

Effectiveness of an Integrated Multidisciplinary Osteoarthritis Outpatient Program versus Outpatient Clinic as Usual: A Randomized Controlled Trial

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ABSTRACT. Objective. Osteoarthritis (OA) is one of the leading causes of pain and disability. Given the constraint in the provision of care, there is a need to develop and assess effectiveness of new treatment models. The objective was to compare satisfaction with and effectiveness of a new integrated multidisciplinary outpatient program with usual care in an outpatient clinic for patients with OA.

Methods. Patients with clinical OA referred to a rheumatology outpatient clinic were randomized to a 3.5-h multidisciplinary group-based educational program followed by individual consultations, or to usual care. The primary outcome was satisfaction with the health service evaluated on a numerical rating scale (0 = extremely unsatisfied, 10 = extremely satisfied) after 4 months. Secondary outcomes included health-related quality of life measures.

Results. Of 391 patients, 86.4% (n = 338) were women, and mean age was 61.2 (SD 8.0) years. At 4 months, patients who received integrated multidisciplinary care were significantly more satisfied with the health service compared with controls, with a mean difference of -1.05 (95% CI -1.68 to -0.43, p < 0.001). Among secondary outcomes, only self-efficacy with other symptoms scale (10-100) improved significantly in the multidisciplinary group compared with controls at 4 months (3.59, 95% CI 0.69-6.5, p = 0.02). At 12 months, the Australian/Canadian Hand Osteoarthritis Index pain (0-10) and fatigue scores (0-10) were slightly worse in the multidisciplinary group with differences of 0.38 (95% CI 0.06-0.71, p = 0.02) and 0.55 (95% CI 0.02-1.07, p = 0.04), respectively.

Conclusion. Patients receiving an integrated multidisciplinary care model were more satisfied with healthcare than those receiving usual care, whereas there were no clinically relevant improvements in health outcomes. (J Rheumatol First Release December 15 2015; doi:10.3899/jrheum.150157)

Key Indexing Terms:
OSTEOARTHRITIS
EDUCATION

MULTIDISCIPLINARY

INTERDISCIPLINARY
SATISFACTION

Osteoarthritis (OA) is the most frequent chronic musculoskeletal joint disorder and a leading cause of pain and disability¹. The hands, hips, and knees are frequent sites of disease involvement^{2,3}. Recommendations for the management of OA focus on a combination of pharmacological, surgical, and nonpharmacological interventions^{4,5,6,7}. Most of the nonpharmacological treatments have been studied in

patients with hip and knee OA with a special emphasis on exercise, physical activity, patient education, and weight control³.

Despite widespread support for OA recommendations, the implementation in clinical practice is suboptimal⁸. In particular, qualitative studies suggest that patients experience unmet needs with regard to information about OA, its

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treatment, and management⁹. Data from Australia have drawn attention to compliance challenges with extensive patient education programs¹⁰. Only about 11% of the eligible patients in an Australian study agreed to take part in an educational program with 6 sessions, and finally, 30% of the included patients missed all educational sessions¹⁰. We therefore developed a brief, patient-oriented educational program designed to enhance self-management in patients referred to a rheumatology outpatient clinic because of moderate to severe OA¹¹.

Given the high number of patients diagnosed with OA, and constraint in the provision of services for these kinds of patients, there is a need to develop and assess clinical effectiveness and cost effectiveness of new models of service delivery that support the implementation of pharmacological and nonpharmacological recommendations to patients with OA¹². The objective of our study was to compare satisfaction and clinical effectiveness of a traditional outpatient clinic with the new multidisciplinary integrated model for service delivery.

MATERIALS AND METHODS

Study sample and setting. This was a randomized, single-blind, controlled study with 1-year followup. A total of 391 participants referred to an outpatient hospital clinic with a known diagnosis of OA were recruited for our study. All patients were prescreened¹³ to ensure that OA was their primary complaint prior to inclusion.

Inclusion criteria were age between 40 and 80 years, and clinical OA in the hand, hip, knee, or generalized OA. The classification of hand, hip, or knee OA was based on the primary localization of complaints (primary OA complaint both at the referral from their general practitioner and confirmed by a rheumatologist), and data on tender and swollen joint counts were collected at baseline based on 66 joint counts. However, some of the patients clearly had a more generalized disease with 2 or more affected joint groups¹⁴, and these were classified as having generalized OA by the rheumatologist at the specialist OA clinic. OA manifestation in the spine was not considered. Exclusion criteria were cognitive impairments, inability to read and understand Norwegian, recent trauma or major surgery, or other ongoing diseases such as rheumatoid arthritis, primary crystal arthritis, or cancer.

Before the first visit at the outpatient clinic, all patients filled in a questionnaire including standardized instruments for measuring symptoms, functioning, and health-related quality of life (HRQOL). The questionnaire also included information on sociodemographics (age, sex, height, weight, marital status, work situation, emotional distress, and physical activity).

Patients were thereafter randomly allocated to 1 of the 2 interventions. To ensure equal-sized treatment groups, random permuted blocks of 4–8 participants were used¹⁵. Randomization was stratified by location of the main OA diagnosis: OA in hand, hip, knee, or generalized OA. The stratified random allocation schedule was generated by a person not otherwise involved in recruitment, assessment, or treatment of participants (statistician PM). The randomization sequence was carried out in computer-generated, sequentially numbered and sealed envelopes.

Followup procedure. At 4 and 12 months of followup, the participants filled in mailed questionnaires. The inclusion of patients and administration of questionnaires was carried out by a research secretary (AF) not otherwise involved in the treatment of participants. Health professionals involved in any interventions were not involved in collecting clinical data. Blinding providers and patients is not possible in this type of study, but those handling patient data were blinded for the treatment allocation.

All patients involved in the project gave informed consent and were

informed according to the Declarations of Helsinki. The regional ethical committee reviewed and approved the project (REK ref 156-06073 1.2006.598). The International Standard Randomised Controlled Trial Number is 25778426. The details of the recruitment procedure are described elsewhere¹⁶. Data collection took place from April 2006 to January 2012.

Interventions. The experimental intervention was a new multidisciplinary approach, in which the referred patients first received a 3.5-h multidisciplinary group-based educational program about OA¹¹, immediately followed by individual consultations with a rheumatologist and members of the multidisciplinary team as needed (orthopedic surgeon, physical therapist, occupational therapist, pharmacist, or dietitian).

The educational program was developed by a multidisciplinary OA team at the hospital¹¹ including 4 main themes: (1) What is OA? (2) Activity possibilities or limitations, what can we do ourselves? (3) Treatment options; and (4) How to live with OA.

Control patients received usual individual outpatient care where a nurse received and a rheumatologist examined the patient. The rheumatologist referred the patient to other health professionals similar to the multidisciplinary group, according to identified needs. At 4 months, patients in the multidisciplinary (usual care) group reported having consulted general practitioners in $n = 5$ (5), physical therapists in $n = 3$ (0), and occupational therapists in $n = 0$ (0) cases, 1 or more times in addition to the study protocol.

Outcomes. The primary outcome measure was patient satisfaction with the health service assessed at 4-month followup, which was evaluated on an 11-point numeric rating scale (NRS; anchors 0 = extremely unsatisfied, 10 = extremely satisfied).

Secondary outcomes included pain and global disease activity measured on NRS (range 0–10) with higher numbers indicating more pain or disease severity. Disease- and location-specific pain and physical functioning were assessed by the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)¹⁷ and the Australian/Canadian Hand Osteoarthritis Index (AUSCAN)¹⁸. The WOMAC is developed for patients with hip or knee OA (scored 0–30, where 0 is best). This instrument has been found responsive and valid for measuring pain (5 items), stiffness (2 items), and physical function (17 items), and the results can be displayed as 1 sum score or as separate subscores. The AUSCAN is a hand OA disease-specific measure, which consists of 15 items relating to pain (5 items), hand stiffness (1 item), and problems with performance of activities (9 items). The results can be presented as a sum score or as subscores. Response options are none, mild, moderate, severe, and extreme (scored 0–10, where 0 is best)^{18,19}.

HRQOL was measured by the generic Medical Outcomes Study Short Form-36 (SF-36)²⁰, which is a widely used generic instrument that consists of 8 health scales that contribute to 2 higher order health scales, the physical component summary (PCS) and mental component summary (MCS) scores, which give a mean (SD) score of 50 (10) based on normative data from the general population in Norway²¹. The SF-36 is often used to assess HRQOL in the general population and in different diseases (scored 0–100, where 100 is best), and the English version has been translated to and validated in Norwegian^{22,23}.

Emotional distress was assessed by the Symptom Checklist 25, consisting of 25 questions about symptoms of anxiety, depression, and other common psychiatric symptoms²⁴ and scored 1–4, where 1 is best (not bothered) and 4 is the worst (extremely bothered). Self-efficacy was evaluated using the Arthritis Self-Efficacy Scale for pain and for other symptoms (Scored 10–100, where 100 is best)²⁵.

Statistics. Baseline and demographic descriptive statistics are presented using counts and percentages for categorical variables, and mean and SD for continuous variables. Student *t* tests were used to assess differences between the groups on patient satisfaction measured after 4 months. To assess the treatment effect of 4 and 12 months after treatment, we used mixed model analyses with baseline value, time, treatment, and time × treatment interaction as fixed factors, and individual patient intercept as random factor. Effect measures were estimated using marginal means (EMM) with 95% CI. Analyses were also performed on standardized measurements to compare

the effect estimates between outcomes. These estimates are denoted standardized mean differences and were computed by the change divided by the SD of the change.

Power calculations. In this randomized controlled trial, 2 independent, equally sized groups were compared. Data from the pilot study and other published research articles^{26,27} were used for power calculations. An $\alpha = 0.05$ and 80% power, as well as a smallest worthwhile detectable difference between the groups of 0.20, were based on an estimated difference for pain measured by WOMAC or AUSCAN, depending on the joint site mainly affected. The standardized difference $(0.20) \div SD (0.70)$ was 0.25, and about 200 patients were needed in each group.

Data analyses. Both parametric and nonparametric statistical analyses were used as required. Student t tests were used to assess differences between the groups on patient satisfaction measured after 4 months. Mixed model analyses with random intercept were used to assess group differences on symptoms at 4 and 12 months, with effect measures presented using EMM with 95% CI. Analyses were also performed on standardized measurements to compare the effect estimates between outcomes. These estimates are denoted standardized mean differences and were computed by the change divided by the SD of the change.

All analyses were performed according to modified intention-to-treat principles, i.e., all randomized patients were included in the analyses except

those who failed to satisfy major eligibility criteria or had no followup observations after baseline²⁸. Further, multivariable analyses were used to study effects of the different treatment strategies. Descriptive statistics and Student t tests were performed in IBM SPSS statistics 20. Mixed models analyses were performed in SAS version 9.2.

RESULTS

For each group, the number of participants who were randomly assigned received intended treatment and were analyzed for the primary outcome (Figure 1).

Of the 391 included participants, 86.4% (n = 338) were women and the mean age (SD) was 61.2 (8.0) years (Table 1). Most patients had hand OA (n = 263), 71 patients had knee, 27 patients had hip, and 30 had primarily generalized OA²⁹. There were no statistically significant differences between the 2 groups in baseline variables (Table 1). A total of 291 (74.7%) contributed data at the 1-year followup.

Patients who received a multidisciplinary intervention were significantly more satisfied with the health service at the 4-month followup ($p < 0.001$) compared with control

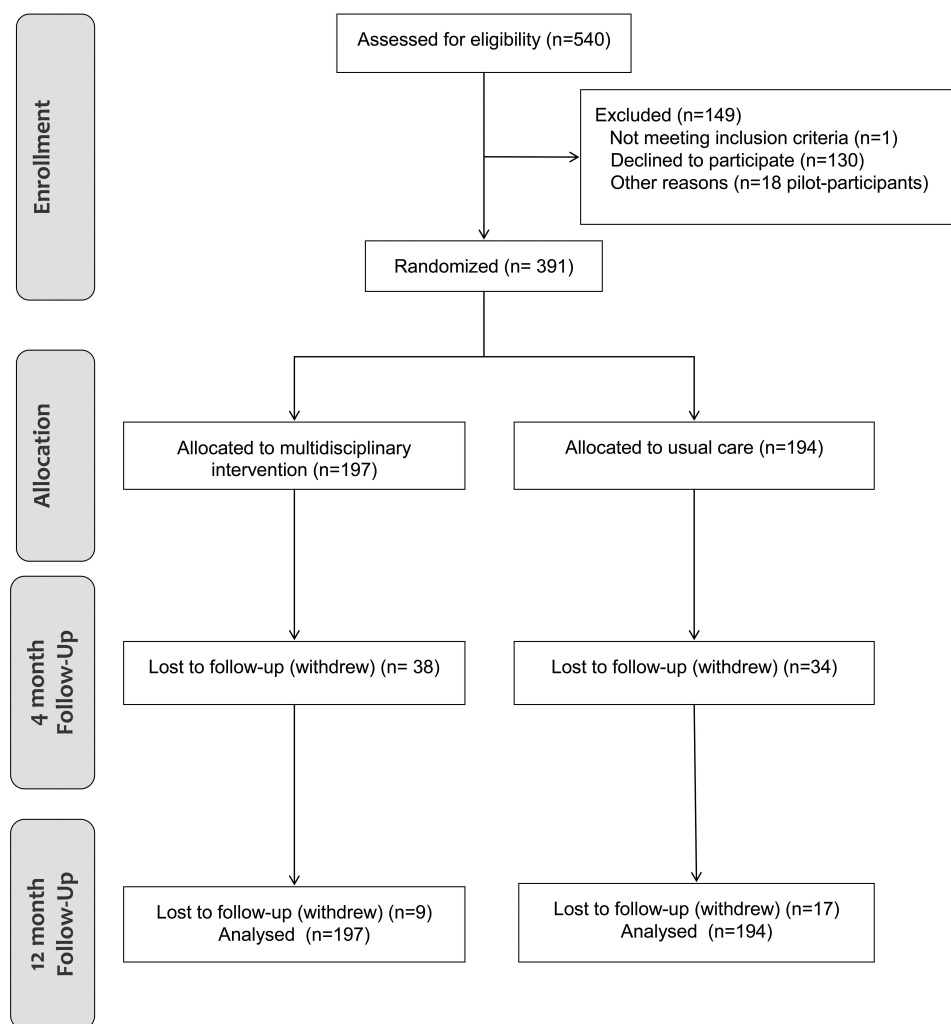


Figure 1. Flowchart showing randomization and allocation of study subjects.

Table 1. Patient characteristics at baseline (n = 391). Values are mean (SD) unless otherwise specified.

Characteristics	Multidisciplinary, n = 197*	Usual Care, n = 194*
Demographics		
Age, yrs	60.98 (8.2)	61.47 (7.5)
Female, n (%)	170 (86)	168 (87)
BMI	25.53 (4.5)	25.77 (5.4)
SJC, 66 joints	6.0 (7.9)	7.3 (8.7)
TJC, 66 joints	8.2 (8.8)	9.9 (10.1)
Analgesics, daily		
Paracetamol, n (%)	34 (17)	34 (18)
NSAID, n (%)	35 (18)	23 (12)
Pain and functioning		
Pain, NRS	5.39 (2.0)	5.23 (2.1)
Fatigue, NRS	4.24 (2.9)	4.11 (2.8)
Stiffness, NRS	5.11 (2.2)	5.30 (2.5)
AUSCAN total	4.65 (1.8)	4.71 (1.9)
AUSCAN pain	4.78 (1.8)	4.79 (1.9)
AUSCAN stiffness	4.63 (2.4)	4.64 (2.2)
AUSCAN physical	4.75 (2.0)	4.9 (2.2)
WOMAC sum	11.09 (5.5)	11.69 (5.5)
WOMAC pain	3.53 (2.0)	3.97 (2.0)
WOMAC stiffness	4.45 (2.1)	4.43 (2.1)
WOMAC physical	3.29 (2.0)	3.62 (1.9)
ASES pain	56.86 (17.9)	57.33 (19.0)
ASES symptoms	67.54 (16.9)	69.27 (16.7)
HSCL-25	1.55 (0.5)	1.54 (0.4)
HRQOL		
SF-36 PCS	31.3 (5.0)	30.8 (4.7)
SF-36 MCS	49.2 (5.6)	49.4 (5.8)
EQ-5D	0.64 (0.2)	0.62 (0.3)

Mixed model analyses. * No significant differences between the 2 groups at baseline $p > 0.05$. BMI: body mass index; SJC: swollen joint count; TJC: tender joint count; NSAID: nonsteroidal antiinflammatory drugs; NRS: numeric rating scale (11-point, range 0–10); AUSCAN: Australian/Canadian Hand Osteoarthritis Index; WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index; ASES: Arthritis Self-Efficacy Scale; HSCL-25: Symptom Checklist 25; HRQOL: health-related quality of life; SF-36: Medical Outcomes Study Short Form-36; PCS: physical component summary; MCS: mental component summary.

patients, who only received individual consultations (Table 2). Among secondary outcomes, the change in self-efficacy with the other symptoms subscale was significantly different ($p = 0.02$) with a difference of 3.59 (95% CI 0.69–6.5) between the 2 groups in favor of the multidisciplinary approach (Table 1, Figure 2).

There were statistically significant differences between

the groups after 12 months on the secondary outcomes AUSCAN pain (0–10) and fatigue (NRS 0–10) in favor of the control intervention with differences of 0.38 (95% CI 0.06–0.71, $p = 0.02$) and 0.55 (95% CI 0.02–1.07, $p = 0.04$), respectively (Table 1, Figure 3).

DISCUSSION

The results of our study showed that a brief multidisciplinary program for patients with OA has a positive effect on patient satisfaction at 4-month followup, but not on secondary outcomes related to patient health.

Patient satisfaction is a multidimensional concept that includes satisfaction with care. Satisfaction with care does not measure satisfaction with the outcome, but is an expression of how the patient rates the quality of health-care^{30,31}, and is an important factor related to adherence and participation in health-related care^{32,33}. Because OA is a highly prevalent disease without effective disease-modifying drugs available, there is a need to learn how to live with the disease, a complex process with no expected short-term relief of signs and symptoms. Focus group interviews with patients during the development of the intervention and data from the pilot study suggested that satisfaction with care was an important outcome of multidisciplinary care for this population. Adherence to the different treatment elements or advice was not measured in our study. The improvement of satisfaction in the multidisciplinary care group could be related to the content of the intervention, to the attention given by a multidisciplinary team, to interaction with other patients, or to a combination of these elements. Such processes of improvement could be explored in qualitative interviews and should be on the future research agenda. The patients may or may not have received information prior to the multidisciplinary approach. However, meeting the multidisciplinary team that supplied coordinated information, and being part of a group of patients in which experiences could be discussed, could be important factors contributing to satisfaction. Improving courtesy and respect have also been suggested as important determinants of patient satisfaction³⁴. The multidisciplinary team was specially trained in health pedagogics, and this could have affected the communication of respect, and possibly satisfaction. To individualize the group-based multidisciplinary approach, the content was tailored to each participant's most important questions related to their OA, as written down and shared with the group of

Table 2. Differences between groups on primary outcome satisfaction with the health service at the 4-month followup examination.

Outcome, NRS	Multidisciplinary, n = 197*	Usual Care, n = 194*	Difference	95% CI
Satisfaction with care, mean (SD)	7.45 (2.68)	6.40 (2.87)	-1.05	-1.68 to -0.43

* Two-sample Student t test $p < 0.001$. NRS: numeric rating scale (11-point, range 0–10).

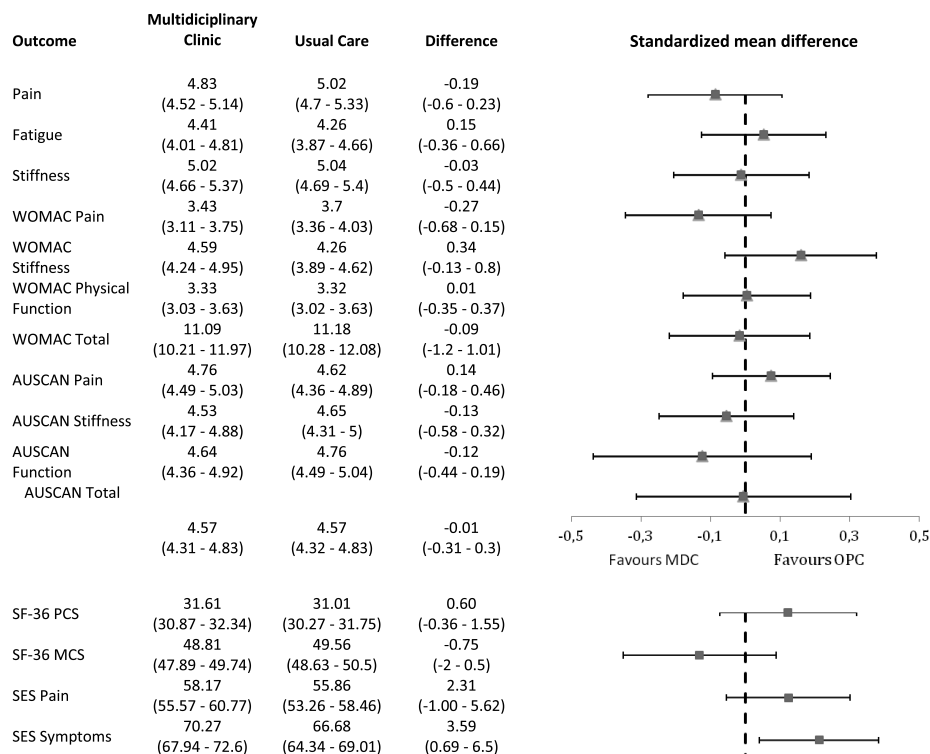


Figure 2. EMM (95% CI) and standardized mean differences (horizontal lines indicate 95% CI) at the 4-month followup examination. Mixed model analyses. Standardized mean difference. Estimate of effect size on standardized measurements. For pain, fatigue, and stiffness, numeric rating scales 0–10, 10 is best. EMM: estimated marginal means; MDC: multidisciplinary clinic; OPC: outpatient clinic; WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index 3 (0–30, 0 is best); AUSCAN: Australian/Canadian Osteoarthritis Hand Index (0–10, 0 is best); SF-36: Medical Outcomes Study Short Form-36, 0–100, 100 is best; PCS: physical component summary; MCS: mental component summary; SES: Arthritis Self Efficacy Scale (10–100, 100 is best).

patients¹⁶. This was an important tool for tailoring the information individually to each patient, possibly also affecting patient satisfaction.

Even if the patients in the integrated multidisciplinary care group were more satisfied, this positive effect was not reflected in improved symptoms and function in our study, or in the pilot study³⁵. It cannot be ruled out that patients in the usual care group were disappointed for not receiving the multidisciplinary approach, and scored lower on satisfaction, reflecting a *nocebo* effect. The usual care group, however, could be referred to other health professionals after consultation, thus stretching the intervention over time instead of receiving the total intervention in 1 visit as the multidisciplinary group did. This time delay in the usual care group could have been reflected in poorer satisfaction at 4 months, but could also have led to a more positive experience with the health service closer to the 4-month followup than the multidisciplinary care group. A systematic review of models of care for OA concluded that the effects of multidisciplinary care were unclear³⁶. Published trials exploring the efficacy

of multidisciplinary care for people with OA also indicated contrasting results^{37,38}.

The secondary outcome self-efficacy (10–100) showed a statistically significant improvement in the multidisciplinary care group compared with a usual individual outpatient intervention after 4 months. Self-efficacy is a positive belief in one's own capability to achieve different goals³⁹, and is regarded as an important factor for positive health outcomes in people with arthritis²⁵. A systematic review has identified evidence for the prognostic value of low self-efficacy, leading to increased disability in patients with OA⁴⁰. Strengthening self-efficacy was one of the goals in the multidisciplinary approach. Positive effects on self-efficacy following educational programs for patients compared with controls has been observed by others⁴¹, or been reported unchanged⁴².

The difference between the groups in favor of the individual outpatient intervention group at the 12-month followup on the AUSCAN pain subscale may be related to the fact that hand OA is underdiagnosed and undercommunicated, and that the majority of the participants were

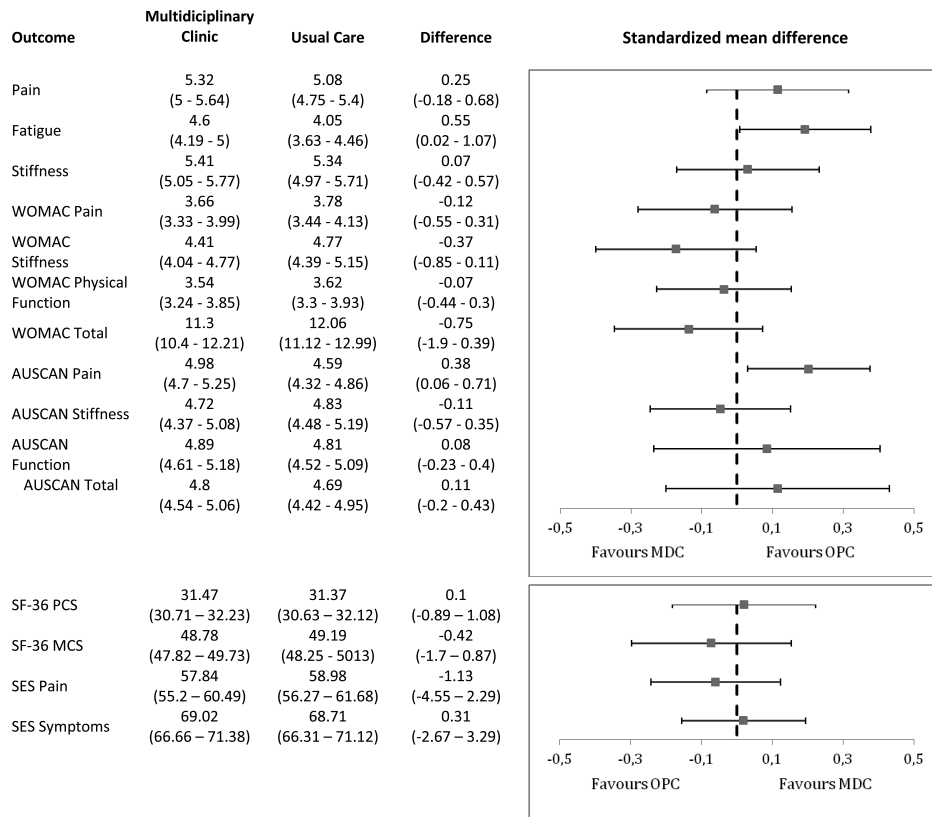


Figure 3. EMM (95% CI) and standardized mean differences (horizontal lines indicate 95% CI) at the 12-month followup examination. Mixed model analyses. Standardized mean difference. Estimate of effect size on standardized measurements. For pain, fatigue, and stiffness, numeric rating scales 0–10, 10 is best. EMM: estimated marginal means; MDC: multidisciplinary clinic; OPC: outpatient clinic; WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index 3 (0–30, 0 is best); AUSCAN: Australian/Canadian Osteoarthritis Hand Index (0–10, 0 is best); SF-36: Medical Outcomes Study Short Form-36, 0–100, 100 is best; PCS: physical component summary; MCS: mental component summary; SES: Arthritis Self Efficacy Scale (10–100, 100 is best).

diagnosed with hand OA prior to or during the intervention. The multidisciplinary care group received information on how to manage hand pain from different treatment perspectives, but the individual outpatient intervention group did not receive such systematic general information. Also, a recent systematic review showed contrasting effects of multidisciplinary approaches³⁶, and another comparable study recruiting only patients with hand OA did not find any beneficial health effects compared with usual care³⁷.

The difference between groups on fatigue was significant, displaying higher fatigue scores in patients who had undergone a multidisciplinary approach. This multidisciplinary approach systematically included information about this symptom. It is possible that this particular focus reinforced experienced symptoms, both fatigue and pain. In the future, there may be more optimal models of care for this group of patients to individually target multifaceted needs.

The other secondary outcomes as described in the protocol, including measures of HRQOL, did not show any statistically significant differences between the 2 groups.

Thus, this study does not indicate that greater patient satisfaction is accompanied by a better quality of life⁴³.

Our study was planned and initiated in the beginning of the 21st century. Availability of instruments and comparable research were limited at the time, and there were no agreed recommendations on how to measure patient satisfaction^{44,45}. There is also no consensus on how extensive a group difference should be to be considered clinically meaningful. Secondary outcomes were used for power calculations and did not indicate a size of difference between groups *a priori*. However, a similar approach to the one used in our study has shown good validity in patients after total hip replacements⁴³. On the outcome pain on NRS, a 1-point difference between groups of patients with rheumatic and musculoskeletal diseases has been considered minimally clinically important⁴⁶. The use of both the WOMAC and AUSCAN to identify function was applied because they were developed for the target population with hand or low limb OA, and there were indications that several patients with hand OA also had low limb OA symptoms²⁶.

The inclusion of the 391 patients in our study was long, stretching over 6 years, partly because the intervention took place in a single specialist care unit with limited referrals, and partly because of the need to organize a whole multidisciplinary team to see the patients. Several of the referrals to the clinic were not applicable because they were second opinions asking if there was inflammatory arthritis or indications for surgery. The study was also limited by a small number of participating men. Age and female sex have both been found to be associated with OA⁴⁷. Women live longer and consult primary care physicians in Norway for their OA-related problems almost 75% more often than men⁴⁸. In general practice, the median OA pain score has been reported to be higher in women than in men⁴⁹. There are also indications that women generally report higher chronic pain prevalence than men⁵⁰. The sex differences would be interesting to explore further, especially to learn why it is more difficult to recruit men than women for this type of study. Disease duration was not systematically recorded in our study because disease onset is difficult to assess and probably unreliable in this clinical setting. Additional radiographic data on joint damage could have brought an addition to the study. All patients had symptomatic OA, and because of the diversity of sites involved and the clinical setting, a clinical diagnosis was applied without formal use of classification criteria. It is well known that symptoms and radiographic findings are dissociated. Because of the clinical approach in specialist care, the current patient sample represents symptomatic patients with OA and not a population-derived sample.

When multiple comparisons are performed, the probability for Type I errors increases, i.e., statistically significant differences can occur by chance. Therefore, it is important to perform analyses of secondary outcomes for explorative purposes only. Agreement on recommended outcomes for various trials may reduce the amount of outcomes used per trial, and contribute to reducing the risk of multiple comparison bias in future research.

The possibility of extrapolating the results is dependent on the generalizability of the study population. In our trial, most eligible patients (74%) were included into the study, but reasons for nonparticipation were not recorded. The effect of the intervention can thus formally only be extrapolated to patients willing to participate⁵¹.

An integrated multidisciplinary educational approach increased patient satisfaction and self-efficacy in patients with OA after 4 months compared with those receiving usual care. Explorative analyses indicated no corresponding improvement in health outcomes after the multidisciplinary approach at 12-month followup.

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