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EXTENDED REPORT

Self-management approaches for osteoarthritis in the hand: a 2×2 factorial randomised trial

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ABSTRACT

Background Osteoarthritis is the leading cause of disability in older adults. Evidence of effectiveness for self-management of hand osteoarthritis is lacking.

Methods In this randomised, factorial trial, we evaluated the effectiveness of joint protection versus no joint protection, and hand exercise versus no hand exercise in adults, 50 years of age or older, with hand osteoarthritis. Following a population survey (n=12 297), eligible individuals were randomly assigned (1:1:1:1) to: leaflet and advice; joint protection; hand exercise; joint protection plus hand exercise. Joint protection and hand exercises were delivered by nine occupational therapists, over four group sessions. The primary outcome was the OARSI/OMERACT responder criteria at 6 months. Outcomes were collected blind to allocation (3, 6, 12 m). Analysis was by intention to treat.

Results Of 257 participants randomised (65:62:65:65) (mean age (SD) 66 years (9.1); female 66%) follow-up was 85% at 6 m (n=212). Baseline characteristics and loss to follow-up were similar between groups. There were no reported treatment side effects. At 6 m 33% assigned joint protection were responders compared with 21% with no joint protection (p=0.03). Of those assigned hand exercises, 28% were responders compared with 25% with no exercises (n.s.). Differences in secondary outcomes were not statistically significant, except for improvement in pain self-efficacy with joint protection (3 m p=0.002; 6 m p=0.001; 12 m p=0.03).

Conclusions These findings show that occupational therapists can support self-management in older adults with hand osteoarthritis, and that joint protection provides an effective intervention for medium term outcome. (Funded by the Arthritis Research UK ISRCTN 33870549).

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INTRODUCTION

Osteoarthritis (OA) is the commonest form of arthritis in the Western world, and is the leading cause of disability in older adults, with the hand being one of the most frequently affected sites.[1] In a country the size of the USA, conservative estimates suggest that there are 12.4 million people aged 65 years and over, with OA (33.6%),[2] and 2.9 million adults aged 60 years and over with painful, disabling hand OA[3 4] which significantly restricts daily activities, such as dressing and bathing, and evidence shows patients and practitioners perceive that there is little that can be done.[5 6] The majority of people with hand OA are managed in primary care but often treatments recommended by guidelines, for example, European League Against Rheumatism (EULAR) recommendations, are not offered.[7]

Community-based self-management programmes have been proposed generally by national bodies in the USA and Europe as a potential, cost-effective approach for reducing the impact of OA.[8 9] While a number of authors have reviewed the effectiveness of self-management programmes for people with OA,[7 10] or evaluated hand OA programmes in secondary care,[11 12] as yet there is limited evidence for effective management of hand OA in community-dwelling populations.

Here we report the findings from the first large-scale randomised trial to investigate the clinical effectiveness of two self-management programmes for community-dwelling adults aged 50 years and over with hand OA. This multicentre two-by-two factorial randomised controlled trial addresses the following questions: Is joint protection education delivered by an occupational therapist (OT) more effective in reducing hand pain and disability than no joint protection education in people with hand OA? Is instruction in hand exercises delivered by an OT more effective in reducing hand pain and disability than no instruction in hand exercises in people with hand OA?

METHODS

Design overview

This was a randomised controlled factorial trial. The main comparisons were between joint protection and no joint protection, and between hand exercises and no hand exercises.

The Self Management in OA of the Hand (SMOotH) trial was conducted from June 2008 through May 2010 at the Arthritis Research UK Primary Care Centre, Keele University, UK. The trial was approved by the North West 7 Research Ethics Committee UK (rec reference: 07/H1008/235) and was monitored by an Independent Trial Steering Committee and Data Monitoring Committee (Trial registration number ISRCTN 33870549). The protocol, including the statistical analysis plan, has been published previously.[13]

Setting and participants

Participants aged 50 years and over, registered with five general practices in Central Cheshire and North Staffordshire, UK, were mailed a health survey between June 2008 and April 2009. Responders to the health survey were invited for an assessment at a research clinic to check eligibility for the trial if they: (1) gave consent to further

contact; (2) reported hand pain in the last 12 months; (3) reported hand pain, aching or stiffness on 'some days', 'most days' or 'all days' in the last month; (4) had an Australian Canadian Hand OA Outcomes Index (AUSCAN) pain score ≥5 or an AUSCAN function score ≥9[14 15]; (5) reported that they had not seen an OT or physiotherapist for their hand problem in the last 6 months; (6) had not had a hand operation, injection nor injured their hands badly enough to see a doctor in the previous 6 months and (7) had no other member of their household participating in the trial. These individuals were mailed a study information sheet about the trial, and a letter inviting them to telephone the research centre should they wish to attend the research clinic.

Those attending the research clinic were assessed for trial eligibility by a research nurse and were included in the trial if they: gave informed consent to participate in the trial; met the American College of Rheumatology (ACR) criteria for features of hand OA,[16 17] or had unilateral or bilateral thumb base OA; did not have an alternative clinical diagnosis, such as inflammatory arthritis, and were able to attend for the trial interventions at participating OT departments. Details of consenting eligible participants were forwarded to the research centre and participants were randomised via a remote randomisation service to one of four groups (see below).

Randomisation and interventions

Randomisation was conducted (with an allocation ratio of 1:1:1:1) by administrative staff at the Keele Musculoskeletal Clinical Trials Unit, Arthritis Research UK Primary Care Centre, who had no clinical involvement in the trial. Randomisation was stratified by participants' general practice, and was completed using random permuted blocks of size 4 (the blocks were randomly selected using a computer-generated random number sequence in an ACCESS database). Randomised allocation of the next patient was concealed from administrative and OT staff until the point of randomisation. Researchers who entered and analysed the data were unaware of treatment allocation.

Participants were randomised to one of four 'cells': (1) joint protection; (2) hand exercises; (3) joint protection and hand exercises combined; (4) no joint protection or hand exercises. Participants in this last cell received written advice only and did not receive occupational therapy sessions. Interventions delivered in all four cells are described in Box 1.

Twelve OTs attended a two-day training programme before delivering the joint protection education and instruction in hand exercises (see online supplementary text S1). A pilot study tested the intervention protocol prior to the commencement of the main trial.

Outcomes and follow-up

Study outcomes were collected at baseline, 3, 6 and 12 months post-randomisation by postal questionnaire, and in a clinical assessment at 6 months. The primary end point for the trial was at 6-month follow-up. The study was designed so that the research nurse conducting the 6-month clinical assessment was blind to treatment allocation. However, if un-blinding did occur this was recorded.

The primary outcome measure combines the pain and function subscales of the AUSCAN[14 15] and global assessment of change[23] to determine if participants were 'responders' to treatment using the OARSI-OMERACT criteria[24] (for further details see footnote to table 1).

Self-reported secondary outcomes included AUSCAN pain, stiffness and function, global assessment of change in hand problem, average pain severity over the past 3 days (0–10 numerical rating scale), severity rating of participant-nominated main functional problem over the past 3 days (0–10 numerical rating scale), satisfaction with hand function over the past 3 days (0–10 numerical rating scale), health-related quality of life as measured by the SF12v2,[25] and the Arthritis Self Efficacy pain subscale.[26] Additionally, the following secondary outcomes were measured by a research nurse at baseline and at the 6-month clinical assessment only[13]: (1) grip strength (JAMAR); (2) pinch strength (B & L pinch gauge); (3) functional performance using the grip ability test (GAT).[27]

Treatment fidelity

Self-reported performance of hand exercises and use of joint protection and energy conservation were recorded to assess level of adherence to the intervention.[13 22]

Sample size

In this factorial trial, the sample size calculation was based on the comparison of participants receiving hand exercises (*intervention* group) and not receiving hand exercises (*comparator* group), (the calculation would be identical for the comparison of joint protection vs no joint protection, as hand exercises and joint protection were assumed to be independent treatments).[28] In participants in the *comparator* group, 50% would receive only a leaflet and advice, and 50% would receive joint protection education. Based on findings from similar populations of older adults with knee osteoarthritis, we estimated that 25% of participants receiving leaflet and advice only would improve using the OARSI-OMERACT responder criteria, and 45% of those receiving joint protection education would improve.[24 29] This gave a combined improvement of 35% in participants in the *comparator* group, that is, those not receiving hand exercises, assuming equal allocation of participants between treatment groups.

Published information was not available to define a minimum clinical important difference for the primary outcome measure. Therefore, after a consensus discussion with the OTs delivering the trial interventions, we estimated a worthwhile difference between groups to be 20%. Hence, the estimate of improvement in the *intervention* group which received hand exercises was 55% (ie, between group differences 35%+20%). To detect a difference of 20% or larger between participants receiving and those not receiving hand exercises, with 80% power and α of 5%, a total of 212 participants with data at baseline and at 6 months was required. To allow for a 15% drop-out over the 6-month post-randomisation period, we planned to recruit 252 participants to the trial, that is, 126 per group for each comparison.

Statistical analysis

The main effectiveness analysis was completed on an intention to treat (ITT) basis with imputation of missing data (see online supplementary text S2 and S3 for full details of analysis methods). Continuous outcome measures were analysed using analysis of covariance (ANCOVA), and binary outcomes by logistic regression with treatment differences expressed as mean differences or ORs, as appropriate, with associated 95% CIs. Descriptive statistics were used to describe baseline characteristics of participants by randomised treatment arm and by loss to follow-up. Adherence to hand exercises and use of joint protection techniques were analysed by treatment arm at 3, 6 and 12 months.

Sensitivity analyses of the trial results were conducted using (1) complete-case data and (2) per protocol data at 6 months using the primary outcome. Analyses were completed in STATA

Box 1 Interventions delivered to participants

Leaflet and advice

All participants were given standardised written information on self-management approaches for hand osteoarthritis (OA) including general information on looking after hand joints, and using analgesia (reproduced with permission from the Arthritis Research UK leaflets 'Looking after your joints when you have arthritis' and 'Osteoarthritis', respectively (http://www.arthritisresearchuk.org/), and the National Institute of Health and Care Excellence (NICE) good practice guidelines.[18] Participants were advised to continue with any self-management approaches they were currently using, and were given advice to consult their general practitioner if symptoms continued to be troublesome.

For 25% of participants this was the sole intervention.

Joint protection, hand exercises

For the remaining 75% of participants, in addition to receiving the leaflet, they received one of three interventions: joint protection, hand exercises, or a combination of the two. The interventions were all delivered over four group sessions (held once a week) by nine occupational therapists (OTs) in two hospital centres. OTs were rotated every 3 months to minimise the potential for bias. The rotation order was determined by the OTs availability to deliver the specific intervention.

Groups included up to six participants, and lasted for a maximum of one hour (1.5 h for the combined intervention). Treatment session duration and participant attendances were recorded by the OTs on case report forms (CRFs). Attendance adherence was audited by the study coordinator (SH), and was defined (a priori) to be per protocol if participants attended: session 1, 2, 3 and 4; sessions 1, 2 and 4; sessions 1, 3 and 4; or sessions 1 and 4. Any participant unable to attend week 1 was booked on to the following course.

Joint protection, hand exercises: core components

Both interventions were based on the 'Looking After Your Joints Programme' for rheumatoid arthritis (RA),[19–22] and included the following core components:

- a general introduction to the programme
- education about hand OA and its management
- managing pain during everyday activities
- how to change habits
- long-term and short-term goal setting
- weekly individually negotiated home programmes to practise skills taught
- weekly review of individually negotiated home programmes

Participants were provided with workbooks (relevant to joint protection, hand exercises, or a combination of the two) including key points from each meeting, photographs of people with hand OA demonstrating the intervention and weekly activity diaries to complete.

Joint protection principles

In addition to the core components outlined above, this intervention included the following joint protection principles:

- distributing the weight of what you lift over several joints (eg, spread the load over two hands)
- avoiding putting strain on the thumb and repetitive thumb movements
- avoiding prolonged grips in one position
- using as large a grip as possible
- reducing the effort needed to do a task (eg, use labour-saving gadgets; avoid lifting heavy objects, and reduce the weight of what you lift)
- energy conservation (activity pacing and planning)

Hand exercises

In addition to the core components outlined above, this intervention included the following stretching and strengthening hand and thumb exercises:

- stretching exercises
- wrist flexion and extension, pronation and supination
- tendon gliding
- radial finger walking
- making an 'O' with the thumb and index finger
- thumb extension, abduction and opposition to the base of the 5th finger

Strengthening exercises

- using an elastic band to provide resistance to thumb extension, thumb abduction and finger extension
- using Play-Doh rolling and forming into a ring to provide resistance to thumb and finger extension, squeezing it into a ball, and pinching off pieces between the thumb and index fingers
- holding a 0.5–0.75 kg weight while doing wrist flexion and extension exercises in pronation then supination

The aims of the hand exercise programme were to give the participants a clearer understanding of their hand problem, and to develop a hand exercise routine to help them improve grip strength and dexterity. Participants were guided to start with three repetitions of each exercise, gradually building up to 10 repetitions of each exercise daily (or most days), and to perform the exercises within their limit of discomfort. Exercises could be spread over several exercise sessions during the day and performed more than once a day. Participants were also asked to write down how many times they aimed to practise the exercises.

Joint protection and hand exercises combined

The individual interventions as described above were combined in the same number of sessions but with an additional half an hour added to each session.

Table 1 Baseline characteristics of randomised participants

Characteristic	Leaflet and advice (L and A) n=65	Joint protection (JP) n=62	Hand exercises (HEx) n=65	Combined therapy (JP and HEx) n=65	All randomised n=257
Demographic data					
Mean (SD): Age (years)	67.2 (9.5)	65.5 (8.6)	64.5 (9.0)	66.0 (9.3)	65.8 (9.1)
Female	40 (62)	43 (69)	41 (63)	46 (71)	170 (66)
Married	44 (69)	43 (71)	36 (55)	42 (65)	165 (65)
Routine or manual occupation*†	34 (52)	24 (39)	32 (49)	31 (48)	121 (47)
Currently working	20 (31)	18 (29)	20 (31)	18 (28)	76 (30)
Mean (SD): Age when left school	15 (1.1)	16 (1.4)	16 (1.2)	15 (1.2)	16 (1.2)
Left school to go to full-time education or university	9 (14)	13 (21)	12 (19)	7 (11)	41 (16)
Gained qualifications through study as an adult	25 (40)	36 (60)	36 (55)	29 (45)	126 (50)
General health and quality of life					
Body Mass Index ≥25.0 kg/m^2 (overweight/obese)‡	39 (63)	41 (71)	48 (75)	41 (65)	169 (68)
Mean (SD): SF-12: Physical component (0–100)*	39.7 (12.5)	39.0 (10.4)	41.9 (9.5)	39.9 (10.1)	40.1 (10.7)
Median (IQR): SF-12: Mental component (0–100)*	52.2 (44.0, 58.0)	55.5 (47.7, 60.0)	50.5 (39.9, 57.7)	56.4 (43.0, 60.5)	53.4 (43.3, 59.2)
Clinical characteristics of hand problem					
Pain in both hands in last 12 months	60 (92)	52 (84)	57 (88)	56 (88)	225 (88)
Median (IQR): Number of years with hand problem*	5.0 (3.0, 10.0)	4.0 (2.0, 8.0)	5.0 (2.0, 10.0)	5.0 (2.0, 10.0)	5.0 (2.0, 10.0)
Mean (SD): AUSCAN—pain (0–20)*	9.5 (4.0)	10.2 (3.5)	8.8 (3.3)	9.4 (3.7)	9.4 (3.6)
Mean (SD): AUSCAN—stiffness (0–4)*	1.6 (1.0)	1.5 (1.1)	1.4 (1.0)	1.5 (1.1)	1.5 (1.0)
Mean (SD): AUSCAN—function (0–36)*	14.5 (8.0)	15.9 (7.9)	13.8 (7.2)	15.0 (7.3)	14.8 (7.6)
Mean (SD): AUSCAN—total (0–12)*	5.2 (2.2)	5.3 (2.4)	4.7 (1.9)	5.0 (2.3)	5.0 (2.2)
Mean (SD): Arthritis self-efficacy pain subscale (1–10)*	4.8 (1.9)	5.3 (1.7)	5.2 (1.8)	5.1 (1.6)	5.1 (1.8)
Mean (SD): Hand pain severity on average last 3 days (0–10)*	4.7 (2.2)	5.2 (2.1)	4.3 (1.8)	4.4 (1.9)	4.6 (2.0)
Mean (SD): Severity of main functional problem on average in the last 3 days (0–10)*	4.9 (2.3)	5.6 (2.5)	4.7 (2.4)	5.0 (2.3)	5.0 (2.4)
Mean (SD): Satisfaction with hand function last 3 days (0–10)*	4.6 (2.2)	5.4 (2.5)	4.6 (2.4)	4.4 (2.0)	4.8 (2.3)
Median (IQR): Grip strength (lbs)*	35.0 (25.5, 47.5)	31.8 (17.0, 47.5)	31.0 (21.5, 51.0)	33.5 (22.5, 48.5)	33.5 (22.5, 47.5)
Mean (SD): Pinch strength (lbs)*	8.8 (3.3)	8.8 (3.8)	9.0 (3.2)	9.0 (3.3)	8.9 (3.4)
Median (IQR): Grip ability test (seconds)*	32.2 (26.8, 43.6)	30.2 (24.9, 39.7)	32.2 (26.6, 35.8)	32.1 (27.2, 41.5)	32.0 (26.5, 40.4)
ACR criteria met§	59 (91)	56 (90)	59 (91)	56 (86)	230 (90)
Unilateral or bilateral thumb OA¶	50 (77)	52 (84)	49 (75)	59 (91)	210 (82)

Figures are numbers and percentages unless otherwise stated. Median (IQR) given for outcome measures with a skewed distribution. Total AUSCAN score calculated as (pain/5) +stiffness+(function/9).
*Data based on imputed data.
†Based on the 'lower supervisory/technical', 'Semiroutine' and 'Routine' groups of the UK Standard Occupation Classification (2000) for current or most recent paid employment.
‡Body Mass Index grouping defined according to the WHO.
§ACR criteria based on clinical features only (symptom frequency assessed prior to clinical assessment).
¶The eligibility criteria for thumb base OA were determined via examination of the hand joints for features of pain and/or tenderness on palpation and observation/palpation of deformity. This definition of thumb OA is in keeping with NICE recommendations for diagnosis of OA in UK Primary Care.[18]
ACR, American College of Rheumatology; AUSCAN, Australian/Canadian Hand Osteoarthritis Index; JP, joint protection; NICE, National Institute of Health and Care Excellence; OA, osteoarthritis; SF-12, Short Form Health Survey 12 (V.2).

12.0.[30] No interim analyses were undertaken during the trial or follow-up period.

Role of the funding source

The trial was funded by the Arthritis Research UK ISRCTN 33870549. The funder played no role in the study.

RESULTS

Study recruitment and follow-up

Trial eligibility, recruitment and follow-up are described in figure 1. Overall follow-up rates (including minimum data collection) were: 3 months, 90% (n=232), 6 months, 85% (n=218), 12 months, 85% (n=219). Rates of loss to follow-up were similar for each intervention arm (figure 1) and were not related to baseline participant characteristics (see online supplementary table S1).

Table 1 shows baseline characteristics of trial participants. The mean (SD) age of participants was 66 (9.1) years, 66% were female; the mean (SD) AUSCAN pain and function scores at trial entry were: pain 9.4 (3.6); function 14.8 (7.6). Overall, differences in participant characteristics across treatment arms at baseline were small, however, some between-group differences were observed for gender, marital status, social class, Body Mass Index and the presence of thumb OA.

Main trial results

Interaction terms for the primary outcome (see online supplementary table S2) and all other outcomes were not statistically significant (p≥0.05), therefore, treatment effects were evaluated from the main effects model (ie, joint protection vs no joint protection; hand exercises vs no hand exercises) after adjustment for predefined potential confounders.

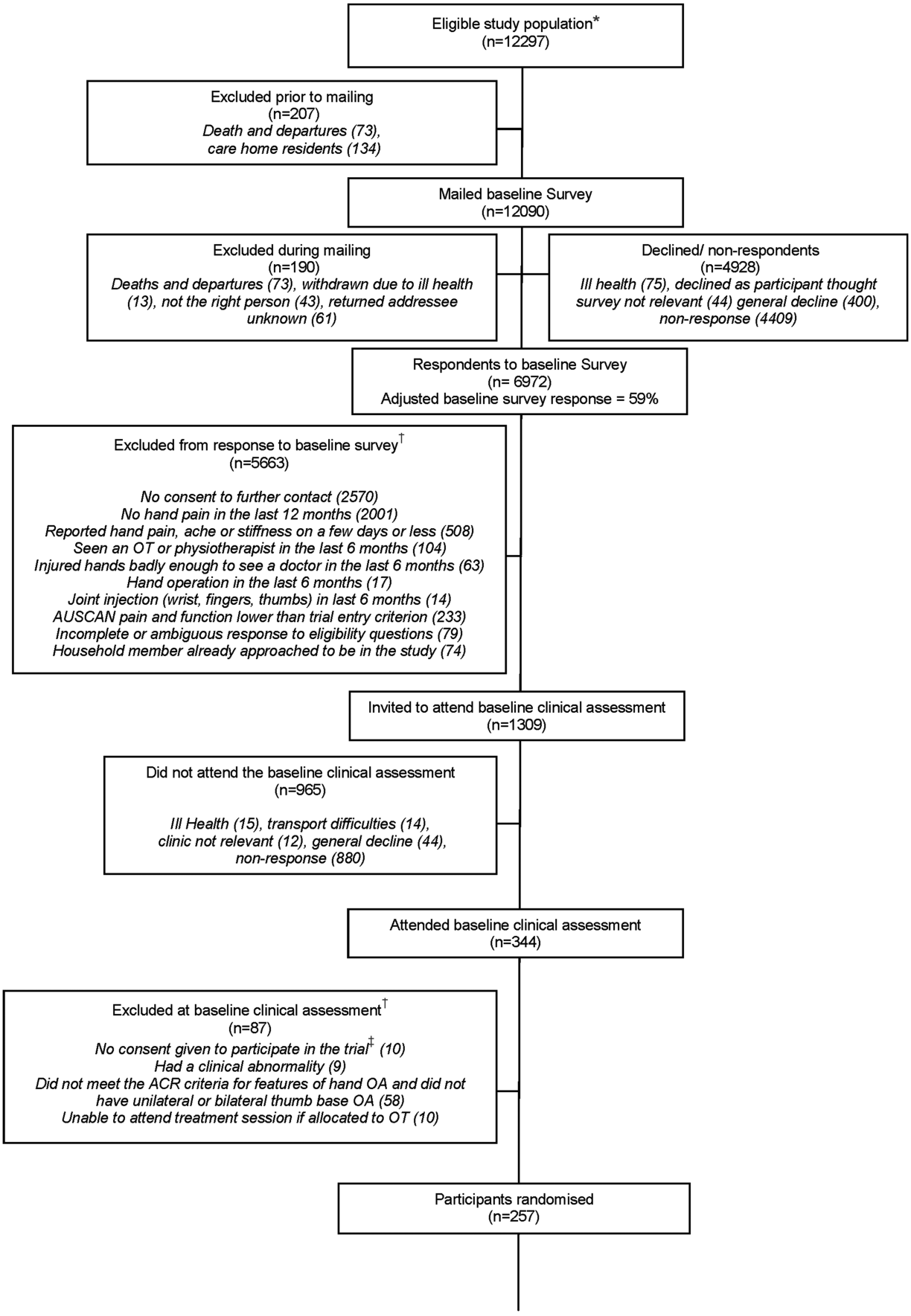

Figure 1 Recruitment flow diagram for the Smooth trial.

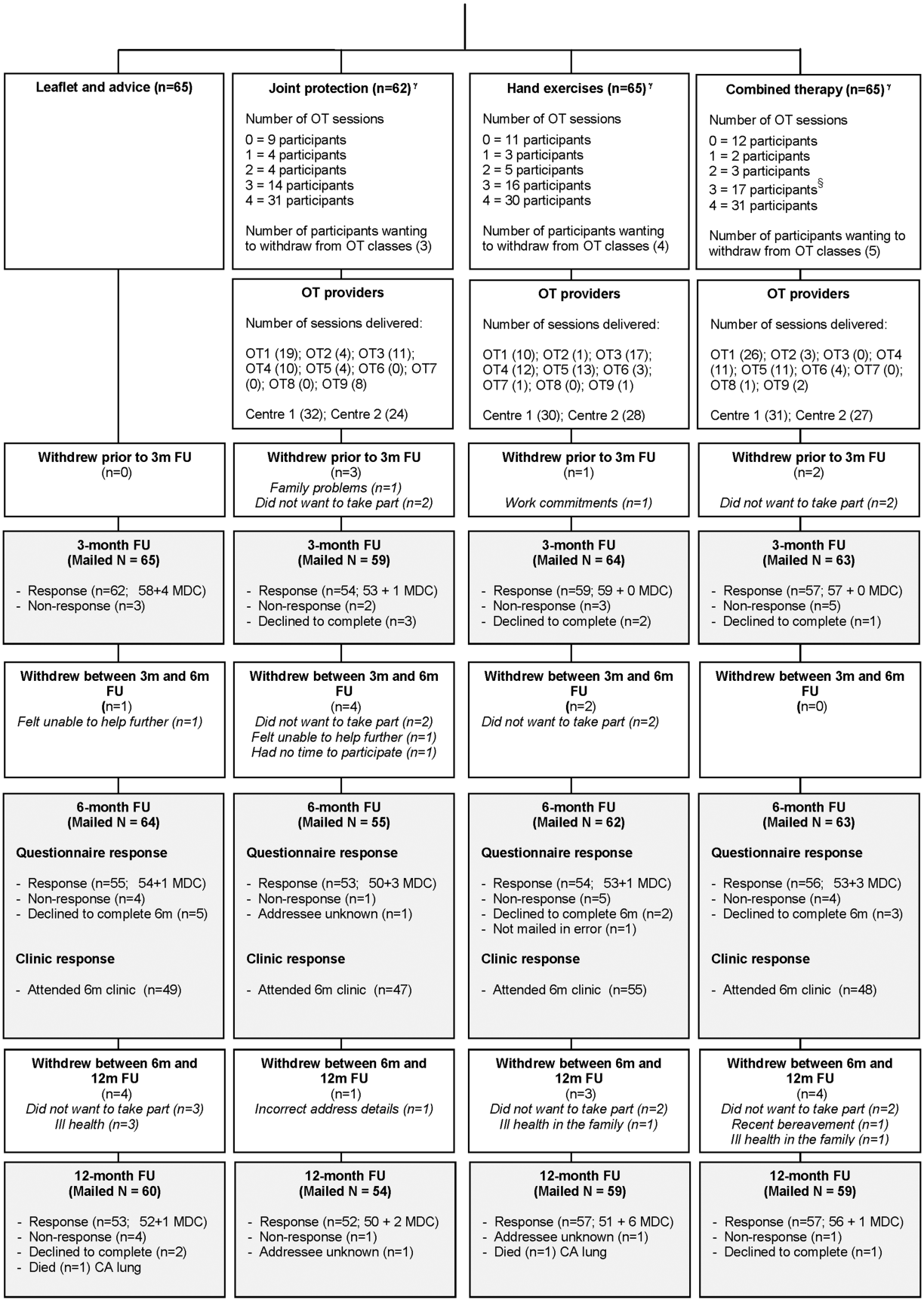

Figure 1 Continued.

Footnotes:

* Eligible study population includes adults aged 50 years and over registered with one of the five study practices, who did not have any of the excluded conditions searched for at the GP practice, eg RA, and who were not excluded by the GP screen, eg vulnerable patients with a record of psychiatric or terminal illness.
† Ineligibility reason is the first to apply on the list as multiple reasons are likely.
‡ This includes one red flag and one participant that withdrew consent after clinical attendance but prior to randomisation.
§ A participant in this group attended four treatment sessions (session 1, 2, and 3, with session 3 repeated twice in error).
γ Participants commenced occupational therapy in a median of 36 days (IQR 22,49) – joint protection 35 (IQR 22, 43); hand exercises 36 (IQR 22, 45); joint protection and hand exercises 44 (IQR 24, 64).
31 participants attended one or more OT class after the 3-month follow-up and 2 participants attended a single class after their 6-month follow-up.
Withdrawn indicates a request for no further study involvement; declined indicates a request that the participant does not want to provide data at the current follow-up but is willing to be mailed at further follow-ups. FU = follow-up; MDC = minimum data collection; 3m, 3-month, 6m, 6-month, 12m, 12-month.

Figure 1 Continued.

Table 2 shows the number (%) of participants classified as 'responders' according to the OARSI criteria. At our primary end point (6 months), the proportion of people meeting the OARSI responder criteria was higher for joint protection (vs no joint protection) and hand exercises (vs no hand exercises). These differences reached statistical significance for the joint protection comparison. No statistically significant differences were observed at 3-month and 12-month follow-up for this measure.

Evaluation of the components of the OARSI responder criteria found no significant differences in mean AUSCAN pain or function subscales for either treatment comparison or any follow-up time point (table 3). The percentage of participants reporting global improvement was significantly higher in the groups receiving joint protection compared with no joint protection, and hand exercises versus no hand exercises at 6 months, and also at 3 months and 12 months for the hand exercises comparison only (table 3 and see online supplementary table S3).

From the remaining secondary outcomes (table 3), arthritis pain self-efficacy consistently showed statistically significant differences between those receiving, and those not receiving joint protection, at all time points, with participants receiving joint projection showing increased pain self-efficacy.

Treatment fidelity

Those allocated to hand exercises performed a structured exercise programme more often than those who were not (see online supplementary table S4). On average, participants allocated to joint protection used joint protection and energy conservation techniques more frequently than those who were not (see online supplementary table S4).

Sensitivity analyses

Overall, these findings were largely replicated in a complete case analysis with no imputation of missing data (see online supplementary table S5). A per-protocol analysis of the OARSI responder criteria at 6-month follow-up replicated results from the ITT analysis, although statistical significance of the joint protection comparison was marginal (p=0.07) (see online supplementary table S6).

Adverse events

No adverse events were reported as a result of the interventions.

DISCUSSION

In this multicentre randomised controlled factorial trial, we evaluated whether joint protection education delivered by OTs was more effective in reducing hand pain and disability than no joint protection in community-dwelling older adults with hand OA. At 6 months, the primary end point, participants who received the joint protection intervention were statistically significantly more likely to be classified as responders to treatment than those not receiving joint protection (33% cf 21%). This was not maintained over 12 months. We also evaluated whether

Table 2 Treatment effectiveness evaluated for the OARSI responder criteria

	3 months				6 months				12 months			
Outcome measure	No JP*	JP	No HEx*	HEx	No JP*	JP	No HEx*	HEx	No JP*	JP	No HEx*	HEx
n	130	127	127	130	130	127	127	130	130	127	127	130
'Responders' (OARSI)†, n (%)	22 (17)	28 (22)	24 (19)	26 (20)	27 (21)	42 (33)	32 (25)	36 (28)	27 (21)	34 (27)	24 (19)	38 (29)
Adjusted‡ OR(95% CI)	1.35 (0.68 to 2.68)		0.99 (0.50 to 1.95)		2.10 (1.09 to 4.04)		1.14 (0.59 to 2.20)		1.57 (0.83 to 3.00)		1.76 (0.93 to 3.34)	

*Reference category.
†Participants met the OARSI responder criteria if (a) relative change in AUSCAN pain or function was ≥50% and absolute change was ≥20 or (b) at least two of the following applied: relative change in pain ≥20% and absolute change ≥10, relative change in function ≥20% and absolute change ≥10 or participants reported they were better, much better, or completely recovered on the global assessment of change question. Absolute change (baseline—follow-up score) and relative change (absolute change/baseline score) were calculated after AUSCAN measures were scaled from 1 to 101 to avoid dividing by 0 when calculating relative change.[24] Responses in the 'better', 'much better' or 'completely recovered' categories on the global assessment of change question were defined as 'improvement'.
‡Adjusted for age, gender, social class, General Practitioner (GP) practice and length of time with a hand condition and the other main effect of interest.
AUSCAN, Australian Canadian Hand Osteoarthritis Index; HEx, hand exercise; JP, joint protection; OA, Osteoarthritis.

Table 3 Treatment effectiveness for secondary outcome measures by main treatment effects

Outcome measure	3 months				6 months				12 months			
	No JP*	JP	No HEx*	HEx	No JP*	JP	No HEx*	HEx	No JP*	JP	No HEx*	HEx
n	130	127	127	130	130	127	127	130	130	127	127	130
Global assessment of change (%)												
n (%) Improved†	39 (30)	43 (34)	29 (23)	53 (41)	30 (23)	52 (41)	28 (22)	55 (42)	34 (26)	46 (36)	28 (22)	51 (39)
Adjusted OR(95% CI)	1.23 (0.67 to 2.25)		2.48 (1.33 to 4.60)		2.71 (1.39 to 5.25)		2.79 (1.44 to 5.40)		1.82 (0.96 to 3.45)		2.22 (1.20 to 4.11)	
AUSCAN pain (0–20)												
Mean (SD)	9.0 (3.5)	9.3 (3.0)	9.5 (3.4)	8.8 (3.1)	9.4 (4.0)	9.0 (3.9)	9.4 (4.0)	9.0 (3.9)	9.4 (3.9)	9.6 (3.8)	9.9 (3.7)	9.1 (3.9)
Adjusted mean difference (95% CI)	0.01 (−0.71 to 0.74)		−0.31 (−1.03 to 0.42)		−0.79 (−1.70 to 0.12)		0.06 (−0.85 to 0.97)		−0.09 (−0.99 to 0.81)		−0.35 (−1.27 to 0.56)	
AUSCAN stiffness (0–4)												
Mean (SD)	1.5 (1.0)	1.5 (1.0)	1.6 (1.0)	1.4 (1.0)	1.6 (1.0)	1.4 (1.0)	1.5 (1.0)	1.5 (1.0)	1.6 (1.0)	1.5 (1.0)	1.7 (0.9)	1.5 (1.0)
Adjusted mean difference (95% CI)	0.02 (−0.19 to 0.22)		−0.13 (−0.33 to 0.07)		−0.21 (−0.43 to 0.02)		0.11 (−0.11 to 0.33)		−0.05 (−0.27 to 0.17)		−0.14 (−0.36 to 0.08)	
AUSCAN function (0–36)												
Mean (SD)	15.1 (7.7)	15.3 (6.9)	15.9 (7.7)	14.5 (6.8)	14.4 (7.9)	14.9 (7.5)	15.3 (7.7)	14.1 (7.7)	15.1 (7.9)	16.3 (7.5)	16.3 (7.6)	15.1 (7.8)
Adjusted mean difference (95% CI)	−0.61 (−1.96 to 0.74)		−0.70 (−2.03 to 0.62)		−0.36 (−1.85 to 1.14)		−0.51 (−2.04 to 1.02)		0.51 (−1.08 to 2.10)		−0.60 (−2.18 to 0.98)	
AUSCAN total (0–12)												
Mean (SD)	5.0 (2.2)	5.0 (1.9)	5.3 (2.1)	4.7 (1.9)	5.1 (2.3)	4.8 (2.3)	5.1 (2.4)	4.9 (2.3)	5.2 (2.2)	5.3 (2.3)	5.5 (2.2)	5.0 (2.3)
Adjusted mean difference (95% CI)	−0.06 (−0.45 to 0.33)		−0.25 (−0.64 to 0.14)		−0.43 (−0.91 to 0.06)		0.09 (−0.39 to 0.57)		−0.03 (−0.51 to 0.46)		−0.26 (−0.74 to 0.22)	
Arthritis self-efficacy for pain (1–10)												
Mean (SD)	5.5 (1.9)	6.3 (1.8)	5.8 (2.0)	6.0 (1.7)	5.7 (1.9)	6.5 (1.7)	6.0 (1.8)	6.1 (1.8)	5.4 (2.0)	6.0 (1.8)	5.5 (1.9)	5.8 (2.0)
Adjusted mean difference (95% CI)	0.66 (0.24 to 1.08)		0.16 (−0.25 to 0.58)		0.74 (0.30 to 1.19)		0.09 (−0.37 to 0.55)		0.54 (0.07 to 1.02)		0.16 (−0.33 to 0.65)	
Hand pain severity last 3 days (0–10)												
Mean (SD)	4.4 (2.2)	4.3 (1.9)	4.6 (2.1)	4.1 (2.0)	4.1 (2.2)	4.4 (2.1)	4.1 (2.1)	4.4 (2.2)	4.5 (2.2)	4.6 (2.3)	4.8 (2.2)	4.3 (2.3)
Adjusted mean difference (95% CI)	−0.29 (−0.75 to 0.17)		−0.09 (−0.56 to 0.38)		0.06 (−0.46 to 0.58)		0.53 (0.01 to 1.05)		0.03 (−0.53 to 0.59)		−0.28 (−0.84 to 0.27)	
Severity of worse problem in the last 3 days (0–10)												
Mean (SD)	4.7 (2.3)	4.7 (2.2)	5.0 (2.3)	4.5 (2.2)	4.8 (2.4)	4.7 (2.6)	4.9 (2.5)	4.7 (2.4)	4.9 (2.2)	4.8 (2.4)	5.2 (2.2)	4.5 (2.3)
Adjusted mean difference (95% CI)	−0.23 (−0.75 to 0.30)		−0.27 (−0.78 to 0.24)		−0.42 (−1.07 to 0.24)		−0.01 (−0.65 to 0.62)		−0.33 (−0.90 to 0.23)		−0.49 (−1.08 to 0.10)	
Satisfaction with hand function in the last 3 days (0–10)												
Mean (SD)	4.8 (2.3)	4.4 (2.2)	4.9 (2.3)	4.3 (2.1)	4.5 (2.4)	4.1 (2.4)	4.2 (2.5)	4.4 (2.4)	4.9 (2.2)	4.8 (2.4)	5.2 (2.2)	4.5 (2.3)
Adjusted mean difference (95% CI)	−0.45 (−0.98 to 0.08)		−0.43 (−0.96 to 0.11)		−0.57 (−1.15 to 0.01)		0.37 (−0.22 to 0.95)		−0.19 (−0.75 to 0.38)		−0.46 (−1.06 to 0.14)	
Grip strength (lbs)												
Mean (SD)	N/A	N/A	N/A	N/A	43.2 (22.8)	41.0 (20.8)	41.3 (21.7)	43.0 (22.0)	N/A	N/A	N/A	N/A
Adjusted mean difference (95% CI)	N/A		N/A		−1.04 (−4.16 to 2.07)		1.17 (−2.13 to 4.46)		N/A		N/A	
Pinch strength (lbs)												
Mean (SD)	N/A	N/A	N/A	N/A	9.2 (3.5)	8.8 (3.6)	8.8 (3.4)	9.2 (3.7)	N/A	N/A	N/A	N/A
Adjusted mean difference (95% CI)	N/A		N/A		−0.27 (−0.88 to 0.34)		0.33 (−0.29 to 0.95)		N/A		N/A	
Grip ability test (seconds)												
Mean (SD)	N/A	N/A	N/A	N/A	33.9 (19.2)	31.3 (10.8)	34.5 (19.4)	30.8 (10.6)	N/A	N/A	N/A	N/A
Adjusted mean difference (95% CI)	N/A		N/A		−1.96 (−5.67 to 1.76)		−2.06 (−5.73 to 1.60)		N/A		N/A	

Continued

Table 3 Continued

Outcome measure	3 months				6 months				12 months			
	No JP*	JP	No HEx*	HEx	No JP*	JP	No HEx*	HEx	No JP*	JP	No HEx*	HEx
SF-12: physical component (0–100)												
Mean (SD)	40.5 (10.6)	40.3 (10.4)	39.9 (11.0)	41.0 (10.0)	41.7 (10.6)	40.0 (10.6)	39.9 (10.8)	41.8 (10.3)	41.4 (10.8)	40.6 (10.5)	39.7 (10.7)	42.3 (10.6)
Adjusted mean difference (95% CI)	0.84 (−0.98 to 2.67)		−0.17 (−2.08 to 1.75)		−0.79 (−2.92 to 1.35)		0.65 (−1.46 to 2.77)		0.01 (−2.24 to 2.25)		1.32 (−0.88 to 3.51)	
SF-12: mental component (0–100)												
Mean (SD)	50.2 (11.0)	51.2 (10.1)	51.1 (10.4)	50.3 (10.7)	50.2 (10.1)	51.4 (10.2)	50.8 (10.7)	50.8 (9.8)	50.4 (11.0)	51.5 (10.5)	50.7 (11.2)	51.1 (10.3)
Adjusted mean difference (95% CI)	−1.40 (−3.39 to 0.58)		0.34 (−1.64 to 2.32)		−0.72 (−2.97 to 1.53)		0.86 (−1.33 to 3.05)		−0.98 (−3.42 to 1.46)		1.35 (−0.98 to 3.69)	

Results based on the sample after multiple imputation of missing data has been completed and after adjustment for baseline (except for global assessment of change), age, gender, social class, General Practitioner (GP) practice, length of time with a hand condition and the other main effect of interest. Total AUSCAN score calculated as (pain/5)+stiffness+(function/9).
*Reference category.
†'Improvement' defined as 'completely better', 'much better', or 'better' on the global assessment of change question.
AUSCAN, Australian Canadian Hand Osteoarthritis Index; HEx, hand exercise; N/A, not applicable; JP, joint protection; SF-12, Short Form Health Survey 12 (V.2).

instruction in hand exercises was more effective in reducing hand pain and disability than no instruction in hand exercises, and found there was no statistically significant difference in the number of 'responders' between those receiving and not receiving hand exercises. Participants receiving joint protection education reported improved pain self-efficacy at 3- , 6- and 12-months.

The research question arose from clinical practice and was shaped by OT and patient and public involvement.[13] We followed the OMERACT-OARSI recommendations for design and conduct of clinical trials of OA.[16] Our trial, therefore, had good internal validity with adequate sample size, high follow-up rates and strategies to minimise potential therapist effect. However, because we selected volunteers who indicated that they were able and willing to participate in an OT programme, the results may not be generalisable to all older adults with hand OA.

All participants received the same advice and leaflet from the research nurse on entry into the trial prior to randomisation, and there were no differences between groups in the timing of this. Additional intervention was delivered using the same protocol for timing of treatment appointments for each arm (no additional treatment; joint protection; hand exercises; joint protection and hand exercises) and appointments for classes were monitored. Benefit of classes may have been diluted at 3 months as some participants failed to attend the first set of classes available so were still completing classes after the 3-month follow-up.

Reviews of non-surgical treatments for hand OA[31–33] and international guidelines[7 8] have identified a gap in evidence for the effectiveness of non-pharmacological approaches in the management of hand OA in community-dwelling older adults. Guidelines acknowledge that the strength of the evidence underpinning recommendations for self-management is weak. They highlight one RCT[12] comparing a joint protection programme plus home-based hand exercise (range of motion) versus information alone in 40 patients with hand OA. Stamm's study, while small, has been instrumental in informing clinical guidelines for hand OA.[7 8] More recently, Stukstette *et al*[11] investigated the effectiveness of an intensive group-based multidisciplinary treatment programme incorporating self-management, ergonomic principles and exercises. The findings of this study in participants recruited from rheumatology clinics suggest that such a programme is not effective in the short term.

Our study has added to this evidence by investigating the independent effects of each intervention and demonstrating the effectiveness of joint protection in hand OA. All exercises were supervised in the classes by OTs experienced in treating hand OA, however, as we did not measure biomechanical outcome, we cannot determine whether our exercise programme had any effect (positive or negative) on joint deformities. Adherence to home exercises was good—those allocated to hand exercises performed a structured exercise programme more often than those who were not—but gains in grip strength and other performance measures were not shown to be statistically significant, contrary to findings of others.[32] Adherence to joint protection approaches was also good, and it is possible that once joint protection principles are established, they may be easier to sustain in the shorter term, but the benefits tailor off in the longer term.

Although the magnitude of benefit for joint protection was lower than our prespecified minimally clinically important difference, it still reached statistical significance due to the additional power available in our study from an overestimation of the percentage of participants meeting the OARSI responder

criteria in the sample size calculation. Our study, therefore, adds to the evidence for expected differences between interventions and comparators for non-pharmacological studies in community-dwelling populations, 50 years and older, with hand OA.

In clinical practice, only those patients who seek help are treated and only a small subgroup of the population with disabling hand pain in community-dwelling populations, aged 50 years and older, see an OT (3% in a 12-month period).[6] Our eligible study population was defined using criteria recommended in secondary care settings,[16] and the treatment approaches should, therefore, be generalisable to patients who are referred to OT. Our findings also highlight the feasibility of supporting self-management in community settings and offer strategies to close the gap between what patients should receive[7–9] and what therapies are offered.[6]

While hand OA is common, and has a significant impact and associated disability,[3,4] consultations with a General Practitioner (GP) are low.[6] People with hand problems consider the diagnosis of 'hand OA' to represent a serious condition, but they often perceive that nothing can be done.[5] Our study population was recruited via the community using the ACR criteria for hand OA, hence, to have achieved any improvement in this group is important.

Joint pain in older adults and OA are public health problems that challenge our healthcare professionals and healthcare delivery systems. We have produced clear evidence about the most clinically effective methods of delivering and supporting self-management at 6 months for older adults with hand OA to justify and inform guidelines and recommendations. We have shown that support for self-management, through a joint protection education programme delivered by OTs, provides an effective approach for community-dwelling older adults with hand OA.

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Contributors All the authors vouch for the data and analyses as well as the fidelity of the study to the protocol. The first and second authors wrote the first draft of the manuscript; all the authors participated in writing subsequent drafts and made the decision to submit the manuscript for publication.

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Data sharing statement Our Centre has established data sharing arrangements to support joint publications and other research collaborations. Applications for access to anonymised data from our research databases are reviewed by the Centre's Data Custodian and Academic Proposal (DCAP) Committee and a decision regarding access to the data is made subject to the NRES ethical approval first provided for the study and to new analysis being proposed. Further information on our data sharing procedures can be found on the Centre's website (http://www.keele.ac.uk/pchs/publications/datasharingresources/) or by emailing the Centre's data manager (data-sharing-pcs@cphc.keele.ac.uk).

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BMC Musculoskeletal Disorders

STUDY PROTOCOL Open Access

Self management, joint protection and exercises in hand osteoarthritis: a randomised controlled trial with cost effectiveness analyses

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Abstract

Background: There is limited evidence for the clinical and cost effectiveness of occupational therapy (OT) approaches in the management of hand osteoarthritis (OA). Joint protection and hand exercises have been proposed by European guidelines, however the clinical and cost effectiveness of each intervention is unknown. This multicentre two-by-two factorial randomised controlled trial aims to address the following questions:

• Is joint protection delivered by an OT more effective in reducing hand pain and disability than no joint protection in people with hand OA in primary care?

• 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?

• Which of the four management approaches explored within the study (leaflet and advice, joint protection, hand exercise, or joint protection and hand exercise combined) provides the most cost-effective use of health care resources

Methods/Design: Participants aged 50 years and over registered at three general practices in North Staffordshire and Cheshire will be mailed a health survey questionnaire (estimated mailing sample n = 9,500). Those fulfilling the eligibility criteria on the health survey questionnaire will be invited to attend a clinical assessment to assess for the presence of hand or thumb base OA using the ACR criteria. Eligible participants will be randomised to one of four groups: leaflet and advice; joint protection (looking after your joints); hand exercises; or joint protection and hand exercises combined (estimated n = 252). The primary outcome measure will be the OARSI/OMERACT responder criteria combining hand pain and disability (measured using the AUSCAN) and global improvement, 6 months post-randomisation. Secondary outcomes will also be collected for example pain, functional limitation and quality of life. Outcomes will be collected at baseline and 3, 6 and 12 months post-randomisation. The main analysis will be on an intention to treat basis and will assess the clinical and cost effectiveness of joint protection and hand exercises for managing hand OA.

Discussion: The findings will improve the cost-effective evidence based management of hand OA.

Trial registration: identifier: ISRCTN33870549

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Background

Osteoarthritis (OA) is the commonest form of arthritis in the UK. It is the source of most of the musculoskeletal pain and disability in adults aged 50 years and over [1] and the hand is one of the most common sites of pain and osteoarthritic change in this age-group [2,3]. In a large cross-sectional survey of older adults with musculoskeletal hand problems in North Staffordshire, participants reported significant hand pain and disability, which affected their everyday lives [4]. The majority of people with hand OA are managed in primary care but often core treatments recommended by European and UK guidelines are not given [5] and patients report dissatisfaction with management [6]; 'I went to the GP (he) gave me a form... with osteoarthritis or something, whatever they call it. I thought that wasn't very helpful. 'Nothing we can do about it' he said and at the time I'd got really bad pain, which was why I went.... down the thumb. I honestly wouldn't ever go back and tell them my hands are playing up 'cause he said there was nothing they could do' [6]. As a consequence few people with hand problems visit their general practitioner (GP), even when severely affected [4], and even fewer attend for occupational therapy (OT) [7]. In our survey, only 3% of those with severe disability reported seeing an occupational therapist (OT) in the last year [4] despite the fact that OTs commonly deliver core treatments for people with hand OA.

Joint protection and hand exercises are core components of OT. Joint protection aims to reduce pain, disability and improve function through the use of ergonomic approaches such as altering movement patterns, modification of task and environment, and use of assistive devices [8]. Patients are helped to understand how strain on the joint when carrying out daily activities can contribute to joint pain and potentially promote joint deformity. Hand exercises also aim to reduce pain and disability, and improve physical functioning and grip strength [9]. Studies in patients with lower limb OA suggest that exercise therapy may delay or even prevent the onset of disease [10] although its effectiveness in hand OA is still uncertain.

Increasingly, OTs use educational-behavioural approaches to enhance the use of self-management and behaviour change interventions such as exercise and joint protection [8,11,12]. Goal-setting and problem-solving, with adequate time to practice new skills in order to develop new habits and routines, are used to facilitate uptake of exercise and joint protection techniques [11,12].

Despite the fact that joint protection and hand exercises are frequently used by OTs and physiotherapists (PTs) in the management of hand OA, and have been recommended for all patients in the European League Against Rheumatism (EULAR) recommendations [13], systematic reviews conclude there is a paucity of evidence to support these interventions [14-16]. One trial in secondary care demonstrated modest benefits of joint protection plus hand exercises compared with an education leaflet for hand OA [17]. A study of yoga exercises in a hand OA population has shown promising findings [18].

The EULAR recommendation to provide joint protection and hand exercises for all patients with hand OA is based largely on expert opinion and has not been evaluated in high quality randomised controlled trials. The majority of patients with hand OA will be managed in primary care and it is therefore important to evaluate the benefits of hand exercises and joint protection before the EULAR recommendations can be adopted in this setting. This paper outlines the protocol for the Self Management in Osteoarthritis of the Hand (SMOotH) trial.

Trial development

The trial was designed with key stakeholders: OTs with experience of treating patients with hand OA, and research users with experience of living with or caring for someone with hand OA.

Occupational Therapists

We have established a clinical advisory group of 10 OTs working in hand therapy and musculoskeletal conditions in North Staffordshire and Central Cheshire, UK. The group helped develop the research questions, interventions and the trial design. We have used this approach successfully in previous studies of physiotherapy [19,20]. The OT clinical advisory group was consulted at all stages of the study development through four half-day workshops, and identified the research questions as important to current clinical practice. These workshops considered the current best evidence for the management of hand OA using critically appraised topics [21].

User involvement

In the UK there is a clear policy directive to involve patients and the public in research [22]. Such involvement is thought to lead to research which is of clinical relevance and of better quality [23-26]. We have an established Research User Group and Virtual User Panel who provide advice and feedback on trial conduct and offer patient representation on the trial steering groups.

We will engage both OTs and Research Users throughout each stage of the trial.

Trial Objectives

Specifically, our study will consider the following main research questions:

• Is joint protection delivered by an OT more effective in reducing hand pain and disability than no joint protection in people with hand OA in primary care?

• 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?

• Which of the four management approaches explored within the study (leaflet and advice, joint protection, hand exercise, or joint protection and hand exercise combined) provides the most cost-effective use of health care resources

These research questions are in line with recommendations of the EULAR guidelines for the management of hand OA [13]. The study has been designed to meet the Osteoarthritis Research Society International (OARSI) recommendations for clinical trials in hand OA [27].

Methods/Design

This is a multicentre two-by-two factorial randomised controlled trial in community-dwelling older adults of non-pharmacological interventions [28] with a superiority design [29]. Participants will be allocated to one of four groups: leaflet and advice; a joint protection programme; a hand exercise programme; or a joint protection and hand exercise programme (see Table 1).

Participants

All participants aged 50 years and over registered with 3 general practices in Central Cheshire and North Staffordshire (estimated n = 9,500) will be mailed a health survey questionnaire asking about their general health and any hand pain or hand problems experienced for a day or longer over the past 12 months. Prior to mailing, general practitioners (GPs) will have the opportunity to screen the participant list for any exclusions e.g. vulnerable adults, those with psychiatric illness. Immediately prior to mailing, a deaths and departure check will be completed to verify that participants are still registered at the GP practice and have not recently died or left the practice. To avoid contamination between participants only one person for each address will be considered eligible for the study. This will avoid any contamination of interventions between individuals in the same household. The first person from the household to respond to the survey will be deemed eligible.

All participants responding to the health survey questionnaire will be screened for eligibility. Those who meet the eligibility screen (see Table 2) will be contacted by post with a letter outlining the trial, a further study information sheet, and an invitation to telephone the research centre should they wish to attend for clinical assessment. Those who wish to take part will be asked to make an appointment to have a brief clinical assessment by a research nurse, undertake a further phase of eligibility screening (see Table 3) and a face-to-face consent procedure. At the end of the clinic, details of eligible participants will be forwarded to the research centre and participants will be randomised to one of four groups: leaflet and advice; joint protection (looking after your joints); hand exercises; or a combined intervention of joint protection and hand exercises.

Eligibility criteria

Participants included in the trial will be aged 50 years and over identified from general practice registers. Eligibility criteria for each stage of the study are based on the recommendations of the OARSI task force on design and conduct of clinical trials in hand OA [27]. Inclusion criteria are: males and females; aged 50 years and over; fulfilling the American College of Rheumatology (ACR) definition of symptomatic hand osteoarthritis [27,30], or symptomatic thumb base OA on clinical assessment; no other household member participating in the trial; ability to understand and capable of giving written informed consent. Exclusion criteria are: consultation or treatment for this hand problem in the previous 6 months including an intra-articular joint injection to wrist, fingers or thumb, fractures or significant injury or surgery to the wrist or hand [27]; consultation for this hand problem with an occupational therapist or physiotherapist; red flags, e.g. history of serious illness or disease (e.g. stroke), progressive neurological signs, acute swollen joint; those with a diagnosis of inflammatory arthritis (e.g. rheumatoid arthritis (RA), psoriatic arthritis); minimal pain and function on the Australian/Canadian hand outcome score (AUSCAN) [31] pain < 5 and function < 9) [27]. Individuals with co-existing hand conditions, such as carpal tunnel syndrome, Dupuytrens contracture, trigger finger, will not be excluded unless the condition is deemed at the clinic to be the primary cause of the hand problem.

Table 1 Two by two factorial randomised trial: leaflet and advice, joint protection, hand exercises, joint protection and hand exercises

	Leaflet and advice alone	Joint protection
Leaflet and advice alone	Leaflet and advice	Leaflet and advice Joint protection
Hand exercises	Leaflet and advice Hand exercises	Leaflet and advice Hand exercises and joint protection

Rows and column headings indicate possible interventions, cells indicate the four possible treatment allocations.

Table 2 Eligibility criteria assessed on the health survey questionnaire

Participants will be eligible to be invited to the baseline nurse clinical assessment if they meet the following criteria on the health survey questionnaire:

- Give consent to further contact
- Report hand pain in the last 12 months
- Report hand pain aching or stiffness on "some days", "most days" or "all days" in the last month
- Have an AUSCAN pain score > = 5 or an AUSCAN function score > = 9
- Report they have not:
  - a. seen an occupational or physiotherapist for their hand in the last 6 months
  - b. injured their hands badly enough to see a doctor in the last 6 months
  - c. had any hand operations in the last 6 months
  - d. had any hand injections in the last 6 months
- No other household member is participating in the trial

Clinic assessment procedures

Invitation to the clinic

Respondents to the health survey questionnaire who meet the eligibility criteria and provide written consent to further contact will be sent a letter of invitation and a study participant information sheet outlining the SMOotH Study and the details of reimbursement for their travel to the clinic. Non-responders will be sent a reminder invitation two weeks later. Those willing to take part in the study will be booked into the next convenient appointment for the assessment clinic and a letter of confirmation and baseline SMOotH questionnaire mailed. The assessment clinic is expected to last approximately one hour. Participants' baseline questionnaire will be checked for completion by the research nurse at the clinic assessment.

Participants who do not attend clinic for their specified appointment will be sent another letter asking them to re-contact the research centre and to book another appointment if they still wish to participate.

On arrival at the clinic the study will be discussed with participants and written informed consent taken prior to assessment and randomisation.

Prior to assessment, all participants will undertake screening to identify possible red flags indicative of potentially serious pathology, e.g. recent trauma to the hands likely to have resulted in significant tissue damage, and acutely swollen and painful hand joints. Further screening will be carried out to determine whether the participants meet the eligibility criteria (see Table 3). This will include examination of the hand joints for features of hand OA using the ACR Classification and whether the participant has thumb base OA. Participants' availability to attend OT sessions in the next 3 months will be ascertained.

Participants who consent to participate in the study and meet the eligibility criteria will be invited to undertake a research interview and hand function assessment with a research nurse [32,33]. Assessment equipment (Jamar Dynamometer and B&L Pinch Gauge [33]) will be calibrated prior to the start of the study.

Irrespective of whether they are randomised, all participants attending the clinic will receive out of pocket expenses, an information leaflet and advice. Those who do not consent to be part of the trial or are ineligible will be asked for their consent to use the information already provided for the study and given advice to consult their GP if their hand problems continue to be troublesome. Consent forms and assessment documentation will be placed in secure storage at the research centre.

The GP will be notified whether the participant has been recruited to the trial. Any significant abnormalities identified in the clinic will be communicated to their GP via a post-clinic fax and letter.

Participant timeline

Participant flow can be seen in Figure 1. Follow-up will be at 3 months, 6 months and 12 months after randomisation to evaluate short, medium and longer-term outcome. Six-months after attending the baseline

Table 3 Eligibility criteria assessed by the research nurse at the baseline nurse clinical assessment

Participants will be randomised to the trial if they meet the following criteria at the baseline nurse clinical assessment:

- Give informed consent to participate in the trial
- Meet the ACR criteria for features of hand OA (symptoms previously assessed on health survey) or have unilateral or bilateral thumb base OA
- Do not have a clinical "red flag" indicative of potentially serious pathology
- Able to attend OT classes

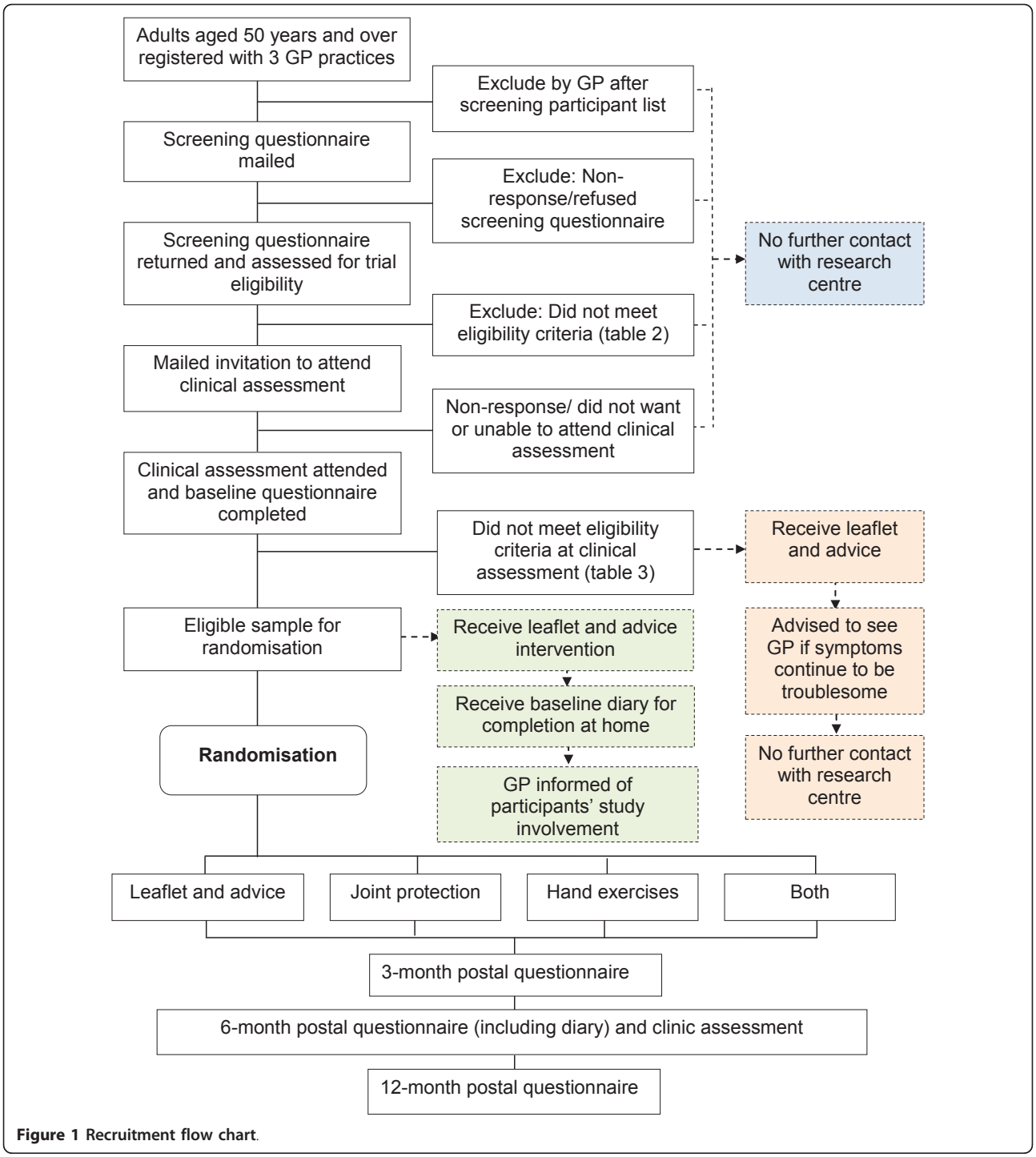

Figure 1 Recruitment flow chart.

assessment clinic, randomised participants will receive a self-administered questionnaire and an invitation to attend a brief clinical assessment of hand functional performance by a research nurse, using the same procedures as at baseline. The 3- and 12-month follow-up will be undertaken by self-administered postal questionnaire alone.

Trial Procedures

Recruitment and retention strategies

Standard research centre procedures will be followed to maximise follow up. Non-responders to the health survey will receive a postcard reminder at 2 weeks followed by a second questionnaire 2 weeks later. If there is still no response, no further contact will be made. At 3- and

12-month follow-up, randomised participants will receive postcard reminders and follow-up questionnaires. Non-responders will be approached for Minimum Data Collection (MDC) 2-weeks after the second questionnaire is mailed. MDC is a shorter version of the health survey questionnaire and will be used to collect the primary outcome measure (OARSI/OMERACT responder criteria) along with date of birth, age and gender to ensure the data are provided by the intended participant. MDC is completed on the telephone, or by post where consent to telephone contact has not been given. The reminder process for baseline and 6 month nurse clinic attendance will include an initial invitation to attend the clinic, and a reminder sent two weeks later. At 6-months, if there is still no response, the follow-up questionnaire will be mailed to participants but without an invitation to attend the clinical assessment. If there is still no response after a further 2 weeks, MDC will be completed if possible. Participants failing to attend an assessment appointment will be offered a second appointment. At all stages of the trial, any reason for non-participation will be recorded, if given.

Consent

Only participants giving consent to further contact on the health survey questionnaire will be mailed an invitation to attend the baseline nurse clinical assessment. Face-to-face consent will also be obtained by the research nurse at the baseline clinical assessment. This consent procedure includes consent to receive follow-up mailings, randomisation to one of four treatment approaches and to attend a follow-up assessment clinic at 6 months. The research nurse will also ask participants if they give consent for the research team to access their medical records. If they do, their medical records will be tagged using an electronic computer system, to support a later review of consultation records. Participants will be informed of the right to withdraw from the study at any time and for any reason without prejudice to future care. Participants will not receive any further mailings if they wish to withdraw from the study at any time.

Confidentiality

Participants will be assured of confidentiality and participant details will not be made available to anyone outside the study team. GPs will be informed of their patients' willingness to be part of the study and their agreement for their inclusion will be ascertained. All participants excluded from entry into the trial at any stage will be offered standard information, on request, by the Principal Investigator and advised to consult their GP should their symptoms remain troublesome.

Randomisation sequence generation, allocation concealment, implementation

Randomisation will be completed at the Arthritis Research UK Primary Care Centre by administrative staff with no clinical involvement in the trial. Details of participants eligible for randomisation will be passed to Centre administrative staff by the research nurse after each research clinic. Administrative staff will enter details of those eligible for randomisation into a Microsoft ACCESS database (housed in a separate geographical location to where the clinical assessments will be conducted). Randomisation will be implemented using random permuted blocks of size 4. The blocks will be selected at random using a random number generator within the ACCESS database and will be selected separately for each GP practice. The randomised treatment of the next patient in the trial will be concealed to both administrative and OT staff until the point of randomisation. Randomisation will be completed using an allocation ratio of 1:1:1:1.

Blinding/masking

During the data collection phase, both the trial nurse and treating OTs will be blind to the block size used in the randomisation procedure. The research nurse will remain blind to treatment allocation until all data collection (including baseline and follow-up) has been completed. Success of blinding will be recorded by the research nurse in the clinic assessment at 6 months and during MDC over the telephone. The trial statistician will be blind to treatment allocation until the main treatment analysis has been completed.

To ensure the nurse and trial statistician remain blind to treatment allocation the following will be observed:

- The password for the database and where it is to be stored will not be known by the statistician.
- Treatment arms in the treatment database will always be stored as ABCD and the key to un-blind the treatments will only be known by the database designer and administrative staff executing the randomisation.
- The research nurse will emphasise to participants at the 6-month clinic assessment that they should not reveal what treatment they have received.
- The nurse will not have access to any of the databases. Any information passed to the research nurse (such as participant name, address and appointment time) will be done via the administrative assistant.
- Consent to participate in the trial will be done by the research nurse who will be unaware of which treatment the patient has been randomised to receive.

Research nurse training

To ensure standardisation, three qualified research nurses will receive training in the use of pre-defined protocols for all components of the research assessment. Training on using the protocols will be carried out prior

to the clinic commencement and the protocols will be described in a Research Nurse Assessment Manual which will be available for use throughout the study period. A pilot study of the procedures using the training manual will also be undertaken.

At regular periods throughout the study, audits will be conducted to ensure quality and consistency of the research nurse assessment.

Study Setting

The study will be conducted in primary care. The setting will be general practices and OT outpatient facilities in Central Cheshire and North Staffordshire, UK. The GP practices, from which the participants will be recruited, cover a heterogeneous population, both socio-economically and geographically. The nurse assessment clinics will be conducted in GP practices and OT departments in local NHS hospitals. Those conducted in OT departments will be carried out in different areas and at different times to the OT interventions. Each clinic will be staffed by a research nurse who will be assisted by receptionists employed by the GP practice or NHS. Two sites in North Staffordshire and Central Cheshire will deliver all 3 OT interventions.

Training of Occupational Therapists

OTs delivering the intervention will initially participate in two consensus workshops to determine the most relevant, evidence-based, joint protection principles and hand exercises for use in hand OA. A literature review and analysis of evidence for joint protection and hand exercises for hand OA and RA will identify a range of principles and exercises that may be used in practice. The OTs will then be asked to identify up to 10 key joint protection and energy conservation principles considered relevant for hand OA (for example, 'distribute load over several joints', 'modify environment to support ergonomic/joint protection principles') and to identify key range of movement and strengthening exercises for the fingers, thumb and hand.

A pool of 12 OTs (2 groups of 6), with a particular interest or expertise in hand OA, will be given two days training at a local OT hospital site by the leader of the OT programme (AH). The OTs will be trained in the principles of patient education and factors affecting adherence and behaviour, including the principles of self-efficacy [34], prior to being introduced to the joint protection and hand exercise programme. The joint protection and hand exercise programmes will use Self-Efficacy Theory [34], the Health Belief Model [35], self-management cognitive-behavioural theory [36], motor learning and adult education as their basis, and will focus on addressing specific factors to support the use of joint protection techniques and hand exercises.

OTs will have the opportunity to practice teaching techniques, joint protection methods and hand exercises. Further details of the programme will be available from the Principal Investigator (KD).

Interventions

There will be four treatment arms to the study; leaflet and advice; joint protection delivered by an occupational therapist in a group setting; hand exercises delivered by an occupational therapist in a group setting; and joint protection combined with hand exercises delivered by an occupational therapist in a group setting.

Previous studies suggest that people with hand OA do not consult their GP very often about their symptoms and adopt their own approaches to self-management, which may or may not have beneficial effects. In order to standardise information given to participants, all eligible participants will receive information on GP headed notepaper from a research nurse prior to randomisation. Participants will be instructed to continue with their own self-management approaches, which they will be asked to record, will receive standardised advice on the use of analgesia and will be given the Arthritis Research UK leaflets 'Osteoarthritis' and 'Looking after your joints when you have arthritis' http://www.arthritisresearchuk.org. Relevant sections in the booklets will be highlighted and discussed. A leaflet on GP headed notepaper, which includes general information on looking after the joints of the hand, how to use the leaflets, and advice to consult their GP if symptoms continue to be troublesome, will be provided. Participants will also receive NICE good practice guidance [37] and advice on effective pain management with the use of paracetamol as first line analgesia, and advice on when to consult their GP. Co-interventions will be recorded and avoided during the first six months of the study.

Leaflet and advice The intervention will be delivered as described above without any additional OT classes.

OT Interventions Participants randomised to any one of the OT interventions will receive in addition to the above, four group sessions held once a week with 4-6 participants. A pool of 12 OTs will be trained to deliver the interventions. In order to develop rapport between participants and therapist it is planned that the same OT will conduct all four sessions. Non-trial co-interventions e.g. splinting, will be avoided during the first six months of the study and recorded if given. To reduce any potential bias, each OT will rotate throughout the interventions every three months. Rotation will be determined by the availability of the OTs to deliver the specific intervention, that is, the single component interventions, or the combined programme.

All three OT interventions will include a general introduction, education on hand OA and its management, and management of pain during everyday activities. The OT interventions will be supported by leader and participant manuals which will be used to promote treatment adherence and to standardise delivery of the

OT interventions. Flipcharts will be used as teaching aids, which will identify key points to be addressed within each session, and copies of the pre-written charts will be included in the leader manuals.

Participants will be encouraged to practice techniques taught in the sessions and illustrated in the participant manual, by setting weekly action plans, homework programmes and weekly review of progress. Participants will be encouraged to continue with their own self-management approaches, which they will be asked to record in their participant manual.

Joint protection classes

The OT intervention will be based on that previously used in inflammatory arthritis and adapted for hand OA, with particular attention to hand and thumb problems [11,12]. Supervised kitchen activities will be undertaken with participants in pairs to allow demonstration and practice of new skills. Classes will be delivered over 4 group sessions (maximum 1 hour each session).

Hand exercise classes

Hand exercises to strengthen muscles and mobilise joints will be developed from those identified in the consensus workshops. These will form the basis of the exercise classes which will be demonstrated and practised with participants seated around a large table. Classes will be delivered over 4 group sessions (maximum 1 hour each session).

Joint protection with hand exercises

Participants will receive both joint protection and hand exercises over 4 group sessions (maximum 11/2 hours each session).

Attendance protocol

The OT will be faxed a copy of the participant consent and a standard proforma prior to each session. The proforma will contain the participant identifier, the type of intervention to be delivered and the session number. At each class, the OT will confirm these details, indicate whether participants have attended and then fax the form to the study co-ordinator (SH) who will then audit adherence to the attendance protocol. The OTs will record the type of intervention received by each participant and the length of time of each treatment session on the proforma. Participants will be required to attend a minimum number of sessions. Participants failing to attend session 1 will be invited to attend session 1 of a subsequent round. Session 4 will be designed to summarise the content of the previous sessions. Participants failing to attend session 4, and not having completed sessions 2 and 3, will be invited to session 4 in a later round. Participants failing to attend session 2, 3 or both, will only be invited to repeat the missed sessions if requested by the OT or participant.

Audit of OT interventions

In addition to the standard proforma, an audit for the group intervention will be devised based on the leader manuals. The study co-ordinator will use these to carry out random audits to assess adherence to the intervention protocol.

Monitoring and reporting of harms

If a patient experiences an adverse event the OT concerned will inform the study coordinator by fax or telephone. The co-ordinator will investigate and record all details of the incident on an "adverse event" form. The Principal Investigator will be notified of the event, and will determine any follow-up action as required, e.g. referral to the participant's GP. All adverse events will be reported to the Data Monitoring Committee and the Trial Steering Committee.

Equipment

All OT sites will be provided with a standardised equipment package for the delivery of the joint protection and exercise programmes. An equipment inventory is available on request from the study co-ordinator.

Electronic OT mailing list

In order to enhance protocol adherence and to offer support to the OTs involved in the trial, the Principal Investigator and study co-ordinator will set up a shared electronic mailing list for participating therapists.

Pilot study

Up to 6 participants will be invited to attend a pilot study of the OT intervention. These participants will be members of the Centre Research Users Forum and will have a history of hand OA. The pilot study will be based on the combined programme of hand exercises and joint protection, and will take place at a local OT Department. The study will test processes and procedures, and any further amendments to the content of the intervention will be made prior to the commencement of the main trial.

Data collection management and analysis

Primary outcome measure

Study outcomes are documented in Tables 4 and 5, and are based on previously validated measures [38,39]. The primary outcome will combine pain and function subscales of the AUSCAN [31,40] and global assessment of improvement [41] to determine a 'responder' using the OARSI-OMERACT criteria [42] at 6 months post randomisation. Response options for the AUSCAN items are on a 5-point scale ranging from none to extreme, and for the purpose of this study the AUSCAN validated for use in older adults with hand pain in the population will be

Table 4 Secondary outcome measures

Outcome	Measurement Scale	Time points
AUSCAN pain [31,40]	0-20	HS, 0Q, 3, 6Q, 12, +
AUSCAN stiffness [31,40]	0-4	HS, 0Q, 3, 6Q, 12, +
AUSCAN function [31,40]	0-36	HS, 0Q, 3, 6Q, 12, +
Total AUSCAN [31,40]	0-12	HS, 0Q, 3, 6Q, 12, +
Pain severity in the last 3 days	NRS: 0-10	0NA, 3, 6NA, 12
Severity of participant nominated worse problem in the last 3 days [44]	NRS: 0-10	0NA, 3, 6NA, 12
Satisfaction with hand function in the last 3 days	NRS: 0-10	0NA, 3, 6NA, 12
Power grip (JAMAR dynomometer) [33]	lbs	0NA, 6NA
Pinch grip (B&L pinch gauge) [33]	lbs	0NA, 6NA
Grip-ability test (GAT) [32]	Timed (seconds)	0NA, 6NA
Short-form 12 (SF-12): physical and mental health component scores [49]	0-100	HS, 0Q, 3, 6Q, 12
Arthritis self efficacy for pain [50]	1-10	HS, 3, 6Q, 12
Global assessment of change in hand problem [41]	Completely recovered/much better/better/no change/worse/much worse	3, 6Q, 12, +

NRS = Numerical rating scale; HS = Baseline Health Survey; 0Q = Baseline Questionnaire; 0NA = Baseline nurse assessment; 3 = 3-month questionnaire; 6Q = 6-month questionnaire; 6NA = 6-month nurse assessment; 12 = 12-month questionnaire; + = included in minimum data collection.

Table 5 Tertiary outcome measures

Outcome	Measurement Scale	Time points
Demographic variables		
Age	Years	HS, 0Q, 3, 6Q, 12, +
Gender	Female/Male	HS, 0Q, 3, 6Q, 12, +
Marital status	Married/Separated/divorced/widowed/cohabiting/single	HS
Employment status	Working full time/working part time/working full time in the home/unemployed or seeking work/not working due to ill health or disability/student/retired	HS
Social class [65]	Higher managerial/Higher professional/Lower managerial or professional/Intermediate occupations/Self employed/Lower supervisory or technical/Semi-routine/Routine	HS, 0NA
Age when left school	Years	HS
Leave school to go to full-time education or university	Yes/No	HS
Age when finished full time education	Years	HS
Gained qualifications through study as an adult	Yes/No	HS
Ethnic origin	White UK or European/AfroCaribbean/Chinese/Asian/African/Other	HS
Height	Feet and inches or centimetres	HS
Weight	Stones and lbs or kilograms	HS
Measures to define trial inclusion/exclusion		
Hand pain in the last year	Yes/No	HS
Pain, aching or stiffness in your hands in the last month [30]	No days/Few days/Some days/Most days/All days	HS, 0Q, 0NA, 3, 6NA, 12
Seen OT or PT for hand problem in last 6-months	No/Right hand only/Left hand only/Both hands	HS, 0NA[1]
Injured hands badly enough to see a doctor in last 6 months	No/Right hand only/Left hand only/Both hands	HS, 0NA[1], 6NA
Had a hand operation in the last 6 months	No/Right hand only/Left hand only/Both hands	HS, 0NA[1], 6NA
Joint injection (fingers, thumbs or wrist) in the last 6 months	No/Right hand only/Left hand only/Both hands	HS, 0NA[1]
Clinical red flags (e.g. swollen painful hot hands or recent trauma to the hands)	Yes/No	0NA, 6NA

Table 5 Tertiary outcome measures *(Continued)*

Clinical assessment for hand swelling, nodes, enlargement or deformity	Yes/No for joints required to apply the ACR criteria for hand OA (ref)	0NA
Characteristics of hand problem		
Handedness	Right/Left/Both	HS, 0NA, 6NA
Hand problems in the last year	Yes/No	HS
Hand pain location in the last year	Right/Left/Both	HS, 0NA[2], 6NA[2]
Hand pain manikin [43]	Hand area shaded to represent pain	0Q, 3, 6Q, 12
Hand that gives most problem	Right/Left/No difference	HS, 0NA, 6NA
Number of days with hand pain in the last year [66]	Less than 7 days/1 to 4 weeks/> 1 month and < 3 months/3-months or more	HS
Hand pain severity in the last month	NRS: 0-10 (no pain to pain as bad as could be)	0Q
Bothersomeness of hand problems (adapted from [67])	Not at all/slightly/moderately/very much/Extremely	0Q, 3, 6Q, 12
Thumb pain during activity in the last month	Yes/No	0NA, 3, 6NA, 12
Ability to make a fist [68]	Right: yes/no/unable; Left: yes/no/unable	0NA, 6NA
Length of time with a hand problem	HS-years 0NA-Separate response for right and left hand < 12 months/1 to 5 yrs/5 to 10 yrs/10+ yrs	HS, 0NA
Previous hand surgery	Operation details, which hand, timing (< 1 yr ago/1 to 5yrs ago/5 to 10yrs ago/10+ yrs ago)	0NA, 6NA[3]
Previous hand injury	Injury details, which hand, timing (< 1 yr ago/1 to 5yrs ago/5 to 10yrs ago/10+ yrs ago)	0NA, 6NA[3]
Past or present job involved excessive use of hands	Yes/No	HS
Past or present hobbies or pastimes involved excessive use of hands	Yes/No	HS
Global assessment of change in hand pain since baseline [41]	Completely recovered/much better/better/no change/worse/much worse	3, 6Q, 12
Global assessment of change in ability to use hands since baseline [41]	Completely recovered/much better/better/no change/worse/much worse	3, 6Q, 12
Body pain and shoulder function		
Pain elsewhere (body manikin)	Body area shaded to represent pain lasting for a day or longer in the last 4 weeks	HS, 3, 6Q, 12
Ability to put hands behind head [68]	Right: yes/no/unable; Left: yes/no/unable	0NA, 6NA
Perception, impact and quality of life		
Illness perceptions	Subset of questions from the illness perceptions questionnaire revised (IPQ-R) [45,51]	HS, 0Q, 3, 6Q, 12
Participation restriction (selected questions from [46])	All the time/most of the time/some of the time/A little of the	0Q, 3, 6Q, 12
- Self-care needs met as and when wanted	time/None of the time	
- Home looked after as and when wanted		
- Belongings looked after as and when wanted		
Hand problems make you feel frustrated in the last month [45]	All days/most days/some days/few days/no days	0Q, 3, 6Q, 12
Adaptation behaviours		0NA, 6NA
- Use gadgets	Yes/No to each question	
- Help from another person		
- Avoidance		
- Find a different way of doing something		
- Stopping/reducing activities		
- Things take longer		
- Other (please state)		
Quality of life: EuroQol-EQ5-D [47,48]	(-0.59-1)	0Q, 3, 6Q, 12
Intervention evaluation		
Satisfaction with care received for hand problem	Very satisfied/Quite satisfied/no opinion/not very satisfied/not at all satisfied	3, 6Q, 12

Table 5 Tertiary outcome measures *(Continued)*

Treatment sessions: Number of appointments	Too many/About right/Not enough/I did not attend any appointments	3
Treatment sessions: Length of each visit	Too long/About right/Too short/I did not attend any appointments	3
Hand exercise frequency [69]	Never/Once a week/Twice a week/Three times a week/Four times a week/ Five times a week/Six times a week/Once every day/Twice every day	6Q, 12
Hand exercise frequency in last week [52]	Never/Almost never/Sometimes/Fairly often/Very often/Always	0Q, 3, 6Q, 12
Hand exercise duration [69]	< Five minutes/5-10 minutes/10-15 minutes/15-30 minutes/30 minutes+/I don't do hand exercises	6Q, 12
Behaviour change in last week: energy conservation/ fatigue [52]	(1-6) i.e. average of 5 items each rated as: Never/Almost never/Sometimes/ Fairly often/Very often/Always	0Q, 3, 6Q, 12
- Regular breaks		
- Breaking up tasks		
- Pacing of activities - Swapping between light and heavy tasks		
- Maintaining good posture whilst sitting, standing, lifting objects or moving about		
Behaviour change in last week: joint protection use [52]	(1-6) i.e. average of 5 items each rated as: Never/Almost	0Q, 3, 6Q, 12
- Use two hands to carry things	never/Sometimes/Fairly often/Very often/Always	
- Avoid gripping or pinching things tightly		
- Change the way everyday activities are completed		
- Use gadgets/labour-saving devices		
- Use stronger, larger joints		
Behaviour change in last week: carry on working through the pain when doing everyday activities [52]	Never/Almost never/Sometimes/Fairly often/Very often/Always	0Q, 3, 6Q, 12
Health care use and co-interventions		
Self-report	Self-help remedies, contact with NHS and private healthcare, over the counter medicines, use of hand splints	HS, 0NA, 6Q, 6NA, 12
GP consultation download	Number of follow-up visits to the GP, prescription of medication including NSAIDs and referral for other treatment such as surgery	Continually collected data
Nurse audit questions		
Did the participant un-blind you during the assessment?	Yes/No	6NA
If yes, what did the participant say and could it have been avoided?	Text	6NA
If yes, what treatment arm do you think the patient is randomised to	Leaflet and advice/Had OT, but not sure which OT intervention/Had OT, joint protection/Had OT, hand exercises/Had OT, joint protection and hand exercises	6NA

NRS = Numerical rating scale; OT = occupational therapist; PT = Physiotherapist; HS = Baseline Health Survey; 0Q = Baseline Questionnaire; 0NA = Baseline nurse assessment; 3 = 3-month questionnaire; 6Q = 6-month questionnaire; 6NA = 6-month nurse assessment; 12 = 12-month questionnaire; + = included in minimum data collection; 1 = time frame last month; 2 = refers to current hand problem; 3 = time frame last 6 months.

used [40]. Global assessment of improvement is on a 6-point scale ranging from completely better to much worse.

Minimum data collection at each follow-up data collection stage will attempt to capture the primary outcomes, AUSCAN and global change scores, in the event of non-response to the mailed follow-up questionnaire.

Secondary and tertiary outcome measures

Self-reported questionnaire at baseline, 3, 6 and 12 months Individual subscales of the AUSCAN (pain, stiffness and function), hand pain manikin [43], average pain severity over the past 3 days (0-10 numerical rating scale), severity rating of participant nominated main functional problem over the past 3 days (0-10 numerical rating scale) [44], satisfaction with hand function over the past 3 days (0-10 numerical rating scale), side effects of treatment and adverse events, co-interventions (from the medical record download: follow-up visits to the GP, prescription of medication including NSAIDs and referral for other treatment such as surgery and from self-reported questionnaires: self-help remedies, contacts with private healthcare, over the counter medicines, use of hand splints), frustration related to hand disability [45], pain elsewhere (pain manikin), participation restriction [46], health-related quality of life using the EuroQol EQ-5D [47,48] and SF12v2 [49], satisfaction with care (3 and 6 months), Arthritis Self Efficacy pain subscale [50], Illness Perceptions Questionnaire-Revised (IPQR) modified for hand OA [45,51] and self-reported behaviour change using selected questions [52].

Clinical assessment at baseline and 6 months only

grip strength (JAMAR) [33], pinch strength (B & L pinch gauge) [33], functional performance using the grip ability test (GAT) [32]. (See Tables 4 and 5).

Diary

All participants randomised to the trial will be given a diary to complete at baseline (nurse clinical assessment) and at 6 months (the primary end point). The diary is based upon the Activity Record (ACTRE) for patients with musculoskeletal disorders [53,54]. The diary aims to capture hand pain and functional limitation experienced when carrying out main activities for each half hour during a typical weekday and a weekend day, along with any rest periods taken during the activities. For each main activity, in each half hour period, participants will rate their hand pain and hand disability on a 0-3 scale, where 0 represents 'no hand pain/disability' and 3 represents 'a lot of hand pain/disability'. The 6-month diary will also include open ended questions to ask participants if they feel they have benefitted from taking part in the study and if not what they feel would have been beneficial. Participants will also be invited to make any additional comments if they wish.

Target sample size

The main study sample size calculation will be based on the comparison of participants receiving and those not receiving hand exercises. The calculation would be identical for the comparison of joint protection versus no joint protection, as hand exercises and joint protection are assumed equally effective and independent treatments [55].

In participants not receiving hand exercises 50% will receive a leaflet and advice, and 50% will receive joint protection. We estimate that 25% of participants in the leaflet and advice group will improve using the OARSI-OMERACT responder criteria and 45% will improve in the joint protection group [42,56]. This gives a combined improvement of 35% in participants not receiving hand exercises, assuming equal allocation of participants between treatment groups.

Published information is not available to define a minimum clinical important difference for the primary outcome measure. Therefore, after a consensus discussion with the OTs we estimate this at 20%, and hence the estimate of improvement in the group who receive hand exercises to be 55% (i.e. 35% + 20%). To detect a difference of 20% or larger between participants receiving and those not receiving hand exercises, with 80% power and alpha of 5%, a total of 212 participants with data at baseline and at 6 months are required. To allow for a 15% drop-out over the 6 months post randomisation period, 252 participants will be randomized, i.e. 63 per treatment arm.

Statistical methods, between group comparisons, handling of non-adherence and missing data

The main statistical analysis will be based on reporting guidelines for the design and conduct of factorial trials [55] and will be conducted for all primary and secondary outcomes. The main treatment analysis will be conducted blinded to treatment allocation and will be analysed on an intention to treat basis with all randomised participants retaining their original randomised group. Outcome measures that are continuous will be analysed using analysis of covariance (ANCOVA); for binary outcomes, logistic regression will be used. The data will be analysed at 3, 6 and 12 month follow-up, however, 6 months is the primary end point for the study.

An initial treatment model will be fitted (for each primary and secondary outcome and end-point) to predict the outcome of interest and will include the two treatment effects of interest: no joint protection versus joint protection; no hand exercises versus hand exercises, and their interaction. If the interaction term is not statistically significant ($p > = 0.05$) it will be dropped from the model. The model will be re-run, and the treatment effects for joint protection and hand exercises determined individually from this model, either as mean differences or odds ratios with associated 95% confidence intervals, as appropriate. If the interaction term is statistically significant ($p < 0.05$), the effect of joint protection and hand exercises will be evaluated from a model with treatment represented as a 4-level variable (i.e. leaflet and advice, joint protection, hand exercises, joint protection and hand exercises) and the reduced statistical power of this model noted. This model will also be used as a secondary analysis to compare the effectiveness of the individual treatments to the leaflet and advice arm.

All analysis models will be adjusted for the baseline value of the outcome of interest (with the exception of the OARSI/OMERACT responder criteria which is not computable at baseline) and also for age, gender, social class, length of time with a hand condition and general practice (covariates defined a priori as those that may influence treatment outcome). Missing data will be imputed using the multiple imputation routines in STATA version 11.0 [57].

A sensitivity analysis will be completed to examine the effectiveness of joint protection and hand exercises for those participants attending all four treatment sessions. This analysis will only be completed if there are sufficient participants attending all four treatment sessions. Treatment concordance will also be evaluated descriptively by (self-reported) frequency and duration of hand exercise completion at 3-, 6- and 12-month follow-up.

Generalisability of the trial findings and the success of the randomisation procedure will be explored descriptively

by comparing key characteristics of participants at recruitment and each follow-up stage and for each randomised treatment arm. No interim analyses will be planned during the trial follow-up period.

Health economics

The purpose of economic evaluation is to inform decision makers about competing claims for health care resources. Uncontaminated estimates of costs and effects of alternative treatments are the key parameters for the provision of cost effectiveness evidence and, accordingly, the clinical analytic framework for factorial design randomised controlled trials is not suitable because of the combination of treatment regimens.

The estimation of cost-effectiveness within this 4-arm study will focus on the principles of dominance and extended dominance. Dominance is a straightforward concept; if an intervention is less effective and more costly than at least one of its comparators, it is not for further consideration with regard to the estimation of cost-effectiveness. Extended dominance is applied in incremental cost-effectiveness analysis when an intervention is less effective and more costly than a linear combination of two other strategies; the purpose is to remove from consideration those strategies whose costs and benefits are improved by a mixed strategy of two other alternatives [58]. The practical application of cost-effectiveness analysis is to compare an intervention with the next most effective strategy; failure to remove all dominated or extendedly dominated strategies may lead to comparisons that are not with the next best alternative but with irrelevant alternatives.

In the base case analysis, the estimation of costs relating to the UK National Health Service (NHS) will be based on responses to health care resource use questions within the 6-month and 12-month postal questionnaires; responses will be aggregated to generate a 12-month cost estimate for each responder. The resource use questions will capture details covering a broad range of health care resources, including prescribed medications, primary care and secondary care (inpatient and outpatient) attendances, treatments and investigations. The primary unit of benefit is the quality-adjusted life year (QALY), calculated by applying area-under-the-curve techniques to EuroQol EQ-5D index scores at baseline, 3 months, 6 months and 12 months [59]. The EQ-5D is a generic health status measure that provides utility values for all possible responses to the 5-dimension questionnaire based on health state valuations elicited from a large representative sample of the UK population [60]. The values range from 1.00 (no problems on all dimensions) to -0.59 (severe or extreme impairment on each dimension). Accordingly, the maximum number of QALYs per patient is equal to 1 (equivalent to 12 months spent in full health), with QALYs less than 1 reflecting less than perfect health. Following the identification of appropriate pair-wise comparisons through extended dominance principles, differences in costs and QALYs will be expressed using the incremental cost-per-QALY ratio. This ratio measure provides an estimate of the additional cost necessary to generate one additional QALY. Multiple imputation techniques will be used to deal with missing EQ-5D scores and resource use data, ensuring that all eligible trial participants are included in the base case economic evaluation [61,62].

Probabilistic sensitivity analysis will address uncertainty around the incremental ratio through the application of bootstrap techniques to generate cost-effectiveness planes and acceptability curves [63,64]. Further sensitivity analysis will explore the robustness of the results to variation in key parameters and methodological techniques; namely, the adoption of alternative costing methodologies (e.g. 'generic' verses 'hand OA-specific' health care resource use), a broader analytic perspective that incorporates costs beyond those attributable to the UK NHS, a complete-case analysis to consider the implications of missing data, and the impact of using different generic health status measures to provide utility values.

Trial monitoring

The research centre's independent Data Monitoring Committee (DMC) will monitor the study 6-monthly and reports will be written in line with Arthritis Research UK recommendations (http://www.arthritisresearchuk.org). The independent DMC has also agreed to act as the trial steering committee.

Research Ethics

Ethical approval was obtained from the Central Manchester Research Ethics Committee, UK on 21st February, 2008 [ref number 07/H1008/235]. Any subsequent amendments will be reported in the DMC reports.

Discussion

There is limited evidence for the clinical and cost effectiveness of OT approaches in the management of OA despite the important role that OTs play in the treatment of people with hand OA. Joint protection and hand exercises have been proposed by European guidelines for hand OA [13]. However, the clinical and cost effectiveness of each intervention and the combined approach is unknown.

This protocol outlines the SMOotH study, a multicentre two-by-two factorial randomised controlled trial in community-dwelling older adults. The aims are (i) to compare the effectiveness of joint protection delivered by an OT with no joint protection, (ii) to compare the effectiveness of hand exercise delivered by an OT with no hand exercises and (iii) to determine which of the four management approaches explored within the study (leaflet and advice, joint protection, hand exercises, or joint protection and

hand exercise combined) provides the most cost-effective use of health care resources.

Findings from this study will contribute to the cost-effective evidence based management of hand OA and to existing recommendations published by EULAR.

Role of individual parties

Principal investigator: Krysia S. Dziedzic; Study Coordinator: Susan Hill; Trial Statistician: Elaine Nicholls; Leader of the OT programme: Alison Hammond; Informatics Manager: Tracy Whitehurst; Centre Operations Manager: Jo Bailey; Health Economist: David G.T. Whitehurst, Sue Jowett; Trial Steering Committee and Data Monitoring Committee: Chris Roberts (Chair), James Selfe, Christina Jerosch-Herold and Richard McManus; Study Design: Helen Myers, Charlotte Clements, June Handy, Rhian W. Hughes, Elaine Thomas, Elaine M. Hay.

Abbreviations

AUSCAN: Australian/Canadian Osteoarthritis Hand Index; DMC: Data Monitoring Committee; EULAR: European League Against Rheumatism; GP: General Practitioner; NICE: National Institute for Clinical Excellence; OA: Osteoarthritis; OARSI/OMERACT: Osteoarthritis Research Society International/ Outcome Measures in Rheumatological Clinical Trials; OT: Occupational Therapy/Occupational Therapist; PT: Physiotherapist; RA: Rheumatoid arthritis.

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Authors' contributions

All authors participated in the design of the study and drafting the manuscript. All authors read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

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SMOotH

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Hand Exercises for Hand Osteoarthritis and Hand Pain

Hand Exercises
Work Book

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HAND EXERCISES

FOR HAND OSTEOARTHRITIS AND HAND PAIN

Further copies of this workbook are available from the Principal Investigator Dr Krysia Dziedzic and Dr Alison Hammond co-investigator and programme developer.

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13.6.08

If you have any questions about the **SMOotH** study, please telephone the study co-ordinator, **Sue Hill, on 01782 734706.**

WELCOME!

This programme is for people with hand osteoarthritis (OA) and **hand pain**.

The programme helps you learn how to do hand exercises to help you in managing any hand problems. There are 4 meetings of about 1 hour each. Each workshop is a mix of short talks and exercise practice. **The meetings are fun!** People say they really enjoy them and time flies by. We look forward to seeing you!

Hand Exercise Programme

We focus on:

- What is hand OA and
- Keeping hands mobile

We discuss what hand pain and hand OA are and focus on:

- Hand exercises; keeping your hands more mobile is vital because we use our hands for almost everything we do.

This workbook shows you how to do the exercises. People who do regular exercise have less pain, joint stiffness and better ability to do everyday activities.

We hope you enjoy it – it's up to you to make the most of it!

PURPOSE OF THIS WORKBOOK

Read the workbook in the days following each meeting. This helps you to remember key points discussed and new methods we try. The weekly home programmes help you to put what you learn into practice. The more time you are able to put into doing your home programme now, the quicker the changes will be and the more benefits you gain.

By following the programme and completing the workbook you will:

- Have a clearer understanding of your hand problem.

- Be able to do a regular hand exercise programme to keep your hands mobile. Regular hand exercises will help improve grip strength and dexterity.

The programme and workbook help you to gradually develop a hand exercise routine over the 4 weeks of the programme and beyond.

We know people who make these changes have:

- Less pain
- Less stiffness
- Less frustration
- And can do everyday tasks more easily.

But YOU need to do these exercises OFTEN ENOUGH for them to work. Do them regularly, not just when in pain. Don't think "I'll do that later, I'm not that bad yet."

We will take a step-by-step approach to helping you make changes.

Feel free to ask any questions you want to during the programme and we will try our best to help.

USING THIS WORKBOOK

The main points from each meeting are here in this workbook.

- After each meeting, please **do read through the notes for that session.**
- At the end of each meeting's notes is the "Home Programme" to help you follow the exercises. It also helps you check your progress.

Please keep the workbook as a resource for the future.

CONTENTS:

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MEETING 1:

What is hand OA and hand pain?

Making a start……

MEETING 1: What is Hand OA? Making a start…

Osteoarthritis (OA) is a condition causing joint pain. It can lead to difficulties doing everyday activities and can affect your quality of life.

- OA is the commonest form of arthritis in the UK.
- It is one of the leading causes of pain and disability worldwide.
- OA is **not** caused by ageing.
- It does **not** necessarily get worse.
- OA is slow to develop. It can change the structure of joints.
- Joints can still be symptom-free despite OA.

Recommended reading:

Read the Arthritis Research UK booklet "Osteoarthritis"

- Particularly sections on how joints are affected (pages 2-7) and hand OA (page 11)

OA most often affects hands. OA in your hands affects the joint and surrounding tissues (eg the joint capsule, ligaments). It may cause pain, stiffness and limited movement. Occasionally, joints get inflamed (that is red, swollen and more painful). How bad symptoms are varies a lot. Pain and other symptoms often flare up and settle back down again.

Young people as well as older people have OA. It may occur in more than one joint at a time. The hips, knees and the lower part of the spine are also often affected. Shoulders, elbows, wrists and feet can be affected too, but this is less common.

Many people think OA is just part of getting older. They think OA always gets worse and can't be treated.

- OA does **not** always get worse as you get older.
- There **are** treatments available and changes to your lifestyle that you can make to help ease the pain and symptoms.

The **arc** booklet explains about the process of OA. It can be caused by a number of factors. OA is actually a repair process. Cartilage may be lost and bone may change shape. If the repair process is successful, the joint may change in shape and structure but is symptom-free.

Additional information:
The NICE guideline (National Institute for Health and Clinical Excellence) **for Osteoarthritis** summarises the treatment, advice and support that people who have OA should be offered. The website is in appendix 2 on page 46.

The effects of OA and what you can do

There are many different possible effects of OA. They can all interact to make each problem worse. See chart 1 overleaf. There are lots of lifestyle management strategies to help reduce these. Using a wide range of these means you are more likely to increase your physical activity, live successfully with your OA and reduce long-term problems.

Why make changes?

Hand Exercises help you do everyday activities with less pain. You will need to make changes in your lifestyle to do these exercises. Ask yourself: **is it worth it for you to use exercises?** It can help you to think about WHY it could be useful to exercise in your daily life. How we spend our days helps give us meaning and enjoyment to life. Sometimes we do things because we have to. But we also need a balance of things we want to do, enjoy doing, and get satisfaction out of as well. Joint pain and OA can upset that balance. Think about: **what things are important for you to do in life?** Do you have any problems doing them because of your hand problems?

Are any of these making it difficult to do things in life you want to do?

	Tick below
Pain	
Fatigue / tiredness	
Limited mobility / fitness	
Stiffness	
Any other?	

If you have problems with any of the above, hand exercises can be of benefit to you.

Making changes

The commonest joints affected by OA are the hands (fingers and thumbs). This programme particularly looks at avoiding or limiting hand problems, but you can apply the principles learnt to problems with any other joints.

Chart 1: **MANAGING HAND PAIN AND OA SUCCESSFULLY**

Respect pain

Follow any pain medication prescriptions

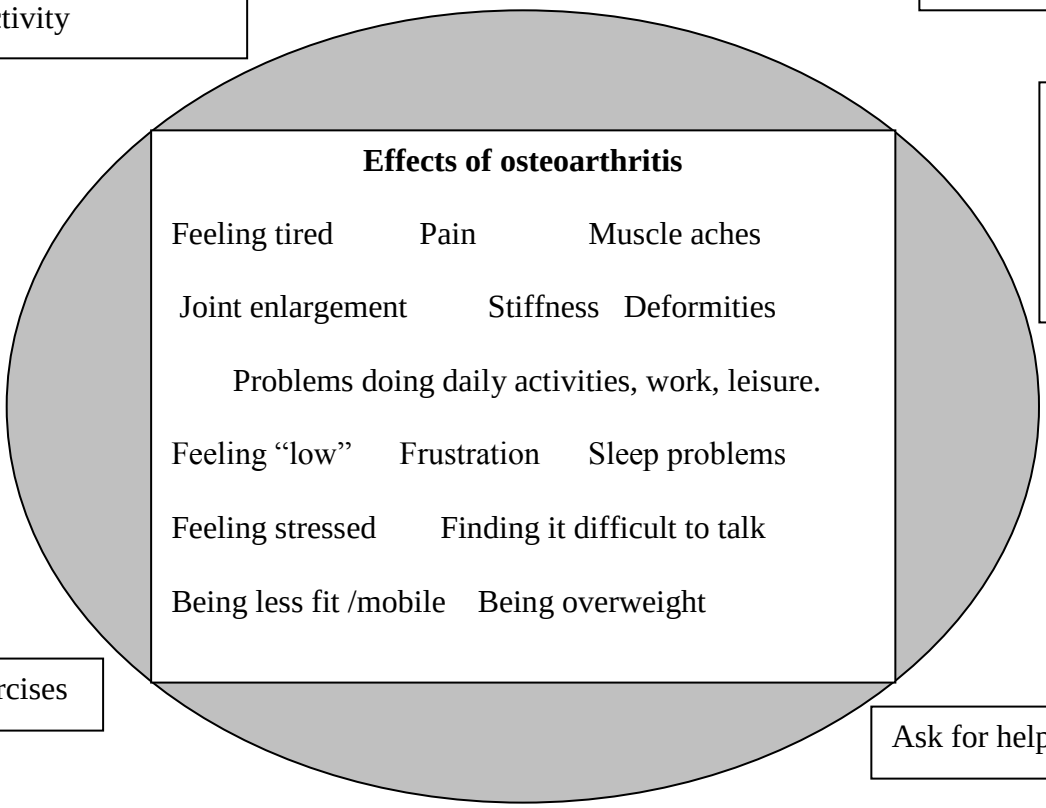
Managing pain and fatigue:
- use of heat and cold
- planning

Using painkillers and non-steroidal anti-inflammatory gels

Learn more about osteoarthritis and helping yourself

Take up new hobbies and social activities to increase physical activity

Pain management methods



For hip and knee OA: wearing insoles/ good supportive shoes

Hand exercises

Ask for help appropriately

Get a good night's sleep

Learn to relax effectively

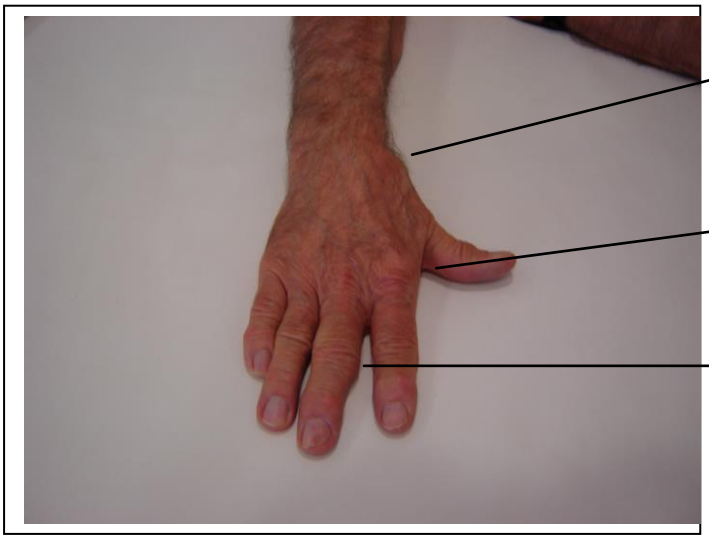
Healthy eating

Exercise:
Look good and feel good!

Have some fun and laugh!

Alternative/ complementary therapies

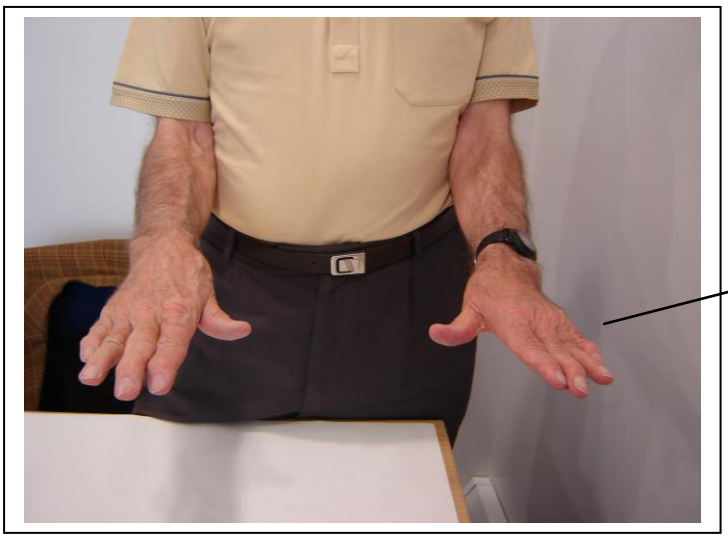
These pictures show some changes people with hand OA can develop:



"Squaring" of the thumb

Loss of "web space"

Finger joints "knobbly"



Finger joints may buckle

It is **making the change** – putting the exercises into practice – that is the main aim of these meetings. The home programme helps you make these changes. **It is up to you** to carry out the advice given or the programme can only be of limited benefit.

HOME PROGRAMME – MEETING 1.

1. During the week think about how your hand pain / hand OA is affecting you.

    - Is it worth it for **you** to change?

2. Start some gentle hand exercises for the wrists and fingers (as discussed today). See Appendix 1 on page 35 for guidelines.

3. Read the recommended reading from the **arc** booklet “Osteoarthritis”.

Appendix 2 lists other books and websites you may like to look at during the programme or in future.

MEETING 2:

Hand Exercises, Changing Habits

MEETING 2: Hand Exercises, Changing Habits

In the first meeting, we looked at how your hand movement is affected. Exercise is important. You need to move joints fully or they stiffen up and muscles weaken.

Changing habits and routines

It can be difficult at times to fit in hand exercises into daily routines. **There are 3 main stages to LEARNING NEW HABITS:**

1. **LEARNING**
   - Getting an "overall picture" in your mind of how to do the movement. We learn by watching demonstrations, hearing and reading instructions, seeing pictures, watching others and being physically guided.
   - We also learn by "mental rehearsal" (or visualisation) – imagining in our minds how to do the exercise, making this "overall picture" clearer. This is a very helpful way to get in extra practice and to learn the exercises faster.

2. **FIXING**
   - Developing the exercise skill until it feels comfortable and no longer awkward or clumsy. This stage needs:

     PRACTISE – as regularly and often as possible
     FEEDBACK – are you getting it right? You get this from….

   - Yourself: Watch what you do and tell yourself in your mind if you are doing it right or wrong and how to improve.
   - Others: The clearer the feedback, the quicker you correct yourself and do the movement properly.

3. **AUTOMATIC**
   - Doing the exercises automatically even whilst you are doing or thinking something else or being distracted. This takes MORE PRACTICE.

   Even when you think you're doing them, it may still only be part of the time. KEEP ON PRACTISING!

HAND EXERCISES

Many people with hand osteoarthritis, like you, slowly lose some movement in their hands. You may have problems with gripping and pinching. So it gets frustrating doing things. Regular hand exercises keep your hands as mobile as possible. They help strengthen hand muscles – making all your everyday activities that bit easier.

Exercise helps keep your joints moving. In meeting 1 we saw how joints are affected by hand OA. Muscles help support joints, but they too can weaken because of pain and osteoarthritis. Exercise keeps your muscles as strong as possible and joints moving as normally as possible.

- All the hand exercises are shown on **pages 34-43 in Appendix 1 towards the end of the workbook**, along with an exercise diary.

Starting out – range of movement/ flexibility exercises

Start doing the exercises **slowly.** Move your joints as far as feels comfortable to you - **do not force.**

Before you start you can optionally:

- Soak your hands for a few minutes in warm water first – helps relax muscles.
- If your thumb web space/s have got smaller: Gently press the muscles in the web space between the other thumb and index finger using a circular movement. This also helps relax muscles.

First week

1. Start with just 3 repetitions of each of the range of movement (or flexibility) exercises.

2. Do a steady "warm up:"
- First repetition: move your joint/s about 70-80% of how far you think it will go
- Second repetition: move to 90%
- Third repetition: stretch as far as you can comfortably go. Hold the movement at your "end of range" (that is, as far as the joint will go) for 3-5 seconds – see how you feel the next day.

3. No problems? Continue the exercises once a day *everyday* if possible - or at least 4-5 times a week.

4. If you feel any pain or discomfort, start off gently and do just one or two movements at first. Keep trying.

Second and later weeks

5. If 3 repetitions are easy – gradually BUILD UP EACH DAY over the next few weeks. Add on a 4^{th}, 5^{th}… up to 10 repetitions.

6. If you want to do the exercises a couple of times a day – this is fine. Build up your exercise to suit you.

Starting out - strengthening exercises

If you had no difficulty with the range of movement exercises on the first two or three days you tried these, add the strengthening exercises using the elastic bands or Play-Doh.

First week

1. Again start slowly, do only 3 repetitions. See how your hands feel the next day.

- If you have any pain or discomfort, continue with the range of movement exercises only for the first week (or two or three weeks as suits you).

2. Increase the number of repetitions doing exercises or time spent using Play-Doh as your hands get more used to exercising.

3. No problems? Continue the exercises every day or on most days.

- You can split the exercises up over the day. You don't need to do them all in one go.

This week's home programme suggests a schedule of hand exercises. This helps you build up week by week. When you are used to exercising, you will find you can easily do them whilst watching TV, during a break at work or home, in bed – whatever suits you.

- Do them more than once a day if you want to.

HANDY TIP: PLAY-DOH EXERCISES

When starting to exercise:

- Use a small portable kitchen timer (or your mobile phone) to set an alarm for 5, 10, or 15 minutes time (you decide).
- This means you won't accidentally get "carried away" and exercise for too long!

What do I do if I get any pain?

If you have any pain or discomfort:

1. First check if you have done anything unusual with your hands over the last few days. Maybe you over-strained them doing something else without being aware at the time. This should settle in a day.

2. Do all the exercises within your limit of discomfort. All exercises are difficult at first because our joints and muscles may not be used to being stretched so far and may be weak. Decide if what you are feeling is discomfort (muscle ache from exercise and stretching of muscles) or joint pain.

3. If it is joint pain (OA often varies from day to day) then take a rest from the exercises that day.

4. If you feel that you can't do an exercise on a particular day, or all of them, this is OK. Start the exercises again as soon as you can.

5. If your hand / or finger pains start during the exercises, just rest for 15-20 minutes and try again.

6. If after 2 hours the pains still remain, leave the exercises for that day and try again the next.

7. If the pains last until the **next** day, leave the exercises for that day, but try again the next.

8. Once the pain settles, restart the exercises. Start doing just the range of movement exercises. Do a few repetitions every other day. Build up again slowly.
Osteoarthritis may go through periods of flare-ups when joints are more stiff and painful. You may find that you need to reduce the number of repetitions you do and leave out the strengthening exercises if your hands are hurting more.

9. Use painkillers if you need to. Use heat / cold – see Arthritis Research UK Osteoarthritis booklet.

Exercise **cannot** damage your joints. Do them sensibly and carefully and "listen to your body." When your hands hurt - do less. When they are better, do more and add in the strengthening exercises.

Several short periods of exercise are better than one long session. Doing them for too long is more likely to cause aches and pains. Your muscles may not be used to that much activity. Once you get used to the exercises, spread them throughout the day.

- **The exercises are shown at the end of the workbook in Appendix 1**

Recommended reading:

You might be interested to read the Arthritis Research UK leaflet "**Keep Moving**". A copy of this is in your pack.

HOME PROGRAMME – MEETING 2

Try and do as much of this as you can. Spread it over the week. Most of the activities are quick.

1. Spend time “mentally rehearsing” or picturing the exercises in your own mind, that you are learning.

2. Start the hand exercise programme (see Appendix 1 for pictures) – just the range of movement exercises first. Add the strengthening exercises during the week **if** you can. (It’s OK to leave this to next week). Decide how often you think you can do the hand exercise programme and write your decision down below.

I AIM TO PRACTISE …… TIMES DURING THE WEEK.

There is an exercise diary in this workbook (Appendix 1, page 42) to help you track how often you do these.

MEETING 3:

Hand Exercise Practice

Making Changes: Goal-setting.

MEETING 3: Making Changes: Goals-Setting

CHANGING HABITS

For exercises to work, you need to put in regular, frequent practice for them to begin to feel natural and automatic to you. However, it's all very well to say "do it regularly at home" but this is not always so easy. There are many barriers, for example:

- Too busy, too much to do
- Too many demands from others at home and work
- Getting bored or forgetting
- Feeling there are too many things to change and it's impossible
- Not being sure you want to change.

Look back at the section on **Why Make Changes** in Meeting 1 (page 12). People move through different "**Stages of Change**" as they make any changes:

0 Not thinking of changing (eg not planning to use exercise)
1 Starting to think about change (if you are at this course – you're at least here!)
2 Deciding about your attitudes and beliefs towards exercise (will it work for you?)
3 Getting started.
4 Sticking with it.
5 Doing the exercises enough at an effective level
6 Looking out for and overcoming problems and barriers and keeping it up!

Hopefully now you are at Stage 2 – 3 and you want to make sure you keep moving along these stages. The barriers you face are very real problems. One way of motivating yourself to overcome these is to make an agreement with yourself, ie SETTING GOALS.

There are two types – long term and short term:

Long term goals:

These are general eg:

"I want to reduce the amount of pain or aching I have when working (at home or work) and feel less tired at the end of the day."
" I want to keep up my hobby / work…."

Whatever is important to you, look at the steps to help achieve this goal step-by-step. These are:

Short term goals:

The small steps that you need to make today and this week to help you on your way. They need to be **specific.** It helps to **write** an **ACTION PLAN.**

ACTION PLANS

To successfully exercise set yourself realistic goals each week.

1. **ASSESS** yourself honestly and start where you are. Be realistic about your current ability and the time you have to practise.

    - Start with something reasonable. Don't be over-optimistic. If you don't succeed you are more likely to give up. Any improvement is better than none! Build up slowly. Aim to change a few things at a time.

2. **ACTION** – be specific about what you will do. For example, practise the range of movement hand exercises.

3. **HOW MUCH** – will you do? For example, how many times will you do each hand exercise (3 repetitions?).

4. **HOW OFTEN** – will you practise these? For example, twice a day, 4 times a week. Give yourself time off. Don't feel you have to do the exercises everyday. That way if you have a bad day or are busy, you won't feel guilty.

5. **HOW SURE** – are you that you can do this? On a scale of 0 – 10 (with 0 totally unsure and 10 totally sure):

    - "How sure are you that you can complete this specific goal?"
    - "How sure are you that you can do the whole ACTION PLAN?"

    - If you score **7 or more** out of 10 – you probably will do it. If you score less – drop your plan down a bit until you feel sure.

6. Give yourself a reward for achieving your action plan!

A reward may be, for instance, a rest, a cup of tea and a biscuit when you have completed a goal. If you do all the things you planned to for the week – do something you find a treat. Give yourself a "pat on the back" – tell yourself how well you are doing by achieving these! Plan your reward ahead, so you have something to look forward to.

Some weeks you may do less than others – you may not be feeling so well, or there may be a lot of other things happening that week (or you are on holiday). Don't see this as a failure and a step backwards – keep on doing what you can realistically each week – **take things one step at a time.**

Make the Action Plan REALISTIC. Something you know that you could do, but is still a bit of a challenge. (How many New Year's resolutions have you broken in the past, because you bit off more then you could chew?)

There is an example of an Action Plan on the next page. Most of all, decide what is important for you to do.

Writing it down increases the chance that you will do it!

ACTION PLAN

Dates from: Monday_____ to: Sunday_____

The Plan:

1. Practise the range of movement hand exercises 3 times each for 3 days
2. Practise with Play-Doh 5 mins on 3 evenings
3.
4.

I am sure I can complete this plan (circle):

0 1 2 3 4 5 6 (7) 8 9 10
(not at all sure) (totally sure)

When I complete the plan, my reward will be:

Put feet up with a cappuccino and a biscuit!

How well did I do with my plan?

The home programmes so far have already partly set goals for you.

This week set your own goals. When the meetings finish, keep setting goals weekly for yourself so you keep making changes, until you feel the hand exercises are now habits.

HOME PROGRAMME – MEETING 3

Some ideas to try this week are:

1. Mentally rehearse (or practise in your mind) doing the flexibility hand exercises a few times.

2. Continue to practise the hand exercises – use the exercise diary **(Appendix 1)** to keep a record.

3. Decide on your own goals for practice. Some ideas are:

    - doing the range of movement hand exercises 5 times a week
    - doing the strengthening exercises 3 times a week
    - decide how often works best for you…..

Write down your own goals in the ACTION PLAN overleaf for the next week, check how sure you are you will do them – and of course, complete your plan!

ACTION PLAN

Dates from:_____ **to:**_____
The Plan:
1. _____ 2. _____ 3. _____ 4. _____ 5. _____
I am sure I can complete this plan (circle):
0 1 2 3 4 5 6 7 8 9 10 (not at all sure) (totally sure)
When I complete the plan, my reward will be: _____ _____
How well did I do with my plan?

MEETING 4:

Review

Continuing To Make Changes

MEETING 4: Review. Continuing to Make Changes

Remember:

Exercise and rest are complementary.

When your muscles, which help protect and move weakened joints, are tired then more strain is put on your joints. This can cause increased pain.

- Taking short rests helps muscles and the joint support structures (capsules and ligaments) to “recover” from daily strains.
- Exercise helps improve your muscle strength and helps support your joints. “Fitter” muscles tire less easily.

CONCLUSION

This is the last meeting in this programme. On the following pages you will find the last home programme. There are a number of Action Plan sheets and Exercise Diary sheets in **Appendix 3**. Please do use them to help you keep practising what we have tried in this programme.

Good luck with the Action Plans!

HOME PROGRAMME – MEETING 4

Some suggestions for you to try…

1. Decide on your own goals to practise for the next week for hand exercises……. Practise using mental rehearsal too if you found this helps.

2. **Write your Action Plan** - use the diary sheets too if you want to record how well you do with your goals.

3. Continue to make a weekly Action Plan for at least a further 4 weeks. As the weeks go by, the exercises become more of a habit. You will find – your Action Plan changes as you don't need to consciously practise any more – they have just become new habits.

4. Finally, go through this Workbook again in a month's time. Look through all the exercises we have practised. Are they automatic now? How do your hands feel? Improved strength and movement?

Action Plans help you make a contract with yourself that you are less likely to break.

We wish you all the best.

The SMOotH Study Team

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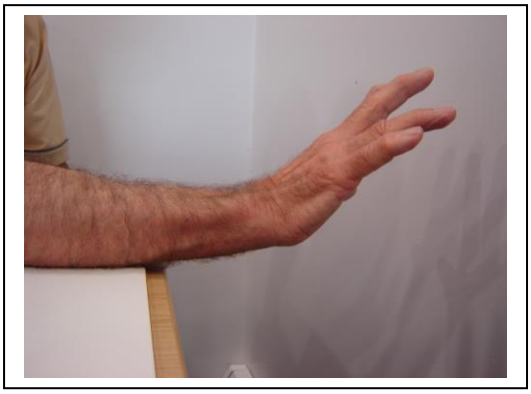
APPENDIX 1

Hand Exercises and Hand Exercise Diary

HAND EXERCISES: Range of movement (or flexibility) exercises.
(Read pages 16-21 before you start the exercises first time).

1. Keep wrists mobile



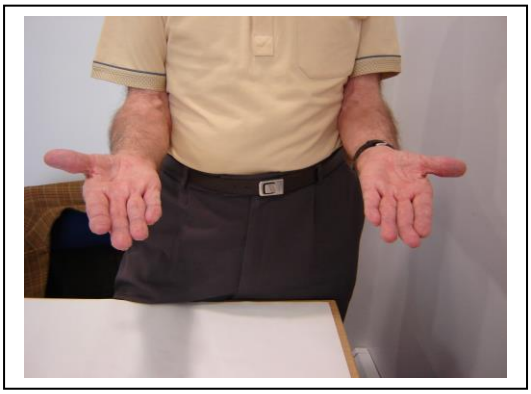
For part (a) and (b), you may find it easier to support your forearm on the arm of a chair or over the edge of a table – make sure the wrist can move freely.

a. Lift your wrist up, until you feel a gentle stretch. Hold for 3-5 seconds. (Do both hands at the same time if you want to. Your fingers can be bent or straight).

b. Then bend your wrist down towards the floor, until you feel a gentle stretch. Hold for 3 - 5 seconds. (Do both hands at the same time if you want to).

Repeat these two wrist movements x 3 in the first week. Increase to x 5 in the second week. Then up to 10x over over next few weeks.

c. Put both hands **and forearms (up to your elbows)** flat and well supported on a table in front of you. (Or tuck elbows into sides if sitting / standing). Keep your palms as flat (face down) on the table as you can – hold for 5 seconds. (Give your thumb a stretch out at the same time).

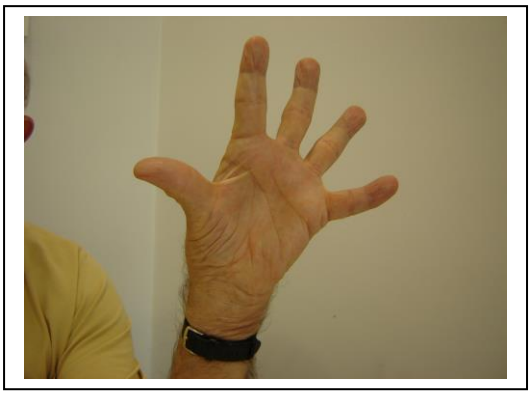


d. Keep your elbows / forearms on the table (don't lift them off or lean sideways) and bring your palms face up (feel the stretch). Bring your thumbs down to the table as far as you can. Hold for 3-5 seconds.

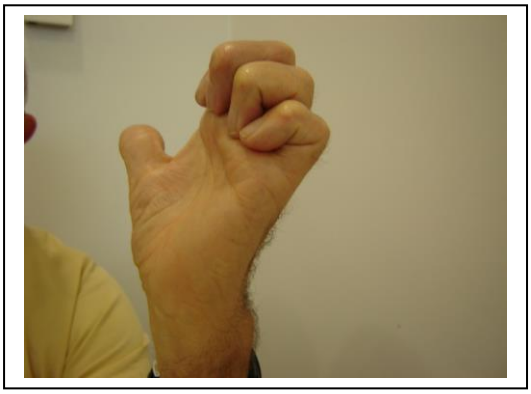
Repeat these two palm actions x 3 in the first week. Increase to x 5 in the second week. Then up to 10x over next few weeks.

HAND EXERCISES: Range of movement exercises.

2. Stretch and slow close



a. Stretch your hand out – hold for 3-5 seconds.

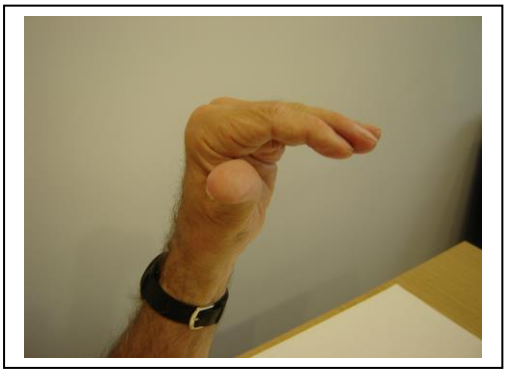


b. Bring your fingers together. Then roll down your fingers (keeping the knuckles straight – just bending at the middle finger joints). Feel the gentle stretch and hold for 3-5 seconds. (If it's hard not to bend the knuckles, then try keeping them straight with your other hand).

c. Roll fingers down to a full fist – wrap your thumb across the top - feel the stretch and hold for 3-5 seconds.

d. Unroll your fingers, and make a Γ shape at your knuckles – knuckles bent at 90° and fingers held straight out.

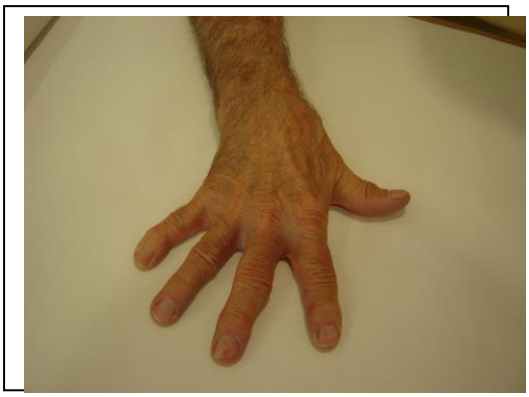
Then go back to (a) above – stretch out your hand.



Do this x 3 in the first week and x 5 in the second week. Then up to 10x over next few weeks.
Repeat this with the other hand.

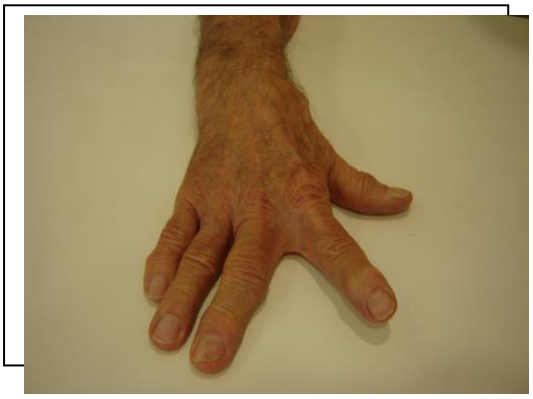
HAND EXERCISES: Range of movement exercises.

3. Finger walk to thumb

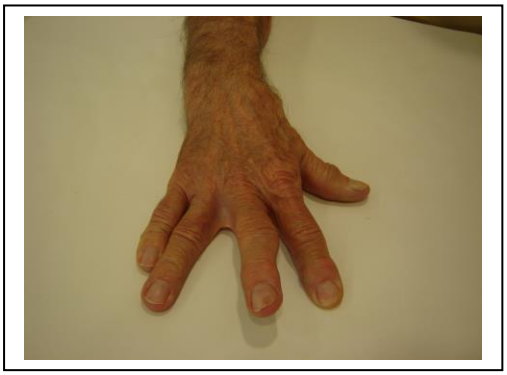


a. Put your hand flat on a table in front of you. Stretch your thumb and fingers as far down at the side as you can – hold for 3-5 seconds.

NOTE: The following is a difficult exercise, which needs practice…..

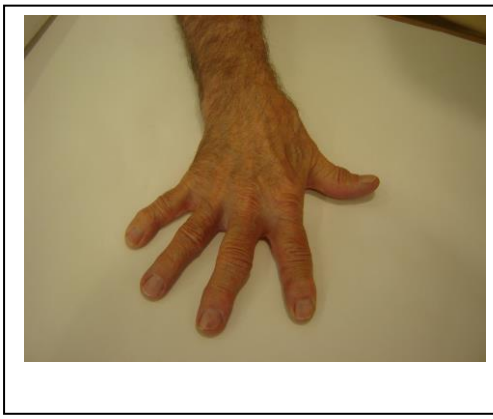


b. Keeping your hand flat on the table throughout – lift the index finger only up off the table – hold it for 3-5 seconds – and "walk" it across towards your thumb.



c. Then lift your middle finger off the table – hold for 3-5 seconds – and "walk" it towards the thumb.

d. (Not shown). Repeat with your ring finger. (This is really hard even if you don't have OA – so don't worry if you can't do it).



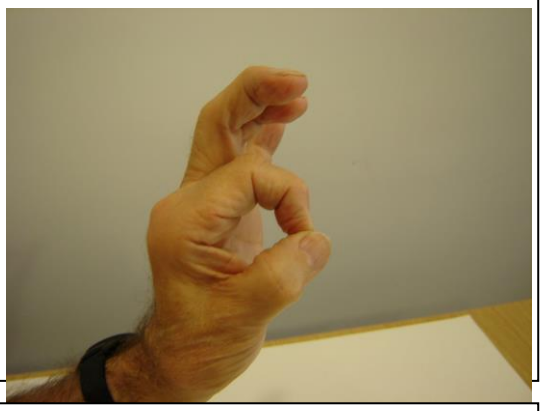
e. (Not shown). Lift your little finger off the table – hold for 3-5 seconds – and "walk" it across towards your thumb.

f. **Finally** lift your hand off the table and put it back down flat to start again. (Never walk your fingers back towards the little finger).

Do this x 3 with each hand, increasing to x 5 (to a maximum of 10).

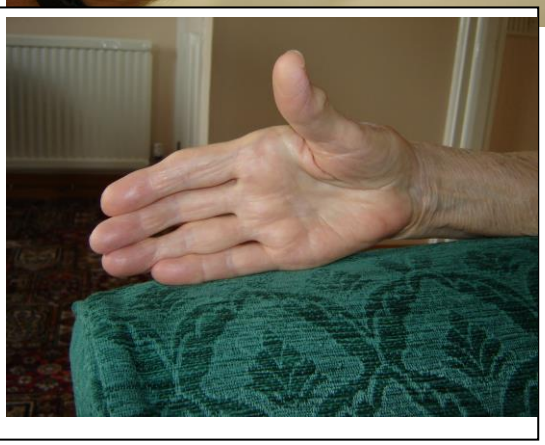
HAND EXERCISES: Range of movement exercises.

4. All thumbs

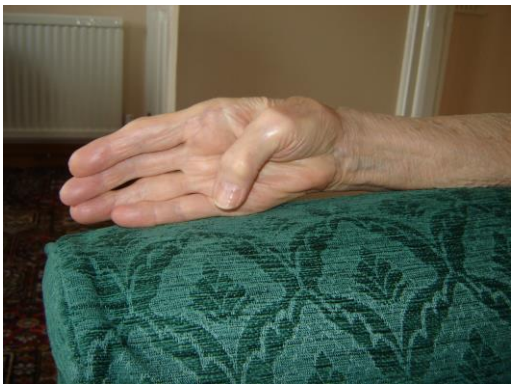


a. Touch the thumb to tip of each finger in turn.

b. Touch thumb to base of 5th finger.



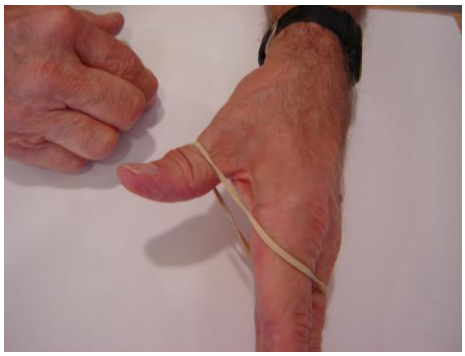
c. Stretch the thumb up to "hitch- hike".



d. Stretch and swing thumb out and down to touch surface resting on. Keep fingers straight and supported.

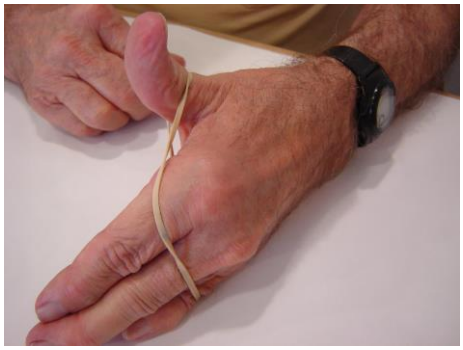
HAND EXERCISES: Strengthening

5. Elastic band – thumbs and fingers



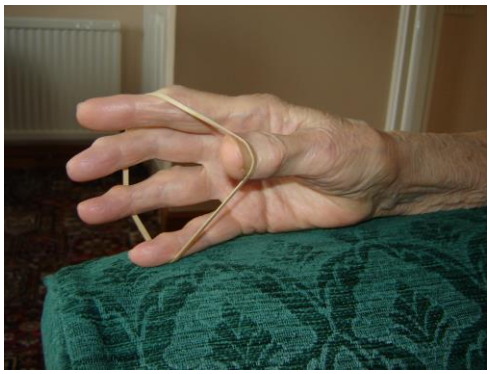
a. With a medium sized elastic band – loop it round the hand (just above knuckles) and over the thumb.

b. Stretch your thumb down, then out to the side.



c. Then bring it up – hitch-hiking.

Start again – just do a few times.
(Make sure the band isn't too strong – just a bit of resistance is needed).

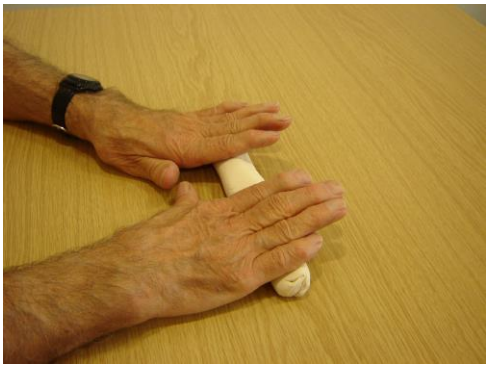


d. Loop band round thumb and fingers. Stretch all of them apart. Repeat.

HAND EXERCISES: Strengthening

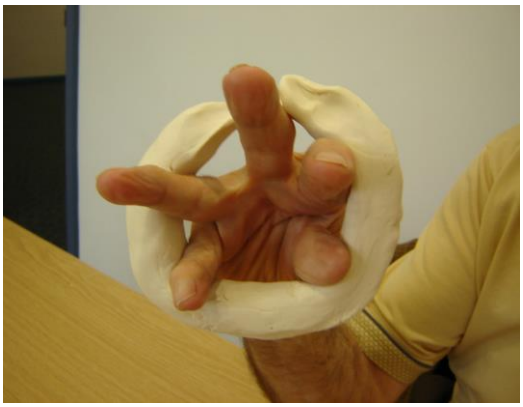
Using Play-Doh – do this on a table or a tray on your lap. Take care it doesn't get on your clothes! Use a small portable kitchen timer to set yourself an alarm for 5 or 10 minutes so you don't do it for too long.

6. Putty roll



a. Using some Play-Doh, roll it out into a sausage shape on a table. Feel your fingers stretch as you push down and forward on the Play-Doh.

b. Straighten and lift up your fingers as much as you can as you push and pull. Swap hands and then use two hands to roll out as the sausage gets longer, until its about 8-9 inches long.



c. Loop the sausage round to form a circle (you need to overlap the ends by 2 –3 inches or so, and squash the ends firmly together – or your loop will break too soon).

d. Put your fingers through the middle of the circle and stretch your fingers out straight – until your loop breaks.

e. **Gently** squeeze the Play-Doh alternately between your hands into a ball shape. Stretch each hand out between each squeeze. Only do this for short periods at a time (eg few minutes) as your hands may ache if you overdo this. Don't twist your fingers as you squeeze – just mould gently into a ball shape.

f. Pinch the Play-Doh between the thumb and index fingers.

Repeat all the exercises with the other hand.

Do each x 3 first week; x 5 second week – increase up to 10 x as it gets easier.

HAND EXERCISES: Strengthening

7. Wrist strengthening

Just the same as “keep wrists mobile” – but with a light weight.

You can use:
- a light exercise weight (0.5 – 1lb, or up to 0.5 kg)
- a can or a small drinks bottle (water or soft drink).

a. Support the forearm for comfort if you want to.

b. Lift the wrist slowly up and down.

c. Repeat x 3 in first week, x 5 in second week, up to a maximum of 10 x afterwards each time you exercise.

d. Turn the wrist over, and repeat bringing the wrist slowly up and down. Repeat x 3 in first week, x 5 in second, up to 10 x maximum each time you exercise.

e. Look for drinks bottles with a “waist” as a narrower bottle is easier to hold.

A 500cl bottle weighs 0.5kg (or about 1lb) is just right. If too heavy just pour some water out. Add it back in as you improve. If too light, replace the water with sand.

HAND EXERCISE DIARY

Range of movement / flexibility exercises:

- Week 1: do 3-5 days a week – 3 repetitions.
- Week 2: do 5-6 days per week, increase to 5 repetitions if possible.
- Week 3 onwards: increase to daily if possible, and slowly build up to a maximum of 10 repetitions.

You can spread the exercises out in the day.

Strengthening exercises:

- Week 2: do on 3 days a week.
- Week 3: build up to 5 days a week, and slowly build up to a maximum of 10 repetitions.

If you find the exercises easy, build up the repetitions and days more quickly. If you can't do as many, then do what is comfortable. Everyone is different and OA changes over time. The more you can do the more benefit you gain.

Tick for each time you practise – note the number of repetitions you can do

DAILY RECORD WEEK:	S	M	T	W	Th	F	S	TOTAL
1. Flexi Strength								
2. Flexi Strength								
3. Flexi Strength								
4. Flexi Strength								
5. Flexi Strength								
6. Flexi Strength								
7. Flexi Strength								
8. Flexi Strength								

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Appendix 2

Further Information

APPENDIX 2: FURTHER INFORMATION

BOOKS

You should be able to order these from any library or good bookshop with a book ordering service. If you have difficulty, try www.amazon.co.uk online. New editions are published every few years – so check if there is a newer edition since the time of writing this workbook.

1. Kate Lorig and James Fries (2006). **"The Arthritis Helpbook: a tested self-management method for coping with arthritis and fibromyalgia."** Sixth edition. Perseus books (Cambridge, Massachusetts, USA).
   - Lots of practical advice

2. Bird H, Green C, Hamer A et al (2006). "**Arthritis: Improve your health, ease pain and live life to the full."** Dorling Kindersley.
   - Lots of practical advice, well-illustrated

3 Arthritis Foundation (2005). **"The Arthritis Foundation's Guide to Good Living with Osteoarthritis."**

4. Arthritis Foundation (2001). **"Tips for Good Living with Arthritis."**

ARTHRITIS CHARITIES

Arthritis Research UK:
Arthritis Research UK produce a wide variety of information leaflets and a quarterly magazine "Arthritis Today" which has lots of practical information as well as up to date information about research and treatment for arthritis. You can download all their information sheets and booklets from their website or write to them direct requesting an order form to receive these by mail:

Arthritis Research UK
PO Box 177
Chesterfield
Derbyshire S41 7TQ

www.arc.org.uk

Arthritis Care

Also produce a wide range of very useful information leaflets/ booklets, all downloadable from their website as well as available free by writing to:

Arthritis Care
18 Stephenson Way
London NW1 2HD
Telephone: 07834 418457
www.arthritiscare.org.uk

If you would like to hear more about other people's experiences of living with osteoarthritis – and you have access to the internet – go to their website

- Click on the video diaries link.

Several of the diaries are made by people with osteoarthritis.

They have a regular magazine with practical tips and information. They also run an excellent arthritis education programme nationally called "Challenging Arthritis". If you want to have a "refresher" or simply another chance to meet others with arthritis and swap ideas – these are very positive programmes – well worth going to. They are run by people with arthritis. Arthritis Care is often looking for people willing to train to run these programmes. Get in contact.

NHS Direct:
NHS Direct provides information and advice about health, illness and health services, to enable patients to make decisions about their healthcare and that of their families. NHS Direct delivers telephone and e-health information services day and night direct to the public. Over two million people now access NHS Direct every month. For health information and advice, contact NHS Direct on 0845 4647 or www.nhsdirect.nhs.uk

Local support groups
Both Arthritis Research UK and Arthritis Care have a network of local branches, which do a variety of activities, including self-help groups, regular information meetings and/or fundraising. Please contact the charities to find details of groups local to you – or ask the programme leader who can give you details.

NICE: National Institute of Health and Clinical Excellence
This national organisation produces guidelines for health professionals in how to assess, treat and manage osteoarthritis. If you are interested in further information, the guidelines can be found at:

http://publications.nice.org.uk/osteoarthritis-cg59/guidance

Arthritis Foundation – USA

www.arthritis.org
This website has a wealth of information on arthritis. Lots of practical tips sections can be found under the Resources section, including advice on managing work, relationships, practical tips on managing everyday activities. There is also a wide range of publications as well as on-line brochures you can download.

In future the site may have an on-line arthritis self-management programme available – so keep an eye out for what develops on the site.

The Arthritis Society – Canada

The website contains lots of practical "Tips on Living Well" with Arthritis. For example in the "Managing Daily Activities" section there are lots of practical ideas on Looking After Joints
www.arthritis.ca

If you are still working and need help at work:

There are some good booklets published with advice on helping people with arthritis stay in work. One is published by the National Rheumatoid Arthritis Society. **Although it has rheumatoid arthritis in the title, the advice is just the same for people with osteoarthritis**.

"I want to work: a self-help guide for people with rheumatoid arthritis."

Available from
National Rheumatoid Arthritis Society
Unit B4 Westacott Business Centre
Westacott Way
Littlewick Green
Maidenhead
Berkshire
SL6 3RT
www.nras.org.uk

Appendix 3

Spare Action Plan Charts and Exercise Diaries.

ACTION PLAN

Dates from:_____ **to:**_____
The Plan:
1. _____ 2. _____ 3. _____ 4. _____ 5. _____
I am sure I can complete this plan (circle):
0 1 2 3 4 5 6 7 8 9 10 (not at all sure) (totally sure)
When I complete the plan, my reward will be: _____ _____
How well did I do with my plan?

ACTION PLAN

Dates from:_____ to:_____

The Plan:

1. _____

2. _____

3. _____

4. _____

5. _____

I am sure I can complete this plan (circle):

0 1 2 3 4 5 6 7 8 9 10
(not at all sure) (totally sure)

When I complete the plan, my reward will be:

_____

_____

How well did I do with my plan?

ACTION PLAN

Dates from:_____ to:_____

The Plan:

1. _____

2. _____

3. _____

4. _____

5. _____

I am sure I can complete this plan (circle):

0 1 2 3 4 5 6 7 8 9 10
(not at all sure) (totally sure)

When I complete the plan, my reward will be:

_____

_____

How well did I do with my plan?

ACTION PLAN

Dates from:_____ **to:**_____

The Plan:

1. _____

2. _____

3. _____

4. _____

5. _____

I am sure I can complete this plan (circle):

0 1 2 3 4 5 6 7 8 9 10
(not at all sure) (totally sure)

When I complete the plan, my reward will be:

_____

_____

How well did I do with my plan?

EXERCISE DIARY (Tick for each time you practise)

WEEK	S	M	T	W	Th	F	S	TOTAL
1. Flexi Strength								
2. Flexi Strength								
3. Flexi Strength								
4. Flexi Strength								
5 Flexi Strength								
6. Flexi Strength								
7. Flexi Strength								
8. Flexi Strength								

EXERCISE DIARY (Tick for each time you practise)

WEEK	S	M	T	W	Th	F	S	TOTAL
1. Flexi Strength								
2. Flexi Strength								
3. Flexi Strength								
4. Flexi Strength								
5 Flexi Strength								
6. Flexi Strength								
7. Flexi Strength								
8. Flexi Strength								

EXERCISE DIARY (Tick for each time you practise)

WEEK	S	M	T	W	Th	F	S	TOTAL
1. Flexi Strength								
2. Flexi Strength								
3. Flexi Strength								
4. Flexi Strength								
5 Flexi Strength								
6. Flexi Strength								
7. Flexi Strength								
8. Flexi Strength								

S1 – DESCRIPTION OF THE OCCUPATIONAL THERAPY TRAINING

Twelve OTs attended a two-day training programme led by Professor Alison Hammond. A range of theories and approaches shaped intervention delivery including: Social Cognitive Theory[35]; the Health Belief Model[36,37]; Self Management and Self Regulatory Theory[38]; effective communication, education and skills teaching strategies[39,40]; Motor learning theory[41]; and included effective features of self-management education[19-22]; specific training on joint protection methods and exercises for hand OA; and the latest research evidence on the presentation of hand OA in the community[5,6]. Sections of the programmes were role-played with OTs acting as both leaders and participants to experience the educational-behavioural methods used. To standardise delivery a leader manual and teaching materials were provided for each intervention, along with additional study materials to support OTs understanding the interventions and education methods. Manuals for patients and health professionals are available on request from the authors. All OTs were trained to deliver both interventions (joint protection education, instruction on hand exercises).

S2 – STATISTICAL ANALYSIS

Treatment models were initially fitted to the primary and secondary outcome measures to include the two main effects of interest - no joint protection versus joint protection; no hand exercises versus hand exercises - and their interaction, adjusted for baseline values of the outcome of interest (except for measures derived using the global rating of improvement), and pre-defined potential confounders (age, gender, social class (coded as manual, non-manual, self-employed[42]), length of time with a hand condition and general practice (a priori covariates which might influence treatment outcome)).

The interaction term was then tested for statistical significance (to test the assumption of independence of treatment effects) and if null ($p \geq 0.05$) the interaction was dropped from the model and the model re-run to determine the main treatment effects for joint protection and hand exercises. If the interaction term was found to be statistically significant ($p<0.05$), the effect of joint protection and hand exercises was evaluated from a model with treatment represented as a 4-level variable (i.e. leaflet and advice (L&A), joint protection (JP), hand exercises (HEx), joint protection and hand exercises (JP&HEx)), with the effectiveness of the individual treatments compared to the leaflet and advice arm.

S3 – STRATEGY TO IMPUTE MISSING DATA

Multiple imputation was used to impute missing data at all time-points for the variables shown in table 4 and for the adjusting baseline covariates included in the treatment models. An imputation model was fitted using Multiple Imputation by chained equations (MICE) in STATA version 12.0[30] and included 25 imputed datasets. Twenty five imputed data sets were derived so that the number of imputations exceeded the overall percentage of missing data in the data[43]. Despite not having any missing data, the treatment main effects and their interaction were also included in the imputation model. This was because they were analysed in the treatment models derived from the imputed data. The imputation model included continuous outcome measures that were modelled using predictive mean matching (nearest neighbours = 1[44]) and ordinal outcomes that were modelled using ordinal regression. Predictive mean matching was chosen so that the imputed values remained on the same scale as their original outcome and because this method is particularly suited to modelling skewed data[43]. As some of the ordinal response options were of low frequency, the augment option in STATA was used to avoid the problem of perfect prediction[44], however, despite this, the categories of "completely recovered" and "much better" on the global assessment of change outcome still needed to be combined for the model to run. After the imputation model had been applied to the data, Rubin's rules[44] were used to combine treatment effects (and their associated standard errors) across the imputed data sets to provide a single estimate of treatment effect for each analysis outcome.

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Table S1: Baseline characteristics of participants who responded[||] at each follow-up time point

Characteristic	Baseline N=257	3-months N=232	6-months N=218	12-months N=219
Demographic data				
General practice				
A	16 (6)	12 (5)	13 (6)	14 (6)
B	39 (15)	36 (16)	33 (15)	34 (16)
C	67 (26)	63 (27)	63 (29)	60 (27)
D	62 (24)	56 (24)	53 (24)	53 (24)
E	73 (28)	65 (28)	56 (26)	58 (26)
Mean (SD): Age (years)	65.8 (9.1)	66.4 (9.2)	66.2 (9.1)	65.6 (9.0)
Female	170 (66)	152 (66)	147 (67)	149 (68)
Married	165 (65)	145 (63)	140 (65)	138 (64)
Routine or manual occupation[*,†]	121 (47)	107 (46)	96 (44)	103 (47)
Currently working	76 (30)	64 (28)	60 (28)	64 (29)
Mean (SD): Age when left school	16 (1.2)	16 (1.2)	16 (1.2)	16 (1.2)
Left school to go to full time education or university	41 (16)	37 (16)	37 (17)	35 (16)
Gained qualifications through study as an adult	126 (50)	113 (50)	111 (52)	112 (52)
General health and quality of life				
Body mass index >=25.0 kg/m^2 (overweight/obese)[‡]	169 (68)	150 (67)	143 (68)	143 (68)
Mean (SD): SF-12: Physical component (0-100)[*]	40.1 (10.7)	40.1 (10.7)	40.1 (10.7)	40.5 (10.6)
Median (IQR): SF-12: Mental component (0-100)[*]	53.4 (43.3, 59.2)	53.8 (44.5, 59.3)	53.8 (44.0, 59.3)	53.7 (43.9, 59.4)
Clinical characteristics of hand problem				
Pain in both hands in last 12 months	225 (88)	202 (87)	193 (89)	195 (89)
Median (IQR): Number of years with hand problem[*]	5.0 (2.0, 10.0)	5.0 (2.0, 10.0)	5.0 (2.4, 10.0)	5.0 (2.0, 10.0)
Mean (SD): AUSCAN - pain (0-20)[*]	9.4 (3.6)	9.3 (3.7)	9.3 (3.6)	9.4 (3.6)
Mean (SD): AUSCAN - stiffness (0-4)[*]	1.5 (1.0)	1.5 (1.0)	1.5 (1.1)	1.5 (1.0)
Mean (SD): AUSCAN - function (0-36)[*]	14.8 (7.6)	14.6 (7.6)	14.8 (7.5)	14.7 (7.4)
Mean (SD): AUSCAN - total (0-12)[*]	5.0 (2.2)	5.0 (2.2)	5.0 (2.2)	5.0 (2.2)
Mean (SD): Arthritis self-efficacy pain subscale (1-10)[*]	5.1 (1.8)	5.1 (1.8)	5.1 (1.8)	5.1 (1.8)
Mean (SD): Hand pain severity on average last 3 days (0-10)[*]	4.6 (2.0)	4.6 (2.0)	4.6 (2.0)	4.6 (2.0)
Mean (SD): Severity of main functional problem, on average, last 3 days (0-10)[*]	5.0 (2.4)	5.0 (2.4)	5.1 (2.4)	5.1 (2.4)
Mean (SD): Satisfaction with hand function last 3 days (0-10)[*]	4.8 (2.3)	4.8 (2.3)	4.8 (2.3)	4.8 (2.2)
Median (IQR): Grip strength (lbs)[*]	33.5 (22.5, 47.5)	33.5 (22.5, 48.0)	32.5 (22.0, 47.5)	32.5 (21.5, 47.5)

Mean (SD): Pinch strength (lbs)*	8.9 (3.4)	9.0 (3.4)	8.9 (3.4)	8.9 (3.4)
Median (IQR): Grip ability test (seconds)*	32.0 (26.5, 40.4)	32.1 (26.5, 40.7)	32.1 (26.0, 41.5)	32.1 (26.4, 41.3)
ACR criteria met §	230 (90)	208 (90)	195 (89)	194 (89)
Unilateral or bilateral thumb OA	210 (82)	193 (83)	182 (84)	183 (84)

Figures are numbers and percentages unless otherwise stated. Median (IQR) given for outcome measures with a skewed distribution. Total AUSCAN score calculated as (pain/5) + stiffness + (function/9). Abbreviations: SF-12 = Short Form Health Survey 12 (version 2), AUSCAN = Australian/Canadian Hand Osteoarthritis Index, ACR = American College of Rheumatology, OA = osteoarthritis. * = Data based on imputed data; † = Based on the "lower supervisory/technical", "Semi-routine" and "Routine" groups of the UK Standard Occupation Classification (2000) for current or most recent paid employment; ‡ = Body mass index grouping defined according to the World Health Organisation (WHO); § = ACR criteria based on clinical features only (symptom frequency assessed prior to clinical assessment); || = Responding is defined as participants who return the self-complete questionnaire or complete minimum data at the respective time point.

Table S2: Interaction effects for the primary outcome measure

	3-months		6-months		12-months	
	N (%)	Interaction coefficient (95% CI)	N (%)	Interaction coefficient (95% CI)	N (%)	Interaction coefficient (95% CI)
OARSI responder criteria						
Leaflet and advice (L&A)	8 (12)		14 (22)		9 (14)	
Joint protection (JP)	16 (26)		17 (28)		15 (24)	
Hand Exercises (HEx)	15 (23)	0.29 (0.07, 1.25)	13 (20)	1.81 (0.53, 6.22)	18 (27)	0.50 (0.13, 1.92)
Combined therapy (JP&HEx)	11 (17)		24 (37)		20 (30)	

Descriptive statistics based on unadjusted imputed data; interaction coefficients on adjusted imputed data (i.e. adjusted for age, gender, social class, length of time with a hand condition, general practice and the two main effects of interest. Interaction coefficients are odds ratios from logistic regression models; confidence intervals containing one are non-significant interactions. Abbreviations: CI = confidence interval

Table S3: Frequencies of the global assessment of change question (percentages estimated from imputed data)

Global assessment of change	No JP N=130	JP N=127	No HEx N=127	HEx N=130
3-months				
Completely better/much better	10 (8)	9 (7)	9 (7)	10 (8)
Better	29 (22)	36 (28)	20 (16)	43 (33)
No change	61 (47)	66 (52)	74 (58)	53 (41)
Worse/much worse	29 (22)	18 (14)	23 (18)	23 (18)
6-months				
Completely better/much better	9 (7)	11 (9)	6 (5)	14 (11)
Better	21 (16)	39 (31)	20 (16)	39 (30)
No change	62 (48)	55 (43)	69 (54)	48 (37)
Worse/much worse	38 (29)	20 (16)	32 (25)	27 (21)
12-months				
Completely better/much better	10 (8)	13 (10)	9 (7)	14 (11)
Better	23 (18)	33 (26)	20 (16)	36 (28)
No change	47 (36)	48 (38)	55 (43)	40 (31)
Worse/much worse	49 (38)	33 (26)	43 (34)	39 (30)

Figures are number (percentages).
JP = joint protection, HEx = hand exercise

Supplementary Table S4: Treatment fidelity

	3-months		6-months		12-months	
	No HEx	HEx	No HEx	HEx	No HEx	HEx
Hand exercise fidelity						
Last week, frequency of completion of a structured exercise program						
Never	47 (43)	11 (10)	46 (44)	8 (8)	35 (34)	11 (10)
Almost never	16 (15)	2 (2)	18 (17)	11 (11)	16 (16)	8 (8)
Sometimes	26 (24)	23 (20)	27 (26)	39 (37)	29 (28)	35 (33)
Fairly often	11 (10)	35 (30)	6 (6)	29 (28)	11 (11)	34 (32)
Very often	7 (6)	38 (33)	4 (4)	14 (13)	8 (8)	17 (16)
Always	3 (3)	6 (5)	3 (3)	4 (4)	3 (3)	2 (2)
Chi-square $(\chi^2)^1$ (d.f.=4)	χ^2 = 67.3; **p <0.001**		χ^2 = 50.6; **p <0.001**		χ^2 = 29.5; **p <0.001**	
Last month, number of times a week done exercises specifically designed for hand problems						
Never	α	α	38 (37)	15 (14)	37 (37)	12 (11)
Once a week	α	α	11 (11)	9 (9)	7 (7)	16 (15)
Twice a week	α	α	3 (3)	21 (20)	5 (5)	22 (21)
Three times a week	α	α	6 (6)	19 (18)	10 (10)	22 (21)
Four times a week	α	α	6 (6)	10 (10)	3 (3)	4 (4)
Five times a week	α	α	2 (2)	4 (4)	2 (2)	6 (6)
Six times a week	α	α	2 (2)	2 (2)	3 (3)	3 (3)
Once every day	α	α	19 (18)	12 (12)	19 (19)	11 (10)
Twice every day	α	α	17 (16)	12 (12)	15 (15)	11 (10)
Chi-square$(\chi^2)^2$ (d.f.=4)			χ^2 = 25.6; **p <0.001**		χ^2 = 34.2; **p <0.001**	
When doing hand exercises, how long do you spend doing them?						
Less than 5 minutes	α	α	44 (43)	30 (28)	37 (39)	29 (28)
Five minutes to less than ten minutes	α	α	24 (24)	38 (36)	25 (26)	47 (45)
Ten minutes to less than fifteen minutes	α	α	2 (2)	14 (13)	3 (3)	17 (16)
Fifteen minutes to less than an hour	α	α	1 (1)	8 (8)	1 (1)	0 (0)
Half an hour or more	α	α	1 (1)	2 (2)	0 (0)	1 (1)
I don't do hand exercises	α	α	30 (29)	14 (13)	30 (31)	11 (11)
Chi-square$(\chi^2)^3$ (d.f.=3)			χ^2 = 25.8; **p <0.001**		χ^2 = 25.1; **p <0.001**	
Joint protection fidelity						

	No JP	JP	No JP	JP	No JP	JP
Energy conservation/fatigue (1-6)[13,22]						
N	114	110	107	103	101	106
Mean (SD)	3.4 (1.2)	3.9 (1.0)	3.4 (1.1)	3.8 (1.0)	3.4 (1.1)	3.8 (1.1)
Adjusted[5] mean difference (95% CI)	0.40 (0.17, 0.63)		0.46 (0.23, 0.69)		0.39 (0.18, 0.60)	
p-value	**p=0.001**		**p <0.001**		**p <0.001**	
Joint protection use (1-6)[13,22]						
N	115	110	107	103	103	106
Mean (SD)	3.4 (1.1)	4.2 (1.0)	3.5 (1.2)	4.2 (1.0)	3.7 (1.2)	4.2 (1.0)
Adjusted[5] mean difference (95% CI)	0.73 (0.52, 0.93)		0.71 (0.48, 0.94)		0.50 (0.27, 0.72)	
p-value	**p <0.001**		**p <0.001**		**p <0.001**	
Carry on working through the pain when doing everyday activities[13,22]						
Never	5 (4)	3 (3)	5 (5)	3 (3)	1 (1)	3 (3)
Almost never	6 (5)	15 (14)	6 (6)	10 (10)	10 (10)	20 (19)
Sometimes	29 (25)	35 (32)	37 (35)	37 (36)	25 (24)	22 (21)
Fairly often	25 (22)	26 (24)	19 (18)	24 (23)	21 (20)	31 (29)
Very often	36 (31)	18 (16)	28 (26)	17 (17)	34 (33)	15 (14)
Always	14 (12)	13 (12)	12 (11)	12 (12)	12 (12)	15 (14)
Chi-square(χ^2)[4] (d.f.=4)	χ^2 = 8.2 (p=0.08)		χ^2 = 3.4 (p=0.5)		χ^2 = 14.0 (**p=0.007**)	

1 = Analysis categories: “Never”, “Almost never”, “Sometimes”, “Fairly often”, “Very often or always” due to small N
2 = Analysis categories: “Never”, “1-2 times a week”, “3-4 times a week”, “5-6 times a week”, “1-2 times per day” due to small N
3 = Analysis categories: “Never do hand exercises”, “< 5-minutes”, “5-10 minutes”, “10 minutes or more” due to small N
4 = Analysis categories: “Never or almost never”, “Sometimes”, “Fairly often”, “Very often”, “Always” due to small N
5 = Adjusted for the baseline for the outcome of interest and the main effect: No HEx vs HEx
α = Data not collected at the 3-month time point
Abbreviations: HEx = Hand exercises, JP = Joint protection. CI = confidence interval, d.f. = degrees of freedom. P-values <0.05 are highlighted

Table S5: Treatment effectiveness for primary and secondary outcome measures by main treatment effects – missing data not imputed

Outcome measure	3-months				6-months				12-months			
	No JP†	JP	No HEx†	HEx	No JP†	JP	No HEx†	HEx	No JP†	JP	No HEx†	HEx
OARSI responder criteria (%)												
N	115	107	112	110	108	108	107	109	100	102	94	108
N (%) meeting responder criteria	16 (14)	23 (22)	20 (18)	19 (17)	20 (19)	35 (32)	24 (22)	31 (28)	20 (20)	30 (29)	18 (19)	32 (30)
Adjusted odds ratio (95% CI)	1.76 (0.83, 3.73)		0.81 (0.39, 1.67)		2.61 (1.32, 5.15)		1.20 (0.62, 2.31)		1.91 (0.95, 3.83)		1.96 (0.98, 3.94)	
Global assessment of change (%)												
N	118	110	115	113	109	109	108	110	103	103	97	109
N (%) improved*	36 (31)	38 (35)	26 (23)	48 (42)	23 (21)	45 (41)	21 (19)	47 (43)	25 (24)	38 (37)	20 (21)	43 (39)
Adjusted odds ratio (95% CI)	1.15 (0.61, 2.17)		2.73 (1.44, 5.18)		3.49 (1.76, 6.92)		3.41 (1.75, 6.66)		2.20 (1.15, 4.22)		2.47 (1.29, 4.74)	
AUSCAN Pain (0-20)												
N	116	109	114	111	109	108	107	110	108	109	103	114
Mean (SD)	9.2 (3.4)	9.2 (3.0)	9.5 (3.4)	8.9 (3.0)	9.5 (3.9)	9.0 (3.9)	9.6 (3.9)	8.9 (4.0)	9.4 (4.0)	9.4 (3.7)	9.7 (3.7)	9.1 (4.0)
Adjusted mean difference (95% CI)	-0.17 (-0.87, 0.53)		-0.26 (-0.95, 0.44)		-0.76 (-1.69, 0.16)		-0.23 (-1.14, 0.69)		-0.36 (-1.28, 0.57)		-0.22 (-1.14, 0.70)	
AUSCAN Stiffness (0-4)												
N	118	110	114	114	109	108	107	110	108	105	103	110
Mean (SD)	1.5 (1.0)	1.4 (1.0)	1.6 (1.0)	1.3 (1.0)	1.6 (1.0)	1.4 (1.0)	1.5 (1.1)	1.5 (1.0)	1.6 (0.9)	1.5 (1.0)	1.7 (0.9)	1.4 (1.0)
Adjusted mean difference (95% CI)	0.00 (-0.20, 0.20)		-0.19 (-0.39, 0.01)		-0.22 (-0.45, 0.00)		0.09 (-0.13, 0.31)		-0.09 (-0.31, 0.14)		-0.19 (-0.41, 0.04)	
AUSCAN Function (0-36)												
N	118	108	112	114	109	108	107	110	108	105	102	111
Mean (SD)	15.2 (7.8)	15.0 (6.9)	15.8 (7.8)	14.4 (6.8)	14.6 (7.9)	15.1 (7.6)	15.7 (7.6)	14.0 (7.9)	15.2 (7.9)	16.1 (7.6)	16.3 (7.6)	15.0 (7.9)
Adjusted mean difference (95% CI)	-1.10 (-2.40, 0.19)		-0.70 (-1.97, 0.57)		-0.79 (-2.33, 0.75)		-0.83 (-2.34, 0.69)		-0.22 (-1.85, 1.40)		-0.74 (-2.35, 0.87)	
AUSCAN Total (0-12)												
N	115	107	112	110	109	108	107	110	106	104	100	110
Mean (SD)	5.1 (2.1)	4.9 (1.9)	5.2 (2.2)	4.7 (1.9)	5.1 (2.4)	4.9 (2.4)	5.2 (2.4)	4.8 (2.3)	5.2 (2.3)	5.2 (2.4)	5.4 (2.2)	4.9 (2.4)
Adjusted mean difference (95% CI)	-0.19 (-0.58, 0.19)		-0.30 (-0.69, 0.08)		-0.47 (-0.97, 0.02)		-0.03 (-0.52, 0.46)		-0.20 (-0.72, 0.32)		-0.30 (-0.82, 0.21)	
Arthritis self-efficacy for pain (1-10)												
N	114	110	110	114	107	103	104	106	101	104	100	105
Mean (SD)	5.6 (1.9)	6.3 (1.7)	5.7 (2.0)	6.1 (1.6)	5.7 (1.9)	6.5 (1.7)	6.0 (1.8)	6.2 (1.8)	5.4 (2.0)	6.0 (1.7)	5.6 (1.8)	5.8 (2.0)
Adjusted mean difference (95% CI)	0.78 (0.36, 1.21)		0.17 (-0.24, 0.59)		0.81 (0.37, 1.25)		0.24 (-0.19, 0.68)		0.66 (0.18, 1.15)		0.16 (-0.31, 0.64)	
Hand pain severity last 3 days (0-10)												
N	115	109	109	115	104	95	96	103	102	103	101	104
Mean (SD)	4.4 (2.2)	4.2 (1.9)	4.6 (2.2)	4.1 (1.9)	4.1 (2.2)	4.4 (2.1)	4.1 (2.0)	4.3 (2.3)	4.5 (2.2)	4.6 (2.3)	4.8 (2.2)	4.2 (2.3)
Adjusted mean difference (95% CI)	-0.30 (-0.77, 0.16)		-0.19 (-0.65, 0.27)		-0.02 (-0.54, 0.51)		0.42 (-0.09, 0.94)		-0.12 (-0.68, 0.44)		-0.31 (-0.86, 0.24)	

Severity of worse problem in the last 3-days (0-10)														
N	114	108	108	114	101	93	95	99	101	102	101	102		
Mean (SD)	4.7 (2.3)	4.6 (2.2)	5.0 (2.3)	4.4 (2.2)	4.8 (2.4)	4.7 (2.6)	4.9 (2.5)	4.7 (2.4)	4.9 (2.2)	4.7 (2.5)	5.2 (2.2)	4.4 (2.4)		
Adjusted mean difference (95% CI)	-0.24 (-0.76, 0.29)		-0.42 (-0.94, 0.09)		-0.63 (-1.26, 0.00)		-0.08 (-0.70, 0.55)		-0.50 (-1.09, 0.09)		-0.62 (-1.19, -0.04)			
Satisfaction with hand function in the last 3 days (0-10)														
N	115	108	109	114	104	95	96	103	103	103	101	105		
Mean (SD)	4.7 (2.3)	4.3 (2.2)	4.9 (2.4)	4.2 (2.1)	4.5 (2.4)	3.9 (2.3)	4.2 (2.4)	4.3 (2.4)	4.9 (2.3)	4.7 (2.4)	5.2 (2.2)	4.4 (2.4)		
Adjusted mean difference (95% CI)	-0.48 (-1.03, 0.06)		-0.52 (-1.06, 0.02)		-0.79 (-1.41, -0.18)		0.33 (-0.28, 0.93)		-0.30 (-0.89, 0.29)		-0.58 (-1.17, 0.00)			
Grip strength (lbs)														
N	N/A	N/A	N/A	N/A	104	95	96	103	N/A	N/A	N/A	N/A		
Mean (SD)	N/A	N/A	N/A	N/A	42.9 (23.5)	39.8 (20.5)	39.9 (21.7)	42.8 (22.5)	N/A	N/A	N/A	N/A		
Adjusted mean difference (95% CI)	N/A		N/A		-0.44 (-3.29, 2.42)		1.57 (-1.27, 4.41)		N/A		N/A			
Pinch strength (lbs)														
N	N/A	N/A	N/A	N/A	103	95	96	102	N/A	N/A	N/A	N/A		
Mean (SD)	N/A	N/A	N/A	N/A	9.2 (3.6)	8.9 (3.6)	8.7 (3.4)	9.3 (3.7)	N/A	N/A	N/A	N/A		
Adjusted mean difference (95% CI)	N/A		N/A		-0.18 (-0.75, 0.39)		0.26 (-0.31, 0.82)		N/A		N/A			
Grip ability test (GAT) (seconds)														
N	N/A	N/A	N/A	N/A	104	95	96	103	N/A	N/A	N/A	N/A		
Mean (SD)	N/A	N/A	N/A	N/A	33.7 (20.4)	31.0 (10.2)	34.5 (20.9)	30.4 (10.2)	N/A	N/A	N/A	N/A		
Adjusted mean difference (95% CI)	N/A		N/A		-1.01 (-3.41, 1.39)		-0.82 (-3.20, 1.56)		N/A		N/A			
SF-12: physical component (0-100)														
N	113	104	105	112	106	101	102	105	100	100	100	100		
Mean (SD)	40.7 (10.9)	40.4 (10.2)	39.9 (11.2)	41.2 (9.8)	41.6 (10.7)	40.2 (10.3)	40.2 (10.9)	41.7 (10.1)	41.4 (10.8)	41.1 (10.4)	40.4 (10.4)	42.2 (10.7)		
Adjusted mean difference (95% CI)	0.97 (-0.89, 2.84)		0.59 (-1.25, 2.43)		0.05 (-1.93, 2.02)		1.18 (-0.75, 3.11)		0.08 (-1.89, 2.06)		1.24 (-0.71, 3.19)			
SF-12: mental component (0-100)														
N	113	104	105	112	106	101	102	105	100	100	100	100		
Mean (SD)	50.4 (10.8)	51.5 (9.9)	51.1 (10.4)	50.7 (10.3)	50.8 (9.9)	52.5 (9.7)	51.8 (10.4)	51.4 (9.2)	51.0 (10.7)	52.3 (10.2)	51.5 (11.1)	51.8 (9.7)		
Adjusted mean difference (95% CI)	-1.37 (-3.37, 0.63)		0.00 (-1.96, 1.96)		-0.52 (-2.59, 1.56)		0.44 (-1.59, 2.46)		-0.58 (-2.86, 1.70)		1.03 (-1.23, 3.28)			

Abbreviations: CI = confidence interval, JP = joint protection, HEx = hand exercise, N/A = not applicable, AUSCAN = Australian Canadian Hand Osteoarthritis Index, SF-12 = Short Form Health Survey 12 (version 2). * = "Improved" defined as "completely better", "much better", or "better" on the global assessment of change question; † = Reference category. Results are adjusted for baseline (except for measures derived using the global assessment of change), age, gender, social class, GP practice, length of time with a hand condition and the other main effect of interest. Total AUSCAN score calculated as (pain/5) + stiffness + (function/9)

Table S6: Per-protocol analysis of the primary outcome (OARSI) responder criteria at the primary endpoint (6-month follow-up)

Outcome measure	6-months			
	No JP*	JP	No HEx*	HEx
N	109	85	107	87
"Responders" (OARSI), n (%)	24 (22)	29 (34)	26 (24)	27 (31)
Adjusted[3] odds ratio (95% CI)	1.95 (0.94, 4.02)		1.47 (0.73, 2.96)	

Footnote: Analysis was defined to be per protocol if participants were in the leaflet and advice arm or attended: session 1, 2, 3 & 4; sessions 1, 2 & 4; sessions 1, 3 & 4; or sessions 1 & 4 for the OT intervention arms. JP = joint protection, HEx = hand exercise, CI = confidence interval. * = reference category