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The SMOotH Study - Self Management in Osteoarthritis of the Hand: a randomised controlled trial in the community

Submission date 26/11/2007	**Recruitment status** No longer recruiting
Registration date 23/01/2008	**Overall study status** Completed
Last Edited 01/05/2015	**Condition category** Musculoskeletal Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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

17958

Study information

Scientific Title
Self management, joint protection education and exercises in hand osteoarthritis: a randomised controlled trial in the community

Acronym
SMOotH

Study objectives
Primary questions:
1. Is joint protection delivered by an Occupational Therapist (OT) more effective in reducing hand pain and disability than no joint protection in people with hand osteoarthritis (OA) in primary care?
2. Are hand exercises delivered by an OT more effective in reducing hand pain and disability than no hand exercises in people with hand OA in primary care?

Secondary question:
If joint protection and hand exercises are combined, is this more effective in reducing hand pain and disability than usual care in people with hand OA in primary care?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval pending from the Central Manchester Research Ethics Committee (REC) as of 26 /11/2007 (ref: 07/H1008/235). A favourable opinion was given by Central Manchester REC for our study on 22/02/2008.

Study design
Multicentre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied
Hand osteoarthritis

Interventions
Group 1 - usual care:
Group 1 will receive information on general practice (GP) headed notepaper to continue with their own self-management approaches, which they will be asked to record in a diary, will receive standard advice on the use of analgesia and will be given the Arthritis Research Campaign (ARC) leaflet 'Looking after your joints'.

Group 2 - usual care and joint protection principles:
Participants will receive the same information and instructions as Group 1 above. In addition they will receive four group intervention classes held in a local OT department. The OT interventions will be held once a week for a maximum of 60 minutes and will involve 6 - 8 participants. Participants will be taught joint protection principles.

Group 3 - usual care and hand exercises:
Participants will receive the same information and instructions as Group 1 above. In addition they will receive four group intervention classes held in a local OT department. The OT interventions will be held once a week for a maximum of 60 minutes and will involve 6 - 8 participants. Participants will be taught hand exercises.

Group 4 - usual care and joint protection principles and hand exercises:
Participants will receive the same information and instructions as Group 1 above. In addition they will receive four group intervention classes held in a local OT department. The OT interventions will be held once a week for a maximum of 90 minutes and will involve 6 - 8 participants. Participants will be taught both joint protection principles and hand exercises.

The OT group interventions (groups 2 - 4) will include a general introduction, education on hand OA and its management and management of pain during everyday activities. Educational-behavioural approaches will be adopted with goal-setting, pacing, problem-solving and challenging unhelpful beliefs. Participants will be encouraged to practice techniques taught in the classes, which will be reinforced by a participant manual. The joint protection approaches and hand exercises will be based on those previously used in rheumatoid arthritis with adaptation for hand OA.

Outcomes for Groups 2 - 4 will be compared with outcomes for Group 1.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
The primary outcome will combine the pain and function subscales of the Australian/Canadian hand osteoarthritis measure (AUSCAN) with a global assessment of improvement (6 point scale: completely better, much better, better, same, worse, much worse) according to the Osteoarthritis Research Society International (OARSI)/Outcome Measures in Rheumatology (OMERACT) criteria to determine whether each individual is a 'responder' to treatment.

Outcome measures will be completed at baseline, 3, 6 and 12 months. The primary end point will be 6 months.

Secondary outcome measures
1. Global assessment of change of hand problem at 3, 6 and 12 months
2. Individual subscales of the AUSCAN (Pain, stiffness and function) at recruitment, baseline, 3, 6 and 12 months
3. Hand pain manikin at recruitment, 3, 6 and 12 months. Participants are asked if they have had any ache or pain that has lasted for one day or longer in their hands. Individuals responding positively to this question are then asked to shade in a diagram of the hands (backs and palms) indicating where this ache or pain has been experienced.
4. Average pain severity over the past 3 days, assessed at baseline, 6-month clinic assessment and at 12 months
5. Severity rating of participant nominated main functional problem over the past 3 days, assessed at baseline and 6-month clinic assessment, 3 and 12 months
6. Frustration related to hand disability, assessed at baseline, 3, 6 and 12 months
7. Participation restriction, assessed at recruitment, 3, 6 and 12 months
8. Quality of life:
8.1. EuroQol EQ-5D instrument at baseline, 3, 6 and 12 months
8.2. 12-item short form version 2 (SF-12v2) questionnaire at recruitment, 3, 6 and 12 months
9. Generic measure of disability, assessed by SF-12v2 at recruitment, 3, 6 and 12 months
10. Self-efficacy in relation to pain (Arthritis Self-Efficacy pain subscale), assessed at baseline, 3, 6 and 12 months
11. Illness perceptions, measured by Illness Perceptions Questionnaire Revised (IPQ-R) modified for hand OA, assessed at recruitment, baseline, 3, 6 and 12 months
12. Side-effects of treatment and adverse events
13. Co-interventions:
13.1. From consultation download: follow-up visits to the GP, prescription of medication including non-steroidal anti-inflammatory drugs (NSAIDs), referral for other treatment such as surgery
13.2. From self-reported questionnaires: self-help remedies, contacts with private health care, over the counter medicines, use of hand splints
14. Satisfaction with care, assessed at 3 and 6 months
15. Self-reported behaviour change, assessed at baseline, 3, 6 and 12 months

Overall study start date
01/06/2007

Completion date
31/05/2008

Eligibility

Key inclusion criteria
1. Males and females aged 50 years and over
2. Fulfilling the American College of Rheumatology (ACR) definition of symptomatic hand OA, or symptomatic thumb base OA on clinical assessment
3. No other household member participating in the trial
4. Ability to understand and capable of giving written informed consent
5. Available to attend OT classes if allocated to receive OT intervention
6. Able to give informed consent

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
Total: 252 (63 per arm)

Key exclusion criteria
1. Consultation or treatment for this hand problem in the previous 6 months including:
1.1. Intra-articular joint injection to wrist, fingers or thumb
1.2. Fractures or significant injury or surgery to the wrist or hand
1.3. Consultation for this hand problem with an OT or physiotherapist
2. Red flags e.g., history of serious illness or disease (e.g., rheumatoid arthritis, psoriatic arthritis, stroke), progressive neurological signs, acute swollen joint
3. Minimal pain and function on the primary outcome measures (Australian/Canadian hand outcome score [AUSCAN] pain less than 5, function less than 9)

Date of first enrolment
01/06/2007

Date of final enrolment
31/05/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Keele University
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Sponsor type
University/education

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ROR
https://ror.org/00340yn33

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research Campaign (ARC) (UK) (grant ref: 17958)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol results	11/07/2011		Yes	No

Results article	economic evaluation	01/01/2015	Yes	No
Other publications		01/05/2015	Yes	No