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A comparison of general and specific dynamic stability exercises in osteoarthritis of the carpometacarpal joint of the thumb.

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 19/02/2014	**Condition category** Musculoskeletal Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mrs Barbara Bown

Contact details
Southern Derbyshire Acute Hospitals NHS Trust
Derbyshire Royal Infirmary
London Road
Derby
United Kingdom
DE1 2QY

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0077135302

Study information

Scientific Title

Study objectives
The hypothesis to be tested is that specific exercises to strengthen a stabilising muscle of the thumb (Abductor Pollicis Longus [APL]) will reduce pain at rest and during pinch grip, improve pinch strength and improve function more than a general exercise group.

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: Osteoarthritis of the thumb

Interventions
Subjects will be given information about the study and their consent obtained by staff in the research department.
Baseline assessments will then be completed by the researcher. These will consist of measures of pain (Visual analogue scale), function (Disabilities of the Arm, Shoulder and Hand [DASH] questionnaire), pinch strength (pinch gauge), pain during pinch, Abductor Pollicis Longus (APL) strength (measured by a load cell) and demographic data.

The sample size required has been determined by a power calculation. As there are no previous papers investigating similar physiotherapy interventions for OA in this joint the power calculation is based on the researcher's own clinical experience. Based on clinical observations it has been assumed that general exercise will improve patient's symptoms by 20% and the specific regime will improve patients by 50%. To demonstrate a 50% change in the outcome measures it has been calculated that a sample size of 54 subjects is required with a set at 0.05

and a power of 90%. A pilot study will be performed prior to the study, therefore a total of 70 subjects will be recruited.

Subjects will be randomly assigned to either the specific exercise or general exercise programme by the use of the sealed envelope method. This process will be blinded and performed by research department staff in order to eliminate any potential researcher bias. Subjects will be identified by a number and the researcher will have no access to the data regarding randomisation until the end of the trial. Subjects will not be told which exercise regime they have been assigned to.

All subjects will be treated by the same physiotherapist to improve reliability. All patients will have an initial appointment where they are given the same standardised written and verbal advice. They will then go on to receive different regimes of exercise depending on the group they have been assigned to. All subjects will then be seen by the same physiotherapist at two, four and eight weeks. Exercises will be progressed according to the protocol for that group. The initial measures will then be repeated by the researcher at twelve weeks and six months post commencement of exercise. The researcher will be blinded to the treatment group. The data will be analysed using a Statistical Package for Social Scientists (SPSS) statistical computer package.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
DASH (disability of arm, shoulder and hand) functional outcome questionnaire. Pain will be measured using a visual analogue scale at rest and during a pinch grip. Pinch strength will be measured using a pinch gauge. APL (Abductor Pollicis Longus) strength will be measured using a specially designed load cell.

Secondary outcome measures
Not provided at time of registration

Overall study start date
02/02/2004

Completion date
31/07/2007

Eligibility

Key inclusion criteria
All patients attending hand clinic with osteoarthritis (OA) of the carpometacarpal joint of the thumb will be seen by a specialist hand consultant in a designated clinic and all patients will be considered for inclusion in the study.
Patients referred to occupational therapy via their GP will also be considered for inclusion.
Their diagnosis will be a clinical diagnosis confirmed radiographically and subjects will then have the severity of their OA graded using the Eaton and Littler system.

Participant type(s)

Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
70

Key exclusion criteria
Subjects will be excluded if they have suspected or confirmed inflammatory joint disease, coexisting hand conditions in the affected hand or are unable to cooperate with exercise regime.

Date of first enrolment
02/02/2004

Date of final enrolment
31/07/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Southern Derbyshire Acute Hospitals NHS Trust
Derby
United Kingdom
DE1 2QY

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
Southern Derbyshire Acute Hospitals NHS Trust (UK)

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