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No evidence for the effectiveness of a multidisciplinary group based treatment program in patients with osteoarthritis of hands on the short term; results of a randomized controlled trial

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SUMMARY

Objective: To examine the efficacy of a multidisciplinary non-pharmacological intervention in patients with hand osteoarthritis (OA).
Method: Parallel group randomized controlled trial was performed in three participating rheumatology outpatient clinics in the Netherlands. Block randomization was performed using a computer generated permuted block scheme (blocks of four). An independent person randomly assigned 151 participants with clinical hand OA to four sessions of multidisciplinary non-pharmacological treatment, or 30 min education followed by 3 months waiting time. Participants and therapists were not blinded to the assigned intervention. The research assistant who assessed all outcomes was blinded to the assigned intervention. Subscale limitations in activities of the Australian Canadian Osteoarthritis Hand Index (AUSCAN) and OARSI responder criteria (primary outcomes) and secondary outcome measures, were assessed at baseline and 12 weeks. Linear or logistic regression analyses were used, where appropriate, with the outcome as dependent and the intervention group as independent variable. The analyses were adjusted for baseline values.
Results: At 3 months no significant and no relevant differences were observed between the experimental ($n = 76$) and control group ($n = 75$) in any of the primary or secondary outcome measures. In both groups about one-third of patients were classified as responder.
Conclusion: There is insufficient evidence to confirm a clinically relevant treatment effect on the short term, between patients who followed a multidisciplinary treatment program and those who received only written information. Since hand OA causes a range of impairments and limitations in activities, programs with more guidance to formulate and implement individually tailored treatment plans could be probably more effective. Furthermore, more research is needed on the efficacy of single treatment elements.
(Dutch Trial Register trial number NTR1191).

Background

Osteoarthritis (OA) is the most common arthritic joint disease frequently affecting the joints of the hands[1]. In elderly people (>70 years) the prevalence of symptomatic hand OA is estimated to be 26% for women and 13% for men[2]. Subjects with hand OA have difficulties in carrying, writing and fingering small objects, resulting in limitations in activities and restrictions in participation[2,3].

The European League Against Rheumatism (EULAR) recommends to treat all patients with hand OA with a combination of pharmacological and non-pharmacological treatment options[4]. However, no evidence and no guidelines are available about the optimal content and mix of non-pharmacological components. It has been suggested to combine non-pharmacological treatment options focussing on multiple dimensions (impairments, limitations in activities, and

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personal factors)[3]. These recommendations are based on research findings, indicating that perceived limitations in activities in patients with hand OA are closely associated with hand impairment of grip strength and joint mobility[3], and that satisfaction with the performance of activities are associated with personal factors as self-efficacy and coping strategies[3].

Research on the effectiveness of non-pharmacological treatment programs in hand OA is scarce and of poor quality. Recent reviews concluded that there is currently insufficient high quality evidence regarding the effectiveness of non-pharmacological interventions for hand OA[5–8], due to lack of methodological quality of studies included in these reviews. Furthermore, interventions scrutinized in these reviews were not multidisciplinary and did not simultaneously focus on impairments, limitations in activities, and personal factors such as self-efficacy and coping strategies as recommended[3]. Therefore, we developed a non-pharmacological multidisciplinary and multidimensional treatment programme for patients with hand OA. Treatment components of the programme included self-management, daily home exercises to enhance joint mobility and grip strength and education about ergonomic principles[9]. The objective of the current study is to determine the effectiveness of a multidisciplinary treatment program in patients with hand OA on limitations in activities and pain.

Methods

Design overview

One University based rheumatology outpatient centre and two community based rheumatology outpatient centres participated in this multicentre parallel group randomized controlled study. All patients followed a nurse-led educational session. Then patients were randomly assigned to the intervention group (multidisciplinary treatment) or a waiting time of 3 months (allocation ratio 1:1). Patients were assessed at baseline (prior to the mono-disciplinary educational session) and at 13 weeks follow-up by a research assistant who was blinded for treatment allocation. The study was conducted according to good clinical practice and in compliance with the Helsinki declaration. Each institutional research ethics board approved the study protocol and all patients gave signed informed consent. The trial is registered in the Dutch Trial Register (trial number NTR1191). A copy of the trial protocol (in Dutch) can be requested at the authors.

Setting and participants

Patients were recruited between December 2007 and January 2010. Patients who visited the outpatient clinic due to complaints of hand OA and referral to multidisciplinary treatment was indicated, were informed about the study by their rheumatologist. If patients orally indicated to be interested in participating in the study, the medical record of each patient was screened by the research assistant for eligibility. Patients were excluded on the basis of medical records if they suffered from other rheumatic diseases, previous joint replacement surgery in one of the hand joints, or previous participation in a multidimensional multidisciplinary group treatment program for hand OA. After written information was sent to eligible patients, the researcher contacted patients within 2 weeks by telephone to establish willingness to participate in the study and plan a final eligibility screening at one of the participation centres.

Included during the final eligibility screening were patients with hand OA according to the clinical classification criteria of the American College of Rheumatology (ACR)[10]; of whom complaints due to OA of hands were the most or second most important problem; who had self-reported limitations in activities due to hand OA (measured as a score of at least 9 on the Australian Canadian Osteoarthritis Hand Index – LK3 (AUSCAN) physical functioning subscale[11]). Excluded were patients who were not willing to participate in a group treatment program; not able to write and or understand the Dutch language.

Interventions

Single mono-disciplinary educational session

Both study groups received the same nurse-led educational session consisting of a 30-min explanation of written information about OA. The written information was an adapted version of the information leaflet published by the Dutch Arthritis Association for generalized OA, and included information about the disease and exercises to enhance mobility and grip strength.

Multidisciplinary treatment program

The multidisciplinary treatment program (experimental intervention) started within a week after baseline assessments. The program, consisted of an intake by an occupational therapist, followed by four group based sessions (6–8 patients) of 2½–3 h duration supervised by a specialized nurse and occupational therapist. During an intake session an occupational therapist made an inventory of patient specific problems in daily living, following a semi-structured interview by means of the Canadian Occupational Measurement Scales (COPM)[12,13]. After discussion with the therapist, patients prioritized their own specific problems.

Elements of the multidisciplinary group treatment sessions were: (1) self-management to enhance self-efficacy to cope with pain, fatigue, limitations in activities and participation; (2) ergonomic principles (elements of joint protection); (3) daily home exercises to improve strength and joint mobility; (4) referral for a splint if considered necessary by an occupational therapist.

During the multidisciplinary treatment sessions discussions among patients were encouraged to utilize patients' expert opinions. Each treatment element was repeated and built upon during several sessions. Furthermore, each session included three to four clearly stated take home messages; such as "use of hands and exercises will not damage your joints". The treatment program comprised eight exercises to enhance joint mobility of wrist and finger joints and muscle strength of the intrinsic muscles and extensor muscles of the fingers. All exercises were practiced with an occupational therapist during the first treatment session. Then patients performed the exercises daily at home for a week and registered the number of repetitions, intensity and resistance (colour of putty used). During the second treatment session patients set up an individual scheme with an individual built up for each exercise together with the occupational therapist and specialized nurse. This scheme was based on the registrations of the performance of exercises during the first week. Patients recorded the progress at home daily. During the third and fourth treatment session the progress on the exercise program was discussed and adjusted if considered necessary. For more information about the multidisciplinary treatment program, see Appendix 1. A detailed description of the development and content of the multidisciplinary treatment program, including the exercise program is described elsewhere[9]. To standardize the treatment program a slide presentation for all treatment sessions was developed. Furthermore, manuals for both therapists and patients were developed. Before the start of the trial all participating nurses and occupational therapist followed an education and standardization session. During the study, meetings were planned to perpetuate standardization.

Randomization

Block randomization was performed using a computer generated permuted block randomization scheme using blocks of four. Patients were randomly assigned to the experimental or control group by an independent person, who was not responsible for determining the eligibility of the patients, and had no information about the persons included in the trial and no influence on the assignment sequence. Assignments were communicated by e-mail to the planners of the outpatient clinics. Patients were informed of their allocation by mail.

Measurements and outcomes

All primary and secondary outcome measures were obtained at baseline and 13 weeks. Assessments were performed on a test location by a research assistant (physical therapist).

Demographic and clinical data were collected for each patient, including age, sex, height, weight, location of OA, time since diagnosis, and the presence of other chronic disorders. X-rays of the hands were scored by a rheumatologist according to Kellgren and Lawrence[14] on a five point scale: 0: no OA, 1: doubtful OA, 2: minimal OA, 3: moderate OA and, 4: severe OA[14]. Presence of erosive OA was defined as at least one erosion at one of the hand joints.

Primary outcome measures

Primary outcome measures were the AUSCAN subscale limitations in activities and the OARSI responder criteria[15,16]. Limitations in activities were assessed with AUSCAN subscale limitations in activities[11,17], which contains nine items (scaled on a five-point Likert scale) referring to limitations in activities of daily living during the past 48 h[11]. The possible range of scores on the AUSCAN physical function subscale is 0–36, with a higher score indicating more severe problems. The AUSCAN is valid, reliable and responsive in patients with hand OA[17].

The OARSI responder criteria is a composite index that permits presentation of results of symptom modifying clinical trials in OA based on individual patient responses (responder yes/no). A patient is classified as responder if there is (1) an improvement of pain >50%; or (2) an improvement of >20% in at least two of the following three categories: pain, physical function and patient global assessment[15,16].

Secondary outcome measures

Impairments – Pain in the last 48 h was assessed with the pain subscale of the AUSCAN (range 0–20). Joint mobility of the elbow, wrist, interphalangeal thumb joint, meta carpophalangeal joints, and proximal interphalangeal joints was measured following the Escola Paulista de Medicina (EPM)-range of motion scale[18] and by means of the Kapandji index which measures thumb opposition (range 0–10)[19]. The index has been validated in RA[20]. A minimal score indicates possible to do and a maximal score indicates a normal mobility with completely accomplished movement. Grip strength was measured with the JAMAR hand dynamometer. The mean value (kg) of three efforts, separated by 20 s rest intervals of each hand, was calculated.

Activities and participation – An inventory of individual problems was made in a semi-structured interview by means of the COPM[12,13].

Personal factors – Pain coping was assessed by the Pain Coping Inventory (PCI)[21,22]. Beliefs in the ability to cope with adversity and to achieve goals (self-efficacy) were assessed with the Dutch version of the General Self-Efficacy Scale (GSE)[23] and the Chronic Pain Self-Efficacy Scale (CPSE)[24].

Health-related quality of life – Quality of life was determined with the Medical Outcomes Study Short Form 36 (SF-36). All eight subscales were assessed[25].

Self-perceived change – Patients rated their self-perceived change on an eight-point scale (1: vastly worsened, 8: completely recovered)[26].

Adverse experiences – Participants were asked open-ended questions about adverse experiences at each treatment session.

Blinding – A trained research assistant (physical therapist), blinded for block size of randomization and assigned treatment, performed the assessments. Patients were instructed not to give information about the allocated treatment to the research assistant. During treatment hours the research assistant was not allowed to visit the outpatient clinic in order to further assure blinding. To provide insight in the success of blinding the assessor was asked to guess the assigned treatment immediately after the follow-up assessment at week 13. Because of the type of intervention, patients and clinicians could not be blinded for the assigned treatment.

Statistical analysis

The sample size of the study was based on the ability to demonstrate a difference of 15%[27] between groups at 13 weeks, corresponding with a mean difference of 0.27 units per item on the AUSCAN subscale limitations in activities and assuming a mean item score of 1.8[17] at baseline. Assuming an improvement of 10% (from 1.8 to 1.6) in the control group and an improvement of 25% in the experimental group (from 1.8 to 1.3), the target sample size was estimated at 45 patients per group (two-tailed alpha = 0.05, beta = 0.80). Taking into account a drop out rate of 20% and planned subgroup analyses 75 patients per group were included in this study.

An administrative assistant entered the data, which was double checked by the researcher.

The analysis was done on an intention-to-treat basis. Linear regression analyses and logistic regression analyses were used where appropriate with the outcome as dependent and the intervention group as independent variable and adjusted for baseline values. Additionally (to support the unadjusted analyses which were used for confirmatory testing), we repeated the analyses adjusting for baseline, gender, age, body mass index (BMI) and erosive OA. Values less than 0.05 were considered statistically significant.

The proportions of missing data on the primary outcome measures were 3% at 12 weeks. List wise deletion of missing data was used in all analyses. All analyses were performed by using STATA software version 10 (StataCorp, College Station, Texas).

Results

After screening of the medical history, 373 out of 539 referred patients were invited to participate in the trial of whom 237 patients were willing and invited for a screening visit. 151 patients were included in the trial, of whom 76 were randomized to the intervention group and 75 to the control group (Fig. 1). The majority of participants ($n = 96$) were included in the Maartenskliniek Nijmegen, 47 were included in Maartenskliniek Woerden, and eight patients were included in the University Medical Centre Utrecht.

Most participants were female with a mean disease duration of 4 years [standard deviation (SD) = 7] (Table I). There were no relevant differences in baseline characteristics between groups. Examples of frequently named and prioritized problems at the baseline COPM interview were: doing and undoing buttons, opening jars and/or bottles, carrying heavy objects and holding the steer of a bicycle.

At 3 months follow-up there were no improvements in pain, joint stiffness and limitations in activities within and between the

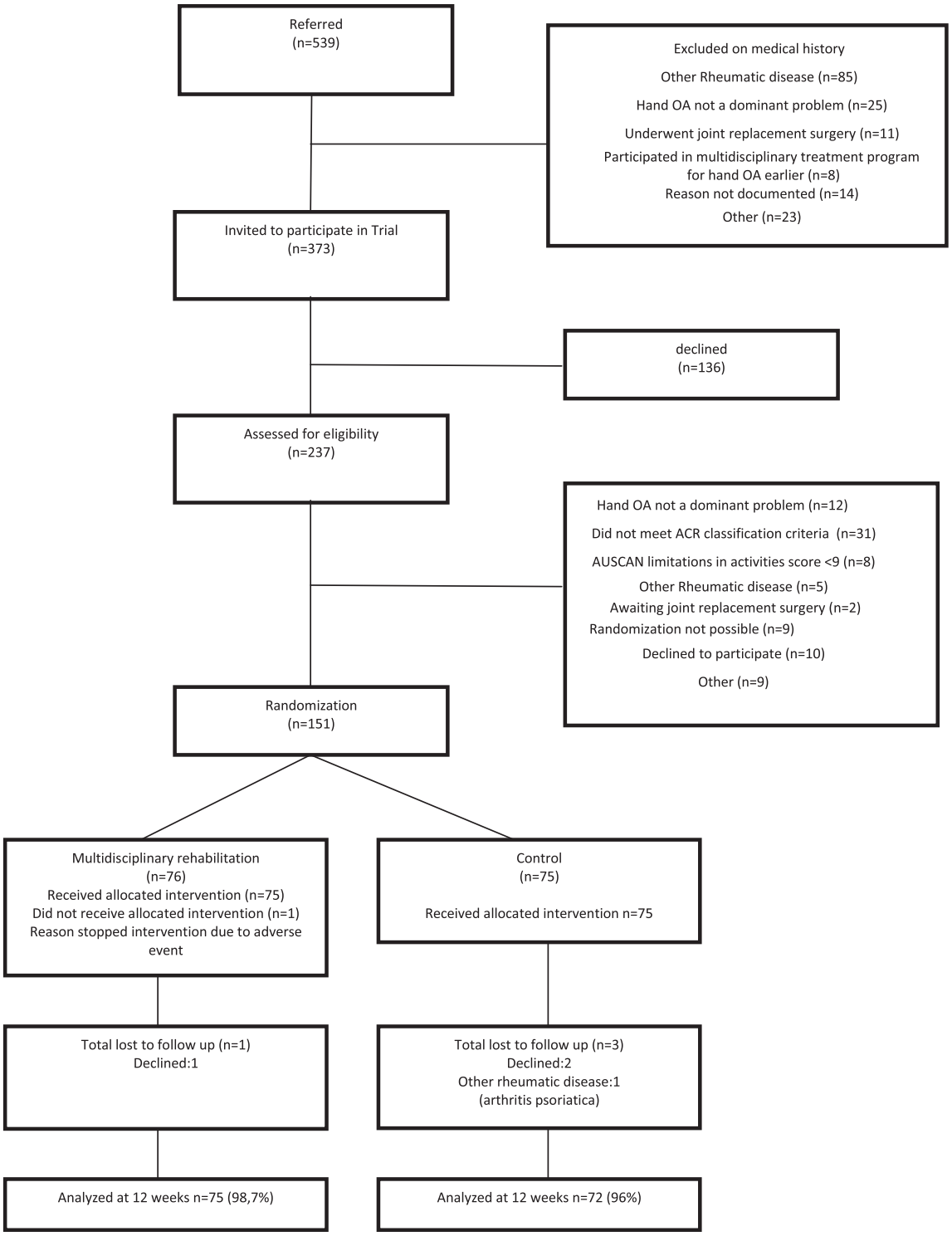

Fig. 1. Flowchart of participants.

experimental and control group. A small but not significant improvement in patient global assessment was observed within both groups (Table II). In both groups about one-third of participants could be classified as a responder [33% *versus* 37% of participants in the experimental group and the control group, respectively: odds ratio 0.82; 95% confidence interval (CI) 0.42; 1.61]. There was no change in any of the secondary outcome measures at 3 months follow-up (Table III). Similar results for all primary and secondary outcome measures were obtained after adjusting for age, gender, BMI, and erosive OA (Table III). At follow-up there was a slight increase in the use of acetaminophen in both groups (Table IV).

Adverse events: one patient reported swollen hand and wrist joints and increased pain after the second treatment session. After contacting the referring rheumatologist, the patient was rediagnosed with psoriatic arthritis.

The research assistant guessed the assigned treatment at 13 weeks in 59.6% (Cohen's $k = 0.19$) of patients correctly.

Table I
Baseline characteristics of participants allocated to the intervention and control group

Characteristic	Intervention group	
	Intervention	Control
Mean age (SD), y	60 (7)	58 (9)
Men/women, *n*/*n* (%/%)	62/14 (82/18)	63/12 (84/16)
Mean BMI (SD), kg/m^2	27 (5)	27 (4)
Mean time diagnosed (SD) y	4 (6)	4 (7)
Radiological evidence OA* (*n* = 135)		
PIP OA (including IP)/no PIP OA *n*/*n* (%/%)	58/10 (85/16)	51/16 (76/24)
DIP OA/no DIP OA *n*/*n* (%/%)	65/3 (96/4)	56/11 (84/16)
CMC I OA/no CMC I OA *n*/*n* (%/%)	20/48 (70/30)	20/47 (70/30)
Erosive/non-erosive OA *n*/*n* (%/%)	39/29 (57/43)	34/33 (51/49)
Medication *n* (%)		
NSAID	28 (37)	24 (32)
Opioids	2 (3)	3 (4)
Bisphosphonates	1 (1)	1 (1)
DMARDs	6 (8)	4 (5)
Glucosamine (chondroitine)	3 (4)	2 (3)

* X-rays of 16 patients were missing for logistic reasons or patients who declined to make an X-ray.

Discussion

This is the first study investigating the effectiveness of an intensive group based multidisciplinary treatment program incorporating self-management, ergonomic principles and exercises. Although several guidelines recommend a multidimensional and multidisciplinary treatment program in hand OA, the findings of this study suggest that such a program is not effective on the short term. We did not observe any differences between the experimental and control group in primary or secondary outcome measures. Furthermore, in general, outcome measures remained stable between baseline and follow-up within both groups. Based on the results of the current study, there is insufficient evidence to confirm an important difference between groups. The results seem to indicate absence of evidence, because the limits of the 95% CIs remain between the predefined limits of equivalence (a 15% difference between groups)[28].

The results of our study partially correspond with the results of earlier research on the effect of treatment programs for hand OA[6,7]. In a study on the effects of a one session program incorporating exercise and joint protection no effect on limitations in activities and pain was found. However, in contrast with our results, positive effects were observed on muscle strength and perceived global hand function in favour of the experimental group[29]. A possible explanation for the difference in effects between studies on muscle strength could be differences in the type and intensity of exercises. In the study of Stamm *et al.* patients were encouraged to do range of motion exercises 10 times daily whereas in our study patients were advised to do both strength and range of motion exercises once or twice daily. In another study investigating the additional effect of the supply of splints and technical aids to education on exercises and joint protection a positive effect on the primary outcome measure (activity performance and satisfaction with performance as measured with the COPM), was found, whereas no effects were observed in other outcome measures[30]. This contrast in findings might be explained by the fact that in the latter study technical aids were supplied by the care provider as part of the intervention whereas patients in our study were encouraged to acquire advised aids themselves.

Our results indicate that a multidimensional self-management programme in a group setting might not be suitable in patients with hand OA. As OA of the hands may cause various impairments and limitations in activities, individual treatment goals could vary considerably among patients. An important feature of our group based multidimensional self-management intervention was that it addressed all possible problems related to hand OA in a non-directive approach. Patients were encouraged to develop and to decide their own treatment plan to achieve individually set treatment goals. The intervention evaluated in the current study existed of numerous treatment elements. Pros and cons of certain treatment options were extensively discussed among group members and therapists. As a result participants may have received too much information on all possible treatment options and were not capable to pick up relevant information for themselves. It is conceivable that this non-directive approach offered insufficient guidance to formulate and implement individually tailored treatment plans. Furthermore, patients may have perceived certain treatment elements such as exercises to improve strength *versus* elements of joint protection to reduce pressure on joints as confusing and contradictory. We believe that it is possible that the single treatment elements of our programme are effective, but that interaction of treatment elements counteracts the positive effects of the single elements. Therefore, in our view and in line with other authors reporting on results of non-pharmacological intervention studies[8,29,31] we advocate that further research should focus on the effectiveness of single treatment elements, targeting on individual patient characteristics and needs.

Table II
Summary results: primary outcome measures for each study group

Measurement instrument	Intervention group								Difference* (95% CI) at 3 months	Difference† (95% CI) at 3 months
	Experimental group (*n* = 76)				Control group (*n* = 75)					
	Total with data available *N* (%)	Baseline [mean (SD)]	Total with data available *N* (%)	3 months [mean (SD)]	Total with data available *N* (%)	Baseline [mean (SD)]	Total with data available *N* (%)	3 months [mean (SD)]	Exp-contr	Exp-contr
AUSCAN										
Pain‡	76 (100)	10.4 (3.4)	74 (97.4)	9.4 (2.8)	75 (100)	10.2 (3.3)	72 (96)	9.0 (3.7)	0.40 (−0.50; 1.29)	0.65 (−0.38; 1.67)
Function§	76 (100)	21.0 (6.9)	74 (97.4)	18.6 (7.3)	75 (100)	21.8 (6.3)	72 (96)	18.8 (6.4)	0.49 (−1.01; 2.00)	0.96 (−0.74; 2.65)
Joint stiffness‖	76 (100)	2.3 (0.9)	74 (97.4)	2.2 (0.8)	75 (100)	2.4 (0.8)	72 (96)	2.1 (0.9)	0.14 (−0.09; 0.37)	0.10 (−0.16; 0.35)
Patient global assessment¶	76 (100)	49.5 (25.1)	75 (98.7)	60.4 (20.6)	75 (100)	51.3 (24.8)	72 (96)	66.0 (20.6)	−5.21 (−11.43; 1.01)	−6.75 (−13.76; 0.25)

* Adjusted for baseline.
† Adjusted for baseline, gender, age, BMI and erosive OA.
‡ Possible scoring range 0–20, lower scores depict more favourable outcomes.
§ Possible scoring range 0–36, lower scores depict more favourable outcomes.
‖ Possible scoring range 0–4, lower scores depict more favourable outcomes.
¶ Possible scoring range 0–100, higher scores depict more favourable outcomes.

Table III
Summary results: secondary outcome measures for each study group

Measurement instrument	Intervention group								Difference* (95% CI) at 3 months	Difference† (95% CI) at 3 months
	Experimental group ($n = 76$)				Control group ($n = 75$)					
	Total with data available *N* (%)	Baseline [mean (SD)]	Total with data available *N* (%)	3 months [mean (SD)]	Total with data available *N* (%)	Baseline [mean (SD)]	Total with data available *N* (%)	3 months [mean (SD)]	Exp-contr	Exp-contr
COPM										
Activity‡	72 (94.7)	5.3 (1.6)	75 (98.7)	5.2 (1.3)	70 (93.3)	5.5 (0.15)	72 (96)	5.5 (0.16)	−0.15 (−0.54; 0.23)	−0.14 (−0.57; 0.29)
Participation‡	72 (94.7)	4.7 (1.5)	75 (98.7)	5.3 (1.5)	70 (93.3)	4.9 (1.4)	72 (96)	5.2 (1.5)	0.14 (−0.30; 0.59)	−0.03 (−0.47; 0.52)
Pain coping (PCI)										
Transformation§	74 (97.4)	2.4 (0.6)	74 (97.4)	2.3 (0.6)	71 (94.7)	2.4 (0.6)	72 (96)	2.3 (0.7)	−0.07 (−0.09; 0,24)	0.06 (−0.13; 0.24)
Distracting§	75 (98.7)	2.5 (0.7)	74 (97.4)	2.5 (0.6)	71 (94.7)	2.5 (0.6)	72 (96)	2.5 (0.6)	−0.01 (−0.17; 0.14)	−0.07 (−0.24; 0.10)
Demands§	73 (96.1)	2.2 (0.6)	74 (97.4)	2.3 (0.6)	71 (94.7)	2.2 (0.6)	72 (96)	2.3 (0.5)	0.01 (−0.16; 0.18)	0.02 (−0.18; 0.21)
Retreating§	74 (97.4)	1.6 (0.4)	74 (97.4)	1.6 (0.4)	71 (94.7)	1.7 (0.5)	72 (96)	1.6 (0.4)	0.10 (−0.00; 0.19)	0.09 (−0.02; 0.19)
Worrying§	75 (98.7)	1.7 (0.3)	74 (97.4)	1.7 (0.4)	71 (94.7)	1.7 (0.3)	72 (96)	1.7 (0.4)	0.01 (−0.1; 0.12)	0.04 (−0.08; 0.16)
Resting§	75 (98.7)	2.0 (0.5)	74 (97.4)	2.0 (0.4)	71 (94.7)	2.0 (0.5)	72 (96)	2.0 (0.5)	−0.00 (−0.11; 0.11)	−0.02 (−0.14; 0.10)
Arthritis self-efficacy										
Pain‖	75 (98.7)	60.1 (13.7)	74 (97.4)	59.3 (12.9)	71 (94.7)	64.0 (13.1)	72 (96)	61.1 (13.7)	0.61 (−3.00; 4.22)	−0.36 (−4.45; 3.73)
Physical function‖	75 (98.7)	73.5 (16.8)	74 (97.4)	70.4 (16.2)	71 (94.7)	73.5 (15.2)	72 (96)	72.9 (15.8)	−2.91 (−6.18; 0.36)	−3.46 (−7.07; 0.15)
Other symptoms‖	75 (98.7)	66.0 (15.0)	74 (97.4)	65.5 (14.4)	71 (94.7)	68.6 (14.7)	72 (96)	67.7 (13.8)	−0.64 (−4.31; 3.04)	0.10 (−3.87; 4.06)
Dutch GSE††	73 (96.1)	33.1 (4.6)	73 (96.1)	32.1 (4.8)	71 (94.7)	32.5 (4.5)	72 (96)	32.6 (4.2)	−0.47 (−1.39; 0.45)	−0.45 (−1.45; 0.56)
SF-36										
Physical function¶	75 (98.7)	41.7 (8.8)	74 (97.4)	41.1 (9.4)	69 (92)	42.5 (6.8)	72 (96)	42.3 (7.6)	−0.14 (−1.90; 1.62)	0.04 (−2.01; 2.09)
Role professional¶	75 (98.7)	36.7 (8.0)	74 (97.4)	37.6 (6.8)	70 (93.3)	36.7 (7.8)	72 (96)	38.7 (7.6)	−1.23 (−2.95; 0.49)	−1.28 (−3.12; 0.56)
Bodily pain¶	75 (98.7)	40.9 (6.9)	74 (97.4)	41.0 (6.3)	71 (94.7)	41.3 (8.0)	72 (96)	41.9 (7.5)	0.08 (−1.71; 1.88)	−0.03 (−1.93; 1.87)
General health¶	74 (97.4)	45.2 (7.8)	74 (97.4)	45.9 (8.1)	71 (94.7)	45.8 (8.3)	72 (96)	45.4 (7.8)	1.10 (−1.01; 3.21)	0.46 (−1.91; 2.84)
Vitality¶	75 (98.7)	49.3 (7.0)	74 (97.4)	49.2 (7.9)	71 (94.7)	50.0 (8.5)	72 (96)	50.1 (8.1)	−0.12 (−2.09; 1.85)	−0.22 (−2.35; 1.90)
Social function¶	75 (98.7)	46.3 (9.8)	74 (97.4)	47.9 (10.2)	71 (94.7)	46.6 (8.8)	72 (96)	48.3 (8.6)	0.16 (−2.25; 2.58)	0.29 (−2.31; 2.91)
Role emotional¶	75 (98.7)	42.7 (11.9)	74 (97.4)	42.9 (11.3)	70 (93.3)	44.7 (10.1)	72 (96)	44.8 (11.0)	−0.17 (−3.28; 2.93)	−0.40 (−3.80; 2.10
Mental health¶	74 (97.4)	48.9 (7.4)	74 (97.4)	49.4 (8.3)	71 (94.7)	49.3 (8.6)	72 (96)	50.6 (8.4)	−0.43 (−2.46; 1.60)	−0.23 (−2.45; 1.99)
Physical component score¶	74 (97.4)	39.5 (7.3)	74 (97.4)	39.8 (6.7)	68 (90.7)	39.4 (6.9)	72 (96)	39.9 (6.7)	−0.14 (−1.62; 1.35)	−0.17 (−1.81; 1.47)
Mental component score¶	74 (97.4)	49.7 (9.0)	74 (97.4)	50.3 (9.4)	68 (90.7)	50.7 (10.0)	72 (96)	51.6 (9.8)	0.27 (−2.13; 2.67)	−0.09 (−2.74; 2.57)
Muscle strength										
Grip	76 (100)	19.9 (9.3)	74 (97.4)	20.9 (9.2)	75 (100)	21.8 (8.9)	72 (96)	23.1 (9.9)	−0.31 (−1.85; 1.22)	−0.54 (−2.09; 1.00)
Pinch	76 (100)	2.8 (1.3)	74 (97.4)	2.9 (1.4)	75 (100)	3.0 (1.4)	72 (96)	3.1 (1.3)	0.10 (−0.13; 0.32)	−0.06 (−0.30; 0.19)
Lateral grip	75 (98.7)	5.4 (2.5)	74 (97.4)	5.4 (2.4)	75 (100)	5.7 (2.2)	72 (96)	5.7 (2.2)	−0.02 (−0.33; 0.29)	−0.07 (−0.41; 0.27)
Joint mobility										
EPM ROM#	72 (94.7)	3.4 (2.3)	75 (98.7)	3.3 (1.96)	71 (94.7)	3.4 (2.2)	71 (94.7)	3.2 (2.0)	0.26 (−0.26; 0.77)	0.11 (−0.44; 0.65)
Kapandji thumb**	75 (98.7)	8.7 (1.8)	75 (98.7)	9.05 (1.04)	74 (98.7)	8.7 (2.1)	72 (96)	9.0 (1.0)	0.20 (−0.17; 0.56)	0.12 (−0.31; 0.54)

* Adjusted for baseline.
† Adjusted for baseline, gender, age, BMI and erosive OA.
‡ Possible scoring range 1–10, higher scores depict more favourable outcomes.
§ Possible scoring range 0–4, higher scores mean more frequent use of this coping style when patients are in pain.
‖ Possible scoring range 1–100, higher scores depict more favourable outcomes.
¶ Norm = 50, higher scores depict more favourable outcomes.
# Possible scoring range 0–27, lower scores depict more favourable outcomes.
** Possible scoring range 0–10, higher scores depict more favourable outcomes.
†† Possible scoring range 10–40, higher scores depict higher level of self efficacy.

Table IV
Medication use for each study group

Medication	Intervention group			
	Experimental		Control	
	Baseline [number (%)]	3 months [number (%)]	Baseline [number (%)]	3 months [number (%)]
Acetaminophen	28 (37)	34 (45)	24 (32)	31 (43)
NSAID	28 (37)	31 (41)	24 (32)	22 (31)
Opioids	2 (3)	2 (3)	3 (4)	4 (6)
Bisphosphonates	1 (1)	2 (3)	1 (1)	0 (0)
DMARDs	6 (8)	5 (7)	4 (5)	2 (3)
Glucosamine (chondroitine)	3 (4)	2 (3)	2 (3)	4 (5)

There are a few limitations to this study that need to be mentioned. First of all, given the number of patients excluded due to other rheumatic diseases or not meeting the ACR classification criteria for hand OA, the patients included in our study only partially represent patients with hand OA in clinical practice. It is likely that patients who fulfil the ACR classification criteria have more severe OA than patients who did not meet these criteria. It is possible that patients in an earlier stage of OA would have benefited from the multidimensional treatment program investigated in this study. Secondly, in the current study no long-term effectiveness was investigated. The Medical Ethics Review Board advised us not to withhold our patients in the control group the experimental intervention for more than 3 months. So, the control group started treatment immediately after 3 months follow-up. The multidimensional treatment

program investigated in this study incorporated several elements directed at behavioural change. Behavioural change occurs gradually and takes time[32]. It is conceivable that a 3 months follow-up is too short to determine positive effects of a treatment program that incorporates elements directed at behavioural change. This study is part of a larger study in which also another research question, namely the added value of a booster session 6 months after completion of the treatment program in both groups will be evaluated. For these reasons, our design does not allow between group comparisons on the long-term effectiveness of our treatment program (Dutch Trial Register trial number NTR1191). Thirdly, there is no consensus about outcome measures or response criteria in trials investigating the effectiveness of non-pharmacological treatment in patients with hand OA[33]. Therefore in the current study both the OARSI response criteria and the AUSCAN subscale limitations in activities were used as primary outcome measures. A frequently mentioned problem when using more than one primary outcome measure, is an inflated chance for false positive conclusions (multiplicity). Despite sufficient power, no difference on any of the outcome measures was found between treatment groups. We therefore decided, not to adjust for type I error (false positive outcome), simply because the risk for a type I error was no issue when interpreting the results of our trial. Furthermore a great disadvantage in the adjustment of a type I error is the increasing risk for a type II error. International consensus about the outcome measures that should be used in non-pharmacological trials in patients with hand OA is necessary to avoid multiplicity issues in future research. Fourthly, we did not measure adherence to the different treatment elements. Research has shown that treatment effects on the short and long term depend on adherence to the recommended treatment[34]. In the current study it was decided not to measure adherence to the different treatment elements to ensure blinding to the assigned group (experimental or control) of the research assistant who was responsible for the data collection. Finally, it is possible that treatment effects were beyond the scope of the primary and secondary outcome measures of our study. Our choice of primary outcome measures, i.e., pain and limitations in activities reflected the most dominant problems in patients with hand OA[1]. Important aspects addressed in our program as adherence to daily exercise regimens, the application of ergonomic principles and the usage of adaptive devices in daily life are not fully captured in our primary and secondary measures. However, given the consistency of our findings we believe that it is unlikely that our intervention had an impact on factors believed to mediate effects on self-efficacy, pain and limitations in activities.

In this randomized controlled trial there is insufficient evidence to confirm an important or clinically relevant treatment effect on the short term, between patients who followed a multidisciplinary treatment program and those who received only written information. Since hand OA causes a range of impairments and limitations in activities, programs with more guidance to formulate and implement individually tailored treatment plans could be probably more effective. Furthermore, more research is needed on the efficacy of single treatment elements.

Author contributions

The authors declare the following contributions to the preparation of the manuscript: Study conception and design (all authors); collection and assembly of data (Stukstette and Westeneng); analysis (Stukstette and van den Ende) and interpretation of data (all authors); drafting of the manuscript (Stukstette); critical revision of the manuscript for important intellectual content (all authors); final approval of the manuscript (all authors); obtaining of funding (van den Ende). All authors take responsibility for the integrity of the work.

Conflict of interest

All authors declare that there are no conflicts of interest.

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Appendix 1

Multidisciplinary treatment program*

Session (duration in h)	Clinicians	Treatment components	Content of the session (and duration in min)	Take home messages
Intake (1)	Occupational therapist	• Screening • Formulating individual treatment goals	• Screenings questionnaire (10 min) • Semi-structured interview (COPM) (50 min)	–
1 (2,5)	Occupational therapist & specialized nurse	• Self-management to enhance self-efficacy to cope with pain, limitations in activities and participation • Ergonomic principles • Daily home exercises to improve strength and hand mobility	• Discussion about common problems due to hand OA and information about the disease (30 min) • Information about treatment options (medication (20 min), splints (5 min), exercises (5 min) • Ergonomic principles (20 min) • Practicing exercises to increase grip strength and joint mobility (20 min) • Instruction to fill in an activity diary (10 min)	• OA: it is not to cure, but there is something to do to deal with it • Know which medication you swallow and how and when to swallow it • Ergonomic principles can help you act easier in daily life • Be smart and act easier • Normal load does not lead to additional joint damage • Exercise and normal use of hands do not lead to additional joint damage • Maintaining/improving muscle strength helps you to continue to perform activities

(*continued on next page*)

Appendix 1 (*continued*)

Session (duration in h)	Clinicians	Treatment components	Content of the session (and duration in min)	Take home messages
2 (3)	Occupational therapist & specialized nurse	• Self-management to enhance self-efficacy to cope with pain, fatigue, limitations in activities and participation • Ergonomic principles • Daily home exercises to improve strength and hand mobility	• Discussion about the relation of daily activities *versus* pain, fatigue, joy and limitations in activities by means of discussing activity diaries (30 min) • Education and discussion about strategies to cope with pain, fatigue and limitations in activities (balance between rest and physical activity, individual use of medication, use of compensatory strategies in daily activities, use of aids, use of splints) (70 min) • Demonstration of aids and practicing with aids and ergonomics (35 min) • Practicing exercises to increase grip strength and joint mobility (15 min) • Formulating an individual action plan to achieve individual treatment goals (20 min)	• Pain is not always a reason to worry • Know your limit and dare to set your limit • Communicate with people in your environment • You are experienced with your disease, find out what helps you • Normal load does not lead to additional joint damage • Exercises help you to reduce joint stiffness
3 (2,5)	Occupational therapist & specialized nurse	• Self-management to enhance self-efficacy to cope with pain, fatigue, limitations in activities and participation • Referral for splints if considered necessary • Daily home exercises to improve strength and hand mobility • Ergonomic principles	• Discussion on the progress of the action plan to achieve individual treatment goals (25 min) • Discussion and reflection on strategies to cope with pain, fatigue and limitations in activities (balance between rest and physical activity, individual use of medication, use of compensatory strategies in daily activities, use of aids) (20 min) • Education and discussion about splints (referral for splints if necessary) (25 min) • Practicing exercises to increase grip strength and joint mobility (15 min) • Practicing with aids and ergonomics in a kitchen (60 min)	Repetition of the aforementioned take home messages
4 (2,5)	Occupational therapist & specialized nurse	• Self-management to enhance self-efficacy to cope with pain, fatigue, limitations in activities and participation • Daily home exercises to improve strength and hand mobility	• Discussion about the relation of daily activities *versus* pain, fatigue, joy and limitations in activities by means of discussing diaries (30 min) • Discussion and reflection on strategies to cope with pain, fatigue and limitations in activities (balance between rest and physical activity, individual use of medication, use of compensatory strategies in daily activities, use of aids, use of splints) (20 min) • Discussion on the progress of individual treatment goals (25 min) • Discussion about problems experienced in daily life and possible solutions by means of diaries (25 min) • Practicing exercises to increase grip strength and joint mobility (15 min) • Evaluation if patients' personal goals were established and evaluation of the treatment program (25 min)	Repetition of the aforementioned take home messages

* Stukstette M, Hoogeboom T, de Ruiter R, Koelmans P, Veerman E, den Broeder A, *et al.* A multidisciplinary and multidimensional intervention for patients with hand osteoarthritis. Clin Rehabil 2012;26:99–110. http://dx.doi.org/10.1177/0269215511417739.

Supplementary material

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References

1. Bijlsma JW, Berenbaum F, Lafeber FP. Osteoarthritis: an update with relevance for clinical practice. Lancet 2011;377:2115–26, http://dx.doi.org/10.1016/S0140-6736(11)60243-2.
2. Zhang Y, Niu J, Kelly-Hayes M, Chaisson CE, Aliabadi P, Felson DT. Prevalence of symptomatic hand osteoarthritis and its impact on functional status among the elderly: The Framingham Study. Am J Epidemiol 2002;156:1021–7.
3. Kjeken I, Dagfinrud H, Slatkowsky-Christensen B, Mowinckel P, Uhlig T, Kvien TK, *et al*. Activity limitations and participation restrictions in women with hand osteoarthritis: patients' descriptions and associations between dimensions of functioning. Ann Rheum Dis 2005;64:1633–8.
4. Zhang W, Doherty M, Leeb BF, Alekseeva L, Arden NK, Bijlsma JW, *et al*. EULAR evidence-based recommendations for the diagnosis of hand osteoarthritis: report of a task force of ESCISIT. Ann Rheum Dis 2009;68:8–17, http://dx.doi.org/10.1136/ard.2007.084772.
5. Kjeken I, Smedslund G, Moe RH, Slatkowsky-Christensen B, Uhlig T, Hagen KB. Systematic review of design and effects of splints and exercise programs in hand osteoarthritis. Arthritis Care Res (Hoboken) 2011;63:834–48, http://dx.doi.org/10.1002/acr.20427.
6. Moe RH, Kjeken I, Uhlig T, Hagen KB. There is inadequate evidence to determine the effectiveness of nonpharmacological and nonsurgical interventions for hand osteoarthritis: an overview of high-quality systematic reviews. Phys Ther 2009;89:1363–70.
7. Mahendira D, Towheed TE. Systematic review of non-surgical therapies for osteoarthritis of the hand: an update. Osteoarthritis Cartilage 2009;17:1263–8.
8. Ye L, Kalichman L, Spittle A, Dobson F, Bennell K. Effects of rehabilitative interventions on pain, function and physical impairments in people with hand osteoarthritis: a systematic review. Arthritis Res Ther 2011;13, http://dx.doi.org/10.1186/ar3254. R28.
9. Stukstette M, Hoogeboom T, de Ruiter R, Koelmans P, Veerman E, den Broeder A, *et al*. A multidisciplinary and multidimensional intervention for patients with hand osteoarthritis. Clin Rehabil 2012;26:99–110, http://dx.doi.org/10.1177/0269215511417739.
10. Altman R, Alarcon G, Appelrouth D, Bloch D, Borenstein D, Brandt K, *et al*. The American College of Rheumatology criteria for the classification and reporting of osteoarthritis of the hand. Arthritis Rheum 1990;33:1601–10.
11. Bellamy N, Campbell J, Haraoui B, Buchbinder R, Hobby K, Roth JH, *et al*. Dimensionality and clinical importance of pain and disability in hand osteoarthritis: development of the Australian/Canadian (AUSCAN) Osteoarthritis Hand Index. Osteoarthritis Cartilage 2002;10:855–62.
12. McColl MA, Paterson M, Davies D, Doubt L, Law M. Validity and community utility of the Canadian Occupational Performance Measure. Can J Occup Ther 2000;67:22–30.
13. Law M, Baptiste S, McColl M, Opzoomer A, Polatajko H, Pollock N. The Canadian occupational performance measure: an outcome measure for occupational therapy. Can J Occup Ther 1990;57:82–7.
14. Kellgren JH, Lawrence JS. Radiological assessment of osteo-arthrosis. Ann Rheum Dis 1957;16:494–502.
15. Pham T, van der HD, Altman RD, Anderson JJ, Bellamy N, Hochberg M, *et al*. OMERACT-OARSI initiative: Osteoarthritis Research Society International set of responder criteria for osteoarthritis clinical trials revisited. Osteoarthritis Cartilage 2004;12:389–99.
16. Pham T, van der HD, Lassere M, Altman RD, Anderson JJ, Bellamy N, *et al*. Outcome variables for osteoarthritis clinical trials: the OMERACT-OARSI set of responder criteria. J Rheumatol 2003;30:1648–54.
17. Bellamy N, Campbell J, Haraoui B, Gerecz-Simon E, Buchbinder R, Hobby K, *et al*. Clinimetric properties of the AUSCAN Osteoarthritis Hand Index: an evaluation of reliability, validity and responsiveness. Osteoarthritis Cartilage 2002;10:863–9.
18. Vliet Vlieland TP, van den Ende CH, Breedveld FC, Hazes JM. Evaluation of joint mobility in rheumatoid arthritis trials: the value of the EPM-range of motion scale. J Rheumatol 1993;20:2010–4.
19. Kapandji A. Clinical test of apposition and counter-apposition of the thumb. Ann Chir Main 1986;5:67–73.
20. Lefevre-Colau MM, Poiraudeau S, Oberlin C, Demaille S, Fermanian J, Rannou F, *et al*. Reliability, validity, and responsiveness of the modified Kapandji index for assessment of functional mobility of the rheumatoid hand. Arch Phys Med Rehabil 2003;84:1032–8.
21. Kraaimaat FW, Evers AW. Pain-coping strategies in chronic pain patients: psychometric characteristics of the pain-coping inventory (PCI). Int J Behav Med 2003;10:343–63.
22. Perrot S, Poiraudeau S, Kabir M, Bertin P, Sichere P, Serrie A, *et al*. Active or passive pain coping strategies in hip and knee osteoarthritis? Results of a national survey of 4,719 patients in a primary care setting. Arthritis Rheum 2008;59:1555–62, http://dx.doi.org/10.1002/art.24205.
23. Luszczynska A, Scholz U, Schwarzer R. The general self-efficacy scale: multicultural validation studies. J Psychol 2005;139:439–57.
24. Anderson KO, Dowds BN, Pelletz RE, Edwards WT, Peeters-Asdourian C. Development and initial validation of a scale to measure self-efficacy beliefs in patients with chronic pain. Pain 1995;63:77–84.
25. Ware Jr JE, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. Med Care 1992;30:473–83.
26. Van der Heijden GJ. Shoulder Disorder Treatment: Efficacy of Ultrasound and Electrotherapy 1996.
27. Anonymous. Philadelphia panel evidence-based clinical practice guidelines on selected rehabilitation interventions: overview and methodology. Phys Ther 2001;81:1629–40.
28. Alderson P. Absence of evidence is not evidence of absence. BMJ 2004;328:476–7, http://dx.doi.org/10.1136/bmj.328.7438.476.
29. Stamm TA, Machold KP, Smolen JS, Fischer S, Redlich K, Graninger W, *et al*. Joint protection and home hand exercises improve hand function in patients with hand osteoarthritis: a randomized controlled trial. Arthritis Rheum 2002;47:44–9.
30. Kjeken I, Darre S, Smedslund G, Hagen KB, Nossum R. Effect of assistive technology in hand osteoarthritis: a randomised controlled trial. Ann Rheum Dis 2011;70:1447–52, http://dx.doi.org/10.1136/ard.2010.148668.
31. Rogers MW, Wilder FV. Exercise and hand osteoarthritis symptomatology: a controlled crossover trial. J Hand Ther 2009;22:10–7, http://dx.doi.org/10.1016/j.jht.2008.09.002. discussion 19–20; quiz 18.
32. Prochaska JO, DiClemente CC, Norcross JC. In search of how people change. Applications to addictive behaviors. Am Psychol 1992;47:1102–14.

33. Maheu E, Altman RD, Bloch DA, Doherty M, Hochberg M, Mannoni A, *et al*. Design and conduct of clinical trials in patients with osteoarthritis of the hand: recommendations from a task force of the Osteoarthritis Research Society International. Osteoarthritis Cartilage 2006;14:303–22.

34. Pisters MF, Veenhof C, Schellevis FG, Twisk JW, Dekker J, De Bakker DH. Exercise adherence improving long-term patient outcome in patients with osteoarthritis of the hip and/or knee. Arthritis Care Res (Hoboken) 2010;62:1087–94, http://dx.doi.org/10.1002/acr.20182.