

An investigation of the Immediate Effects of Physiotherapy Treatment of the Rheumatoid Arthritic Hand

Submission date 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/04/2014	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0515103445

Study information

Scientific Title

Study objectives

The small joints of the hands are often involved in the disease process of rheumatoid arthritis (RA) which can lead to pain, loss of function and problems with activities of daily living. This is not only an expense to the individual in terms of emotional costs and loss of work but also to the wider community in terms of the expense of therapy and health care provision. Currently, anecdotal and clinical experience indicate that the use of vaseline in gloves and hot water during active exercises for subjects with RA hands has a beneficial influence on pain and functional ability. Further investigation is therefore required to test this hypothesis. The benefits of such a study might include the inclusion of findings to the existing body of knowledge, the development of guidelines in the management of RA hands, cost-effective implementation of home exercise programmes which are evidence-based.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Musculoskeletal Diseases: Rheumatoid arthritic hand

Interventions

This is an experimental study with a target population of subjects who have clinically diagnosed RA affecting their hands. The independent variable is the heat treatment (vaseline in gloves and hot water 37 degrees C) while the dependent variable will be the measurement tools. A different-subject design will be used, with subjects (randomly assigned into Group 1- the heat and exercise group or Group 2 - the exercise only group). Range of movement will be measured bilaterally (both hands) of flexion of all fingers in millimetres (mm) from the end of each finger

to the first wrist crease (same measurements as used by Dellhag et al (1992)). Grip strength will be measured with a dynamometer (an instrument which the patient holds tightly). Pain or movement will be measured on a 10 point scale and pain without movement on a 100mm visual analogue scale (VAS) (same measurements as used by Dellhag et al (1992)). Stiffness will be measured on a 100mm VAS scale (as per Dellhag et al (1992)). A table will be compiled using the raw data from the study showing before and after measurements. A Mann Whitney U statistical test will be carried out. An related t-test will be used if the sample size is large enough.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Range of movement, grip strength, pain and stiffness measurements which have been justified for use in previous studies and in particular these will mirror the outcome measures used in the Dellhag et al (1992) study.

Secondary outcome measures

Not provided at time of registration

Overall study start date

24/09/2001

Completion date

31/03/2005

Eligibility**Key inclusion criteria**

1. All subjects will 18-70 years old.
2. 24 patients will be recruited from the rheumatology clinic list and randomly assigned into Group 1 or Group 2.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Upper age limit

70 Years

Sex

Not Specified

Target number of participants

24

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

24/09/2001

Date of final enrolment

31/03/2005

Locations

Countries of recruitment

England

United Kingdom

Study participating centre**Rehabilitation Gym**

Harrow

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Sponsor information

Organisation

Department of Health

Sponsor details

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Sponsor type

Government

Website

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Funder(s)

Funder type

Government

Funder Name

North West London Hospitals NHS Trust (UK), NHS R&D Support Funding

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