measure was added as of 10/07/2008:

14. Adherence to home exercise, assessed at 3 and 12 months

### **Completion date**

30/04/2012

## **Eligibility**

### **Key inclusion criteria**

1. People with RA
2. Those who meet the American College of Rheumatology clinical and immunological criteria, with pain and dysfunction of the hands and or wrist joints
3. Either not on a Disease-Modifying Anti-Rheumatic Drugs (DMARD), or who have been on a stable DMARD regimen, for three months or more

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

**Key exclusion criteria**

1. Patients recovering from upper limb joint surgery, or fracture, in the previous six months
2. Patients on a waiting list for upper limb orthopaedic surgery
3. Patients who are pregnant
4. Aged less than 18 years

**Date of first enrolment**

01/11/2008

**Date of final enrolment**

30/04/2012

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

Warwick Clinical Trials Unit

Coventry

United Kingdom

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**Sponsor information****Organisation**

University of Warwick (UK)

**ROR**

<https://ror.org/01a77tt86>

**Funder(s)****Funder type**

Government

**Funder Name**

Health Technology Assessment Programme

**Alternative Name(s)**

NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## Results and Publications

**Individual participant data (IPD) sharing plan****IPD sharing plan summary****Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	31/01/2015		Yes	No
<a href="#">Results article</a>	results	01/03/2015		Yes	No
<a href="#">Results article</a>	results	12/04/2017		Yes	No
<a href="#">Protocol article</a>	protocol	01/06/2012		Yes	No
<a href="#">Protocol article</a>	protocol	24/11/2012		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes