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SARAH: Stretching and Strengthening for Rheumatoid Arthritis of the Hand

Submission date	Recruitment status	[X] Prospectively registered
11/01/2008	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/02/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/04/2017	Musculoskeletal Diseases	

Plain English summary of protocol
http://www2.warwick.ac.uk/fac/med/research/ctu/trials/ecr/sarah

Study website
http://www2.warwick.ac.uk/fac/med/research/ctu/trials/ecr/sarah

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure

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.

Secondary outcome measures
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

Overall study start date
01/11/2008

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

Age group
Adult

Sex
Both

Target number of participants
480

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
England

United Kingdom

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Warwick Clinical Trials Unit
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ROR
https://ror.org/01a77tt86

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	01/06/2012		Yes	No
Protocol article	protocol	24/11/2012		Yes	No
Results article	results	31/01/2015		Yes	No
Results article	results	01/03/2015		Yes	No
Results article	results	12/04/2017		Yes	No