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Osteoarthritis thumb therapy trial II

Submission date	Recruitment status	[X] Prospectively registered
26/09/2016	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/09/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
01/12/2020	Musculoskeletal Diseases	

Plain English summary of protocol

Background and study aims
Osteoarthritis (OA) is the most common type of arthritis, affecting millions of people worldwide. It occurs when the protective cartilage on the end of bones wears away. The bones then rub against one another, which can cause stiffness, pain and a reduction in a person's range of movement. Osteoarthritis in the joint at the base of the thumb (symptomatic thumb base OA) affects about 20% of people over 55 years of age, and causes more pain, work disability, reduced quality of life and function than OA elsewhere in the hand. International experts recommend splinting (using a rigid strip of material to support the joints and restrict movement) for hand OA but there is limited evidence from robust studies to support this. The aim of this study is to investigate the effectiveness of splinting in people with thumb base OA.

Who can participate?
Patients aged 30 and over with thumb base OA

What does the study involve?
Participants are randomly allocated to one of three groups. Participants in the first group take part in a self-management package, which involves being given information and learning exercises to help reduce pain and improve function in the hand to complete at home. Participants in the second group also take part in the self-management package but are also given a thumb splint to wear, which restricts movement, for at least six hours every day. Participants in the third group take part in the self-management package and are given a thumb splint to wear which is less restrictive of movement, for at least six hours every day. At the start of the study and then again after 8 and 12 weeks, participants complete a number of questionnaires to assess their hand pain and function.

What are the possible benefits and risks of participating?
There are no direct benefits involved with participating. There is a small risk that participants in the thumb splint groups may find wearing the splint uncomfortable.

Where is the study run from?
Poole Hospital (UK)

When is the study starting and how long is it expected to run for?
March 2016 to March 2019

Who is funding the study?
Arthritis Research UK (UK)

Who is the main contact?
Dr Joanna Adams
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
31053

Study information

Scientific Title
Osteoarthritis Thumb Therapy trial: a randomised controlled trial into the effectiveness and efficacy of splints in thumb base osteoarthritis

Acronym
OTTER II

Study objectives
The aim of this study is to evaluate whether there is any benefit of adding a thumb base splint to a self-management intervention for people with thumb base osteoarthritis (OA).

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central - Oxford C Research Ethics Committee, 04/05/2016, ref: 16/SC/0188

Primary study design
Interventional

Study design
Randomised; Interventional; Design type: Treatment, Education or Self-Management, Rehabilitation

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Specialty: Musculoskeletal disorders, Primary sub-specialty: Elective orthopaedic surgery; UKCRC code/ Disease: Musculoskeletal/ Arthrosis

Interventions
Participants are randomised to one of three groups.

Group 1: Participants undertake the self-management package alone for eight weeks. The self management package includes being given booklets containing hand exercises, information about how to protect hand joints and general information about osteoarthritis (booklet produced by Arthritis Research UK). In addition, participants receive a personal exercise guide which is used to facilitate consideration of barriers and enablers to completing the exercises and an exercise diary to record when the exercises are completed.

Group 2: Participants undertake the self-management package plus thumb splint (Procool Thumb Restriction Splint or Orfilight Thermoplastic Trouser Splint) to wear for a minumum of six hours per day for eight weeks; a personal splint wearing guide which is used to facilitate consideration of barriers and enablers to wearing the splint; a splint wear diary to record how much the splint is worn; and a splint wear hours guide which explains when to wear the splint.

Group 3: Participants undertake the self-management package plus thumb splint (DM Orthotics Thumb Sleeve or DM Orthotics Thumb Sleeve Lite) to wear for a minumum of six hours per day for eight weeks; a personal splint wearing guide which is used to facilitate consideration of barriers and enablers to wearing the splint; a splint wear diary to record how much the splint is worn; and a splint wear hours guide which explains when to wear the splint.

Participants in all groups are followed up at 4, 8 and 12 weeks.

Intervention Type
Other

Primary outcome(s)
Hand pain is measured uisng the AUSCAN index for hand pain at baseline, 8 and 12 weeks

Updated 01/03/2019 to remove the 4-week questionnaire.

Key secondary outcome(s)

1. Overall response to treatment is measured using the OMERACT responder criteria that combines:
1.1. Global assessment of change for thumb base problem rating from “completely recovered” to “very much worse” on a 5 point ordinal rating scale
1.2. AUSCAN hand function index
1.3. AUSCAN hand pain index
at baseline, 8 and 12 weeks
2. Satisfaction with hand function over the past week is measured using an ordinal rating scale at baseline, 8 and 12 weeks
3. Hand pain severity over the last week is measured using an ordinal rating scale at baseline, 8 and 12 weeks
4. Thumb pain over the last week is measured using an ordinal rating scale at baseline, 8 and 12 weeks
5. Ability to take part in leisure activities is measured using The Disability of the Arm, Shoulder and Hand Questionnaire (leisure section only, 3 ordinal questions) at baseline, 8 and 12 weeks
6. Generic Quality of Life is measured using the SF12v2 at baseline, 8 and 12 weeks
7. General health is measured using the EuroQol 5 Dimensions 5-Levels questionnaire at baseline, 8 and 12 weeks
8. Self-efficacy is measured using the Arthritis Self-efficacy pain subscale at baseline, 8 and 12 weeks
9. Hand function is measured using the clinician assessed Grip Ability Test at baseline, 4 and 8 weeks
10. Health care resource use and associated costs are measured at 8 and 12 weeks. Costs included will be: provision of intervention splints, hospitalisation and associated length of stay, outpatient and A&E visits and primary care visits (both in practice and at home from general practitioners, nurses and community therapists). Resource use will be valued using readily available NHS Reference costs, UK costs of health and social care and the list prices in the British National Formulary.
11. Work and activity is measured using the Work Productivity and Activity Impairment Questionnaire (WPAI) at baseline, 8 and 12 weeks
12. Perceived splint effectiveness, preference and adherence for a purposive sample of splint group participants (n=40) is measured using a detailed qualitative exit telephone interview placed between 8 week appointment and 12 week follow up questionnaire

Updated 18/02/2019 to remove the 4-week questionnaire.

Completion date
31/08/2019

Eligibility

Key inclusion criteria
1. Males and females aged 30 years and over
2. At least moderate AUSCAN hand pain (AUSCAN Hand pain score >5) and functional hand disability
(AUSCAN hand functional disability score >9)
3. One of the following:
3.1. Hard tissue enlargement of the first carpometacarpal joint (CMCJ)
3.2. Squaring of the thumb base
3.3. Pain that worsens when pinching
3.4 Pain that worsens on span grip (eg opening a jar)

3.5. Crepitus on movement
3.6. Reduction in thumb base range of movement
3.7. Positive thumb adduction provocation test
3.8. Positive thumb extension provocation test
3.9. Pain on palpation of the dorso-radial aspect of the thumb CMCJ
4. No other household member participating in the trial
5. Able to give written informed consent
6. Available to attend Occupational Therapy/Physiotherapy/Hand Therapy sessions

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
349

Key exclusion criteria
1. Consultation with therapy department or treatment for this thumb problem (excluding pain killers and anti-inflammatories) in the previous 6 months
2. Intra-articular joint injection to wrist, fingers or thumb in the previous 2 months
3. Fractures or significant injury or surgery to the wrist or hand within the previous 6 months
4. Red flags e.g. history of serious illness or disease (e.g. rheumatoid arthritis, psoriatic arthritis), progressive neurological signs, acute swollen joint
5. Diagnosis of dementia or significant disorder likely to affect communication
6. Already received thumb splints for thumb base OA
7. Skin disease that may interfere or contraindicate splint wear
8. Participants of a drug or medical device trial in the last 12 weeks

Date of first enrolment
28/02/2017

Date of final enrolment
11/12/2018

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Poole Hospital
Longfleet Road
Poole
United Kingdom
BH15 2JB

Sponsor information

Organisation
University of Southampton

ROR
https://ror.org/01ryk1543

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research UK

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Requests for access to data will be considered by the Chief Investigator and the TSC. Requests will be considered in accordance with the University of Southampton's recommended practices for permitting access to research data and the Chief Investigator will make the final decision.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	30/11/2020	01/12/2020	Yes	No
Protocol article	protocol	22/10/2019	14/09/2020	Yes	No
HRA research summary			28/06/2023	No	No