

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
Registration date 30/09/2004	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 19/02/2014	Condition category Musculoskeletal Diseases	☐ Individual participant data
		☐ 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

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

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(s)

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.

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

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

United Kingdom

England

Study participating centre

Southern Derbyshire Acute Hospitals NHS Trust

Derby

United Kingdom

DE1 2QY

Sponsor information

Organisation

Department of Health

Funder(s)

Funder type

Government

Funder Name

Southern Derbyshire Acute Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration