ISRCTN34847373 https://doi.org/10.1186/ISRCTN34847373

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

Submission date 30/09/2005	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 08/04/2014	**Condition category** Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Not Specified

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(s)
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.

Key secondary outcome(s)
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Not Specified

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
United Kingdom

England

Study participating centre
Rehabilitation Gym
Harrow
United Kingdom
HA1 3UJ

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

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

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration