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Clinical Trial

Longer-term quality of care, effectiveness, and cost-effectiveness of implementing a model of care for osteoarthritis: A cluster-randomized controlled trial

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SUMMARY

Objective: To assess the quality of care, effectiveness, and cost-effectiveness over 12 months after implementing a structured model of care for hip and knee osteoarthritis (OA) in primary healthcare as compared to usual care.
Design: In this pragmatic cluster-randomized, controlled trial with a stepped-wedge cohort design, we recruited 40 general practitioners (GPs), 37 physiotherapists (PTs), and 393 patients with symptomatic hip or knee OA from six municipalities (clusters) in Norway. The model included the delivery of a 3-hour patient education and 8–12 weeks individually tailored exercise programs, and interactive workshops for GPs and PTs. At 12 months, the patient-reported quality of care was assessed by the OsteoArthritis Quality Indicator questionnaire (16 items, pass rate 0–100%, 100%=best). Costs were obtained from patient-reported and national register data. Cost-effectiveness at the healthcare perspective was evaluated using incremental net monetary benefit (INMB).
Results: Of 393 patients, 109 were recruited during the control periods (control group) and 284 were recruited during interventions periods (intervention group). At 12 months the intervention group reported statistically significant higher quality of care compared to the control group (59% vs. 40%; mean difference: 17.6 (95% confidence interval [CI] 11.1, 24.0)). Cost-effectiveness analyses showed that the model of care resulted in quality-adjusted life-years gained and cost-savings compared to usual care with mean INMB €2020 (95% CI 611, 3492) over 12 months.
Conclusions: This study showed that implementing the model of care for OA in primary healthcare, improved quality of care and showed cost-effectiveness over 12 months compared to usual care.
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Introduction

Hip and knee osteoarthritis (OA) is a highly prevalent chronic condition causing a substantial burden for the individual and the society.[1] From 2010–2019, the number of people with OA globally rose by 28%, and the prevalence will continue to increase due to the ageing of the population, increasing obesity, and more joint injuries.[1,2] The increasing prevalence and the increased risk of reduced work ability among people with OA will escalate the pressure on healthcare services and the associated societal costs.[3] While there is no cure, OA patient education, exercise, and weight management may reduce symptoms, improve function, and represent the core treatment modalities in international recommendations for hip and knee OA management.[4–7] Supplementary treatment may involve walking aids and pharmacological treatment. Joint replacement surgery represents a clinical and cost-effective treatment,[2,8] but should mainly be considered for patients who are refractory to non-surgical treatment.[7]

Despite available treatment recommendations, the majority of patients with OA do not receive recommended core treatment modalities.[9] A few structured OA management programs (OAMPs) have been implemented internationally to increase the uptake of best evidence care.[10,11] OAMPs are defined as packages of care with the following: i) a personalized management plan; ii) with re-assessment and progression; iii) using a minimum of two core treatments (education, exercise, weight control); and iv) optional adjunctive therapies.[12] However, it is currently unknown if OAMPs can show long-term effectiveness and cost-effectiveness.

To improve the quality of hip and knee OA care a structured model of care for OA (the SAMBA model[11,13]) was developed based on international treatment recommendations.[4–7] The model was implemented among general practitioners (GPs) and physiotherapists (PTs) in primary care and tested for effectiveness in a randomized controlled trial (RCT).[11,13] The results at 6 months showed that patients in the intervention group were more likely to be treated according to international OA guidelines, to fulfill recommendations for physical activity, to report greater satisfaction with care, and were less likely to have undergone joint replacement surgery compared to patients in the usual care group.[11] The purpose of this study was to examine the quality of care and effectiveness at 12 months and cost-effectiveness over 12 months of implementing the SAMBA model of care among patients with hip or knee OA in a primary healthcare setting.

Method

Study design

A pragmatic, cluster-RCT with a stepped-wedge cohort design was conducted in six Norwegian neighboring municipalities between January 2015 and October 2017.[11,13] Data Inspectorate/Protection Officials approved the study on 22 December 2014. Ethical approval was not required according to the Regional Ethics Committee (Ref. no: 2014/1739 REK South-East C). The procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000. The study was pre-registered (ClinicalTrials.gov NCT02333656), and the protocol has been published.[13] This study is reported according to an extended CONSORT checklist[14] and the CHEER checklist[15] for the cost-effectiveness analyses.

Participants

Participating GPs (n = 40) and PTs (n = 37) in primary healthcare services identified potential eligible patients: aged ≥45 years with symptomatic hip or knee OA diagnosis verified clinically[6] or radiologically by the GP. Patients who did not understand Norwegian, had four joint replacements (all hip and knee joints), inflammatory rheumatic diseases, or other major conditions that restricted their ability to adhere to the intervention were excluded.[13] Written informed consent from patients was obtained upon inclusion.

Randomization and blinding

The municipalities (clusters) were randomly allocated to one of the six sequences for time of crossover from control to intervention phase, by an independent statistician, using a computer-generated list of random numbers, stratified by inhabitants < 20,000 vs > 20,000, to distinguish the three smaller from the three larger municipalities. All six municipalities started the trial simultaneously with a control phase with the GPs and the PTs delivering usual care and being naïve to the SAMBA model. At predefined time points, the municipalities switched, one by one every second month, from the control to intervention phase (use of the SAMBA model). Patients recruited to the study during the control phase constituted the control group, whereas patients recruited during the intervention phase constituted the intervention group. It was not possible to blind the involved GPs, PTs, or patients, but a statistician blinded for group allocation performed the statistical analyses of the primary outcome.

The SAMBA model of care for OA

While usual care may include infrequent GP visits, pharmacological therapy, and occasionally a referral to PT, the SAMBA model was developed by the research team and comprised an integrated and structured pathway for patients with OA through the healthcare system (Fig. 1).[13] The GPs were instructed to explain the OA diagnosis and treatment alternatives, provide pharmacological treatment when appropriate, and suggest referral to physiotherapy. The PT led OA 3-hour patient education program was group-based and was followed by an 8–12-week exercise program with 1-hour supervised group sessions twice a week. Based on patient examination, the PT prescribed individually tailored resistance exercise programs to increase muscular strength. Dose recommendations were based on acknowledged, international guidelines,[16] and included gradually increasing the dose towards 2–4 sets with 8–12 repetitions and 60%–70% of 1 repetition maximum, or more if tolerated. The PTs were instructed to closely monitor the patients' exercise performance and regularly provide appropriate individual adjustments of the exercise program for progression. When the patient could perform 2 extra repetitions in the last set, the resistance was increased ("The 2+ principle"). The patients were encouraged to add a third home-based session consisting of 30–60 min cardiorespiratory exercise like brisk walking, running, or bicycling. Each group enrolled 5–10 patients per PT. An optional 10-hour Healthy Eating Program was also available at Healthy Life Centers, a primary care-based service aiming to support a healthy lifestyle for people with chronic diseases.

Implementation strategy

Informed by theoretical models[17,18] and previously developed behavior change interventions,[19] an implementation strategy was designed to implement the SAMBA model of care for OA among GPs and PTs. Inter-active workshops for GPs and PTs represented the main intervention ensuring the implementation of the SAMBA model. The workshops were arranged near the time of crossover from the control phase (usual care) to the intervention phase (the SAMBA model of care). Implementation interventions to facilitate

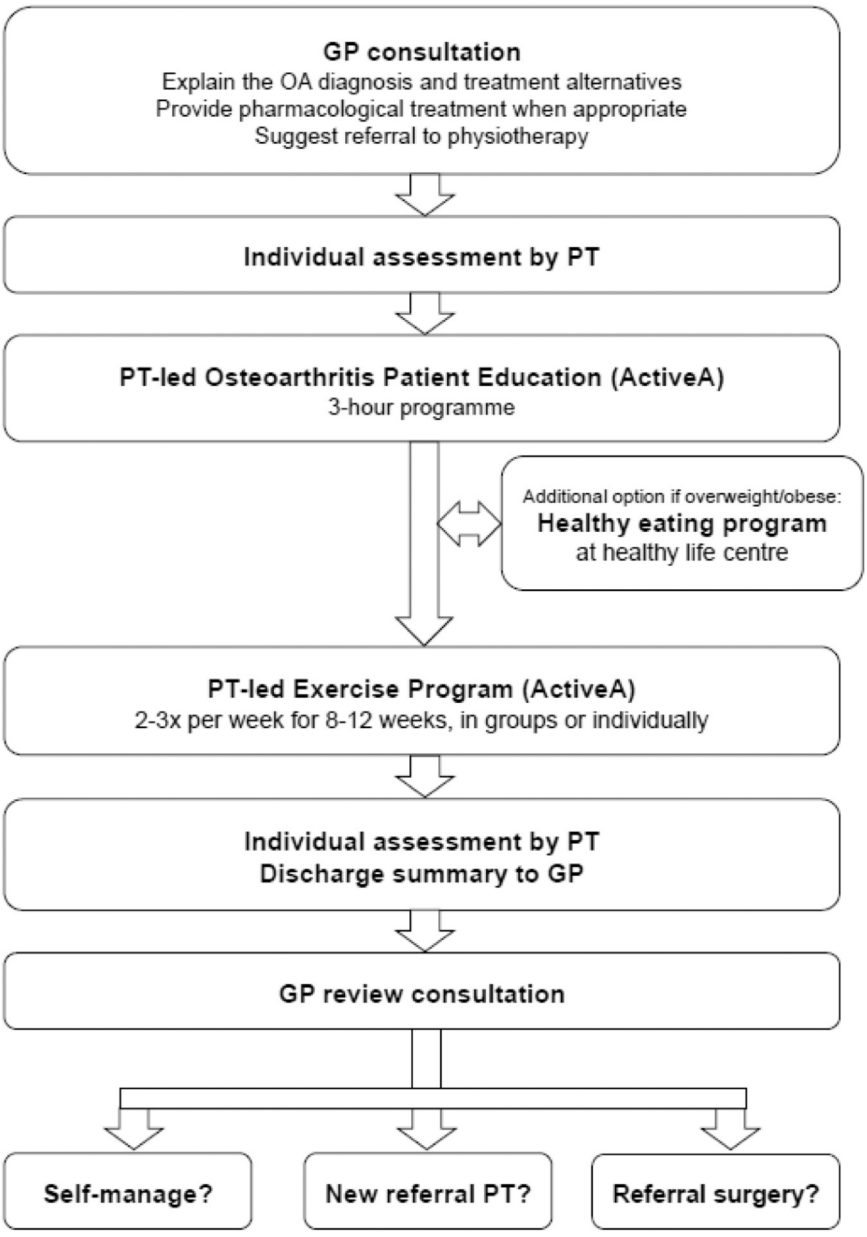

Fig. 1 Osteoarthritis and Cartilage

The SAMBA model of care for OA.

the use of the SAMBA model also included written materials with the summarized treatment recommendations, regular telephone reminders, quarterly letters with feedback, and biannual outreach visits (see published protocol[13]).

PT workshop and multidisciplinary workshop

Implementation of the model was facilitated by interactive workshops for GPs and PTs with an update on OA treatment recommendations. The PTs attended a one-day (9 h) workshop-based education program organized by the 'Active with osteoArthritis' (AktivA) program,[20] which builds on similar Swedish[21] and Danish[22] programs. The workshop included an update on OA epidemiology, clinical features, and treatment recommendations. Education in the delivery of an OA patient education program, individually tailored semi-standardized exercises, performance testing, healthy eating, and weight reduction strategies were given. The PTs received access to the "ready-to-use" standardized patient OA education program (PowerPoint file and manuscript) and access to a database with recommendations for resistance exercises and doses. The pool of recommended exercises was selected from previous OA exercise studies.[23,24] This was followed by a 1.5 h multidisciplinary (GPs, PTs, and orthopedic surgeon) workshop conducted within the General Practice at an established meeting time point to facilitate high GP attendance. It included an update on evidence-based treatment recommendations. The orthopedic surgeon presented views on the appropriate time to refer patients to surgical treatment and which

assessments (clinical and imaging) that should precede a referral. The importance of exploiting conservative treatment before considering surgery was emphasized. The research team presented the SAMBA model and facilitated a discussion between the GPs, PTs, and the orthopedic surgeon regarding OA care and the SAMBA model.

Data collection

Patients self-reported at baseline (shortly after the GP consultation) and at the 3-, 6-, 9-, and 12-months follow-ups using an electronic questionnaire, or a mailed paper questionnaire returned in a prepaid envelope. The research team collected some patient characteristics during the telephone screening pre-baseline (Table I). The GPs and PTs self-reported demographic and practice information during the workshop (Table I).

Outcomes

The primary outcome was patient-reported quality of OA care measured with the OsteoArthritis Quality Indicator questionnaire v2 (OA-QI v2).[25] The OA-QI v2 reflects current OA care guideline recommendations,[4–7] and respondents were instructed to consider what treatment, information, or advice they had received from health professionals in the past 12 months. All 16 items have 'Yes'/'No', and 'Not applicable'/'Don't remember' as response options. Each OA-QI item was considered achieved if the patient had checked 'Yes' and considered 'eligible' if the patient responded 'Yes' or 'No' for that item. Firstly, achievement of the OA-QI items (pass rates) was calculated as the total number of OA-QI items achieved divided by the number of eligible OA-QI items for each patient (in percentage). Using each patient's pass rate, the group mean total pass rates for the OA-QI v2 at baseline and follow-ups were calculated, ranging 0–100% and with 100% representing the best quality of care score. A minimal important change of 20.4 for the OA-QI v2-instrument has been estimated in a pre-post cohort study with an OA patient education intervention.[25]

Secondary outcome measures included patient-reported pain and stiffness in hip/knee, hip/knee function, and global assessment of their OA disease using an 11-point numeric rating scale (NRS 0–11, 0=best score). OMERACT-OARSI responders were calculated using

	Patients			
	Intervention group	Control group	Physio-therapists	General practitioners
Characteristic	(n = 284)	(n = 109)	(n = 37)	(n = 40)
Demographic and clinical characteristics				
Sex, female, n (%)	211 (74)	68 (62)	24 (65)	17 (42)
Age, mean (SD)	63 (10)	65 (10)	42 (8)	50 (12)
BMI, mean (SD)	29 (6)	28 (5)		
Education at university level, n (%)	101 (36)	35 (32)		
Work status, n (%)				
Full- or part-time employed	108 (38)	37 (34)		
Age retired				
On sick leave	112 (39)	50 (46)		
Receiving disability pension				
Other	13 (5)	5 (5)		
	31 (11)	11 (10)		
	20 (7)	6 (6)		
Main affected joint, n (%)				
Knee	174 (61)	54 (49)		
Hip	100 (35)	46 (42)		
Other	9 (3)	9 (8)		
Hip or knee joint prosthesis, n (%)				
No joint prosthesis	258 (91)	99 (91)		
One joint	14 (5)	6 (6)		
Two joints	6 (2)	3 (3)		
Three joints	6 (2)	1 (1)		
Years since OA diagnosis, n (SD)	7 (10)	7 (6)		
Mean pain level past week, mean NRS 0–10 (SD)	5.4 (2.0)	5.1(1.9)		
Other chronic disease, yes (%)	71 (25)	28 (26)		
(H)KOOS ADL subscale, mean (SD)	68 (20)	68 (20)		
Performance tests, mean (95% CI)				
30-s chair stand test (n = 151), mean number of stands (95% CI)	13.5 (12.8, 14.2)	n/a		
6 min walk test (n = 106), mean meters (95% CI)	489 (457, 522)			
Stairs test (n = 115), mean seconds (95% CI)	74 (68, 80)			
Work-related characteristics				
Daily work years, median (IQR)			8 (2,14)	8 (3,23)
Number of treated patients per day, mean (SD)			12 (4)	21 (4)
Exercise groups per week, mean (SD)			2 (2)	n/a
Patient list size, mean (SD)			n/a	1130 (296)

BMI: body mass index; CI: confidence interval; (H)KOOS: Knee injury and Osteoarthritis Outcome Score/ Hip disability and Osteoarthritis Outcome Score ADL subscale; IQR: interquartile range; n/a: not applicable; NRS: numeric rating scale (0–10, 0= no pain, 10 = worst pain), SD: standard deviation

Table I

Osteoarthritis and Cartilage

Baseline characteristics for patients, PTs, and GPs.

pain, function, and global assessment scores.[26] Patients classified their symptom state as acceptable or unacceptable on the Patient acceptable symptom state item.[27] The Knee injury and Osteoarthritis Outcome Score[28]/ Hip disability and Osteoarthritis Outcome Score[29] Quality of Life (K/HOOS QoL) four-item subscale was used and reported on a 0–100 scale, 100=best score. The Arthritis Self Efficacy Scale (ASES) pain and symptom subscales were reported on a 10–100 scale, 100=best score.[30] The proportion of patients who were overweight (BMI≥25) or obese (BMI≥30) was defined using self-reported body height at baseline and body weight at follow-ups. Physical activity was self-reported in three items capturing frequency, duration, and intensity.[31] Using an index,[32] patients were classified as "fulfilling" vs. "below" physical activity recommendations. Patients reported the number of daily hours in a sitting position, referrals to PT, MRI, conventional radiographs, and orthopedic surgeons. Satisfaction with OA care was assessed on a five-point scale ('Very satisfied' to 'Very dissatisfied').[33] Data on adverse events, number of exercise sessions, 6 min walk test, and 30-s chair-stand test were extracted from the exercise diaries. Adherence to the exercise program and adverse effects were captured from exercise diaries and study records. The GPs and PTs completed a questionnaire on knowledge of and attitudes towards recommended OA treatment at three time points (Supplement 1).

Costs were measured from the healthcare perspective and were collected from several sources. Patient-reported visits in primary healthcare were collected at the 3-, 6-, 9-, and 12-months follow-ups. Visits and surgical procedures in secondary healthcare were extracted from the Norwegian Patient Register and The Norwegian Arthroplasty Register. Sick leave and social benefits data was extracted from the register of the Norwegian Labour and Welfare Administration to estimate productivity loss in a supplementary scenario analysis. Data on secondary healthcare, sick leave, and social benefits was extracted for all patients, including non-responders at follow-ups. The health outcome, quality-adjusted life-year (QALY), was estimated based on the EuroQol 5 Dimension (EQ-5D-5L) scores at baseline, 3, 6, 9, and 12 months. The QALYs were derived from the EQ-5D-5L utility score, using the preference score from a UK population.[34] Costs were adjusted to 2016-equivalent price levels and converted into Euros (1€= 10 NOK), and no discount rate (0%) was applied as the follow-up time was one year. According to a white paper on priority setting in the Norwegian healthcare sector, a suggested lowest willingness-to-pay threshold can be set to € 27,500.[35]

Statistical analyses

We estimated that 135 individuals in each group with an average of 50 individuals per cluster would achieve 80% power to detect a 10-unit between-group difference on the primary outcome measure. A two-sided test with a significance level of 0.05 was used with a standard deviation of 24 units for the primary outcome measure and intra-class correlation of 0.01. To account for 30% dropouts, we aimed to include 388 patients in total.[13]

The primary effect analysis was performed on an intention-to-treat basis by comparing OA-QI mean total pass rate in the control vs. the intervention group. Multilevel mixed linear or logistic models were fitted to adjust for the effect of clustering (municipality), participant (patient), and repeated measures over time. Missing data was not imputed since mixed models handle missing data. All regression models included an interaction term of follow-up time point and group, and were adjusted for age, sex, BMI (except in the analysis of primary outcome), and secular time (number of months between study initiation and the patient entering the study). The Student's t-test and the chi-square test were used to compare mean values and proportions among completers vs. non-completers. Statistical analyses were performed with STATA IC 16.

Cost-effectiveness analysis results were estimated by the incremental cost-effectiveness ratio (ICER) defined by the incremental costs (differences in costs summarized over 12 months) divided by incremental QALYs (QALYs gained over 12 months). The ICER was then rearranged and reported using the incremental net-monetary benefit (INMB), defined as the incremental QALYs multiplied with the willingness-to-pay threshold (€27,500[35]) minus the incremental costs. Cost-effectiveness evaluations based on the disease-specific measure, K/HOOS QoL subscale, are reported in Supplement 2. Sensitivity analyses were performed using bootstrapping to assess the robustness of the reported results and is presented in a cost-effectiveness plane. Three sensitivity analyses of cost-effectiveness were done; i) over the first 6 months follow-up, ii) excluding the costs related to total joint replacements, and iii) as a per-protocol analysis (received the intervention). Due to limited data on costs for the individuals and the family, the planned societal perspective was replaced with a scenario analysis on production loss to evaluate the consequence of including a societal perspective on the INMB (Supplement 2).

Results

Of 531 patients screened for eligibility, 393 were included (Fig. 2). The mean age was 63 years (SD 9.6) and 74% (n = 279) were women (Table I). Among these, 109 patients were recruited during the control periods (control group), and 284 patients were recruited during intervention periods (intervention group) (see[11,13] for details). The 12-months follow-up questionnaire was completed by 307 (78%) patients, of which 98 (90%) from the control and 209 (74%) from the intervention group. Non-completers (n = 86) of the 12-months follow-up questionnaire had similar baseline characteristics compared to completers (n = 307) except for shorter disease duration, more pain, and more functional disability in activities of daily living (ADL) at baseline (Supplement 3). In the intervention group, 92% (n = 261) attended the patient OA education, 65% (n = 184) completed the exercise program, and 64% (n = 181) both attended the patient OA education and completed the exercise program.[36] Four patients (1%) in the intervention group attended the Healthy Eating Program in addition. Ten patients in the control group erroneously attended the PT-led OA education and exercise program over the 12 months. There were very few intervention-related adverse events. Four patients in the intervention group discontinued the exercise program at the halfway stage due to increased prolonged knee pain and/or swelling, and two of them withdrew from the study. Forty (50%) of the 80 GPs and 37 (58%) of the 64 PTs in the municipalities (clusters) attended the workshop.

For patient-reported quality of OA care, the mean OA-QI pass rate was 59% for the intervention group and 40% for the control group at 12 months (Fig. 3). The between-group difference in OA-QI pass rate change from baseline to 12 months was statistically significant (mean difference: 17.6 (95% confidence interval [CI] 11.1, 24.0; $p < 0.001$)) (Table II). The improved pass rate in the intervention group was related to higher uptake of recommended non-pharmacological treatment modalities at 12 months (Supplement 4).

For secondary outcomes, there were statistically significant between-group differences for about half of the outcomes (Tables II and III). Most differences would however be considered below or borderline clinically relevant, but the higher proportion fulfilling physical activity recommendations and the higher mean ASES pain subscale score in favor of the intervention group at 12-months could be considered clinically important. In addition, the intervention group had statistically significant lower odds of joint replacement compared to the control at all follow-up time points (Table III). Over

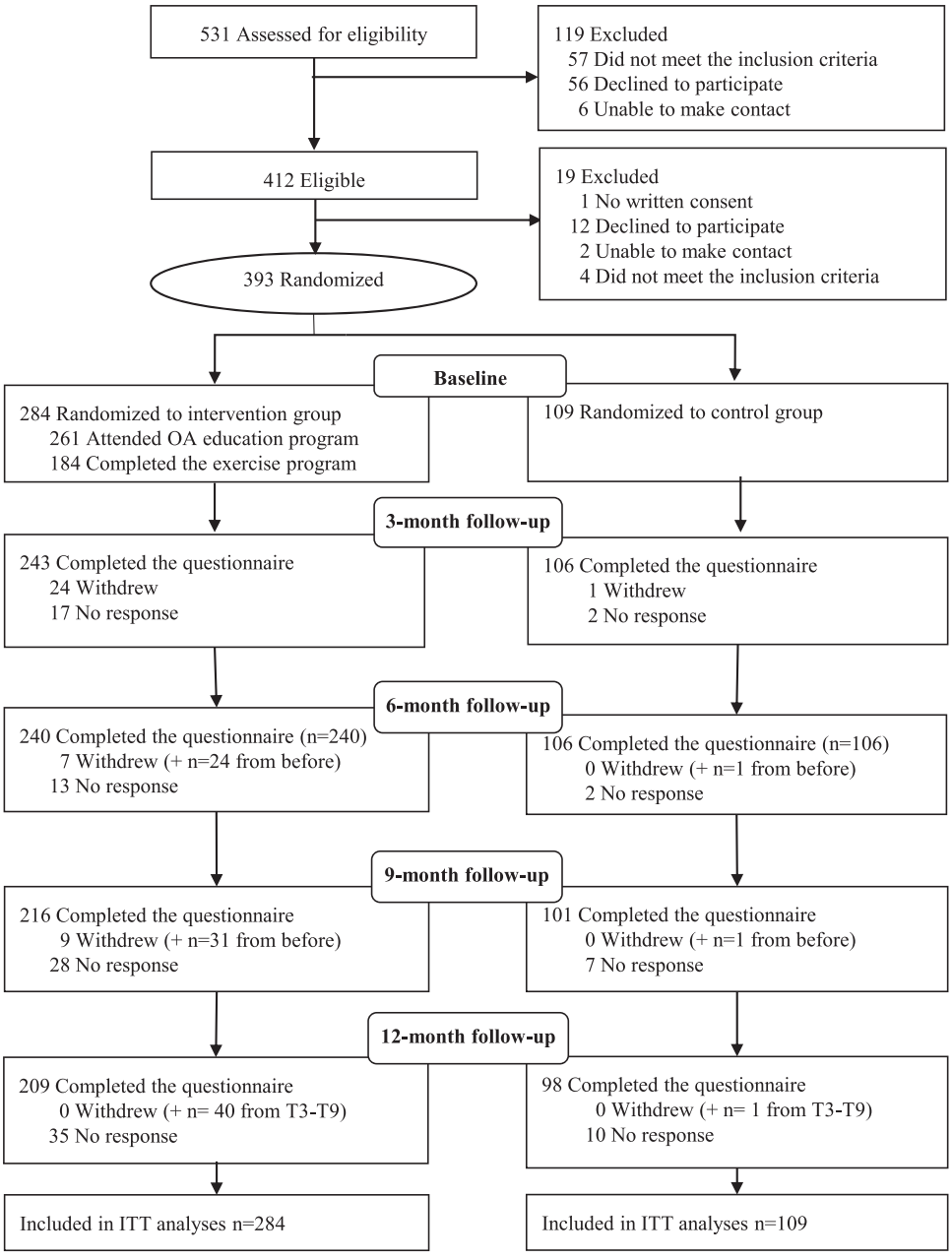

Fig. 2 Osteoarthritis and Cartilage

Consort flow chart.

12 months, a statistically significant (X^2=7.3, p < 0.01) higher proportion of patients in the control group (n = 12 (11%), hip/knee ratio=8/4) as compared to the intervention group (n = 11 (4%), hip/knee ratio=8/3) received joint replacement surgery.

The SAMBA model of care for OA had a cost of approximately €283 per patient with an additional cost of €50 for the Healthy Eating Program. The incremental 12-months healthcare cost per patient was -€1936 (95% CI −3225, −658) in favor of the intervention. Costs related to surgical procedures in secondary healthcare had the largest impact on total healthcare costs in both groups. The QALYs gained over 12 months was 0.02 (95% CI −0.08, 0.12), an uncertain estimate in favor of the intervention (Table IV). The ICER was €- 96,788 per QALY gained, indicating a small, uncertain health gain to a lower cost, and its robustness is presented in the cost-effectiveness plane (Fig. 4). The INMB was €2020 (95% CI 611, 3492), and at a willingness-to-pay threshold of € 27,500, it is 99% likely that the SAMBA model of care is a cost-effective alternative. Analyses of the first 6-month follow-up data gave an INMB of €1470 (95% CI 367, 2741) and 99% probability of the SAMBA model being cost-effective. In a sensitivity analysis that excluded the costs related to surgical procedures, the INMB was €162 (95% CI −129, 466), and in a per-protocol analysis, the INMB was €2128 (95% CI 598, 3756). For detailed cost-effectiveness results, see Supplement 2.

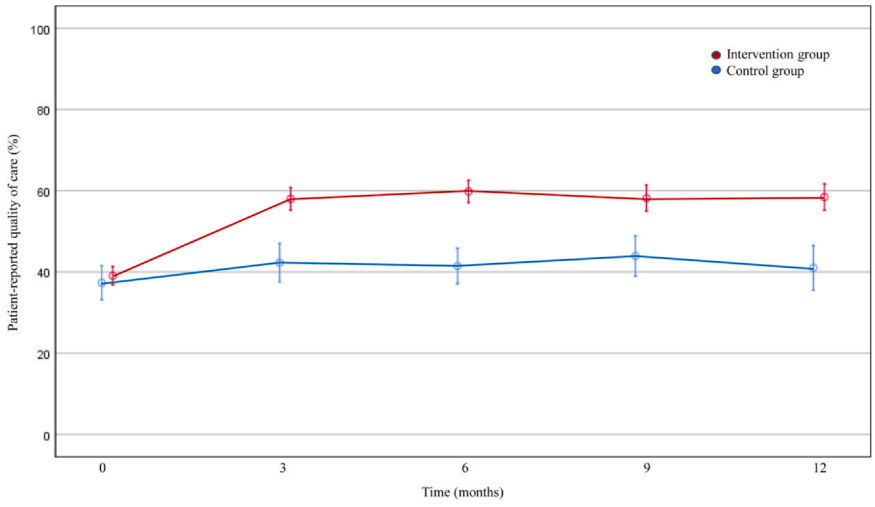

Fig. 3 Osteoarthritis and Cartilage

Quality of care over time by group.

Discussion

This study demonstrated that implementing the SAMBA model of care for patients with hip or knee OA in primary healthcare improved quality of care and showed cost-effectiveness compared to usual care. It led to a significantly higher uptake of recommended core OA treatment modalities and significantly lower joint surgery rate over 12 months as compared to usual care.

To our knowledge, this is one of the first OAMPs implemented in primary healthcare that has been evaluated in a large RCT. Only analyses of pre-post data from other OAMPs have been done[37] in addition to a recent small feasibility study of an OAMP involving orthopedics and allied health professionals[38] and a recent trial providing OA care via telehealth.[39] Our study showed that the significantly higher patient-reported quality of care in the intervention group compared to the control group observed at 6 months[11] was maintained at 12 months, which could be interpreted as a stability of the intervention effect. The change in the quality of care from baseline may be considered small, however, it must be noted that the intervention addressed only a limited number of recommended modalities, whereas the OA-QI includes more aspects. With the intervention focusing on the core elements of non-pharmacological treatment, i.e., education, exercise, and weight management, the observed difference is, although modest, likely to be highly relevant in clinical practice. The CI for the between-group difference includes the previously reported minimal important change, so the between-group difference could potentially be clinically relevant. However, that ten patients (9%) in the control group erroneously received the intervention reduced the contrast so that the observed between-group difference may have been underestimated. Few other implementation studies have used patient-reported quality indicators as an outcome measure of the quality of OA care.[40–43] None have investigated whether an improved patient-reported quality of care level can be maintained over a long-term period, but this study indicates that implementing a structured model of care for OA can reduce the evidence-to-practice gap over a long-term period.

For individual quality indicator items at 12 months a higher uptake of recommended non-pharmacological care, in particularly for OA education and exercise, was seen. For quality indicators related to weight management the change in uptake was minimal and few patients with overweight attended the Healthy Eating Program. Since we did not collect information on barriers and facilitators for usage or referrals from patients, GPs, or PTs, we are unable to examine the reason for this potential underuse with our data. For future implementation studies, alternative strategies for support in weight management may be considered.

Small improvements in pain, stiffness and physical function were achieved, but the effect was most evident for pain and stiffness, and more uncertain for physical function and other clinical outcomes. It may however be questioned whether the improvements represent clinically important changes on a group level. A previous study investigating effectiveness of a model OA consultation delivered by GPs and practice nurses showed a small improvement in uptake on a few quality indicators but did not show effectiveness on clinical outcomes.[41] A study on the GLA:D program, an OAMP which has been implemented in several countries worldwide, showed beneficial clinical outcomes in pre-post cohort analyses, but did not collect data on uptake of OA management recommendations.[37]

A significantly lower proportion in the intervention group compared to the control group underwent total joint replacement surgery over 12 months, which is in line with long-term follow-up results from two RCTs.[44,45] These two studies showed a reduced need for joint replacement surgery after exercise and OA education/multimodal treatment intervention compared to patient education/written advice at the five- and two-years follow-ups, respectively. An Australian budget impact analysis focusing on knee replacement avoidance indicated that a national implementation of first-line OAMPs, as an alternative to joint replacement surgery, could produce substantial cost savings for the healthcare system.[46]

Previous research indicates that trial interventions employing exercise only, or in combination with patient education or diet, appear to be cost-effective in hip and knee OA randomized and non-randomized trials.[45,47] Our study adds to current knowledge by demonstrating that the SAMBA model of care for OA embedded in a real-world clinical setting was cost-effective, also in sensitivity analyses with different scenarios. While the control group had somewhat higher utilization of primary and secondary healthcare services and imaging modalities at the 3- and 6-month follow-ups,

Outcome and time point	Change from baseline (95% CI)		Adjusted mean difference	
	Intervention group	Control group	Intervention – Control (95% CI)	p-value
Primary outcome				
Quality of OA care*, group total pass rate, 0–100%				
Baseline, mean	39	37		
3-months, mean change	19 (16.1, 21.7)	5 (0.7, 9.2)	16.5 (13.3, 22.6)	p < 0.001
6-months, mean change	21 (17.6, 23.6)	4 (−0.1, 8.5)	18.9 (12.7, 25.1)	p < 0.001
9-months, mean change	19 (15.6, 22.4)	7 (1.6, 11.8)	13.8 (7.3, 20.3)	p < 0.001
12-months, mean change	20 (16.2, 23.5)	3 (−2.2, 7.7)	17.6 (11.1, 24.0)	p < 0.001
Secondary outcomes				
Pain level in hip/knee past week, 0–10 NRS				
Baseline, mean	5.1	5.4		
3-months, mean change	−0.9 (−1.1, −0.7)	−0.4 (−0.8, −0.1)	−0.6 (−1.2, 0.0)	p = 0.063
6-months, mean change	−1.1 (−1.4, −0.8)	−0.4 (−0.8, −0.0)	−1.0 (−1.6, −0.4)	p = 0.002
9-months, mean change	−0.7 (−1.0, −0.4)	−1.0 (−1.5, −0.5)	−0.1 (−0.5, 0.7)	p = 0.705
12-months, mean change	−0.9 (−1.2, −0.6)	−0.4 (−0.9, 0.1)	−0.6 (−1.2, −0.1)	p = 0.045
Stiffness in hip/knee past week, 0–10 NRS				
Baseline, mean	4.9	5.3		
3-months, mean change	−0.8 (−1.1, −0.5)	−0.3 (−0.6, 0.1)	−0.6 (−1.2, 0.0)	p = 0.069
6-months, mean change	−1.0 (−1.4, −0.7)	−0.1 (−0.5, 0.4)	−1.0 (−1.7, −0.4)	p = 0.001
9-months, mean change	−0.7 (−1.1, −0.4)	−0.6 (−1.1, −0.2)	−1.3 (−0.8, 0.5)	p = 0.682
12-months, mean change	−1.0 (−1.3, −0.6)	−0.2 (−0.7, 0.2)	−0.7 (−1.3, −0.0)	p = 0.042
Hip/knee function past week, 0–10 NRS				
Baseline, mean	4.9	5.2		
3-months, mean change	−0.7 (−1.0, −0.5)	−0.3 (−0.7, 0.1)	−0.6 (−1.2, −0.0)	p = 0.044
6-months, mean change	−1.0 (−1.3, −0.7)	−0.2 (−0.6, 0.2)	−1.1 (−1.7, −0.5)	p < 0.001
9-months, mean change	−0.5 (−0.8, −0.2)	−0.9 (−1.3, −0.5)	0.2 (−0.4, 0.8)	p = 0.592
12-months, mean change	−0.8 (−1.1, −0.4)	−0.3 (−0.8, 0.1)	−0.6 (−1.2, 0.0)	p = 0.055
K/HOOS Quality of Life subscale, 0–100				
Baseline, mean	44.8	49.0		
3-months, mean change	2.3 (0.7, 4.0)	−3.4 (−5.9, −0.8)	4.7 (−0.1, 9.6)	p = 0.056
6-months, mean change	4.3 (2.5, 6.1)	−1.5 (0.8, 5.3)	4.5 (−0.3, 9.4)	p = 0.066
9-months, mean change	3.1 (0.8, 5.3)	−0.6 (−3.5, 2.3)	1.8 (−3.1, 6.6)	p = 0.479
12-months, mean change	4.1 (1.7, 6.4)	0.7 (−2.8, 4.2)	1.4 (−3.4, 6.3)	p = 0.562
Patient global assessment of the OA disease past week, 0–10 NRS				
Baseline, mean	4.9	5.3		
3-months, mean change	−0.9 (−1.2, −0.7)	−0.1 (−0.4, 0.3)	−0.8 (−1.4, −0.2)	p = 0.006
6-months, mean change	−1.0 (−1.3, −0.8)	−0.1 (−0.5, 0.4)	−0.9 (−1.5, −0.3)	p = 0.002
9-months, mean change	−0.5 (−0.9, −0.2)	−0.5 (−0.9, −0.1)	0.1 (−0.5, 0.7)	p = 0.737
12-months, mean change	−0.9 (−1.2, −0.5)	−0.2 (−0.7, 0.3)	−0.5 (−1.1, 0.1)	p = 0.100
Arthritis Self Efficacy pain subscale, 0–100				
Baseline, mean	55.0	53.0		
3-months, mean change	3.4 (0.8, 6.1)	0.9 (−3.2, 5.0)	8.4 (2.0, 14.8)	p = 0.011
6-months, mean change	4.9 (1.9, 7.8)	0.2 (−4.3, 4.6)	10.1 (3.7, 16.5)	p = 0.002
9-months, mean change	3.4 (0.3, 6.5)	0.2 (−4.3, 4.6)	7.3 (0.8, 13.8)	p = 0.028
12-months, mean change	5.2 (2.0, 8.4)	2.3 (−3.1, 7.7)	7.6 (1.1, 14.0)	p = 0.022
Arthritis Self Efficacy symptom subscale, 0–100				
Baseline, mean	59.0	57.0		
3-months, mean change	3.1 (1.0, 5.3)	2.9 (−0.9, 6.8)	5.1 (−1.1, 11.3)	p = 0.108
6-months, mean change	4.4 (2.0, 6.7)	2.0 (−2.3, 6.3)	5.4 (−0.8, 11.6)	p = 0.088
9-months, mean change	4.4 (1.7, 7.1)	6.5 (2.5, 10.5)	1.7 (−4.6, 8.0)	p = 0.600
12-months, mean change	5.4 (2.8, 8.0)	5.4 (0.5, 10.3)	2.7 (−3.5, 9.0)	p = 0.390
Daily hours in sitting position				
Baseline, mean	6.5	6.8		
3-months, mean change	−0.4 (−0.7, −0.1)	−0.4 (−0.9, 1.2)	−1.2 (−2.0, −0.3)	p = 0.006
6-months, mean change	−0.6 (−0.9, −0.3)	−0.7 (−1.5, 0.0)	−1.2 (−2.0, −0.4)	p = 0.005
9-months, mean change	−0.4 (−0.7, −0.1)	−0.9 (−1.6, −0.1)	−0.9 (−1.7, −0.1)	p = 0.027
12-months, mean change	−0.4 (−0.7, −0.0)	−0.5 (−1.3, 0.3)	−0.9 (−1.7, −0.1)	p = 0.032
Health related quality of life (EQ-5D)				
Baseline, mean	0.73	0.75		
3-months, mean change	0.03 (0.02, 0.05)	−0.01 (−0.04, 0.02)	0.1 (0.01, 0.12)	p = 0.025
6-months, mean change	0.03 (0.01, 0.05)	−0.02 (−0.05, 0.02)	0.6 (0.01, 0.12)	p = 0.024
9-months, mean change	0.03 (0.01, 0.05)	0.01 (−0.03, 0.04)	0.2 (−0.03, 0.08)	p = 0.428
12-months, mean change	0.03 (0.01, 0.05)	0.01 (−0.02, 0.04)	0.0 (−0.02, 0.09)	p = 0.265

Data are estimated means and adjusted mean differences of primary and secondary outcomes by groups and time point from multilevel mixed longitudinal models. Change from baseline values are within-group changes, whereas the Adjusted mean differences represent between-group differences adjusted for baseline values.
CI: confidence interval, K/HOOS: Hip disability and Osteoarthritis Outcome Score/ Knee injury and Osteoarthritis Outcome Score, NRS: numeric rating scale, OA: osteoarthritis
* OA-QI pass rates estimates are adjusted for patient age, sex, and time trends (number of months between study start date and the patients' inclusion date), and all secondary outcomes are adjusted for the same and BMI in addition.

Table II

Study outcomes for numeric data.

Outcome and time points	Proportion (change from baseline)		Odds ratio*	
	Intervention group	Control group	Intervention vs. Control (95% CI)	p-value
Fulfilled OARSI-OMERACT responder criteria, %				
3-months	38	25	2.0 (0.7, 5.38)	p = 0.187
6-months	42	25	2.6 (0.9, 7.1)	p = 0.066
9-months	34	37	0.5 (0.2, 1.4)	p = 0.210
12-months	39	30	1.4 (0.5, 3.8)	p = 0.524
Patient acceptable symptom state, acceptable %				
Baseline	46	62		
3-months (change)	68 (+22)	62 (0)	2.5 (0.9, 7.6)	p = 0.086
6-months (change)	74 (+28)	67 (+5)	2.7 (0.9, 8.1)	p = 0.085
9-months (change)	70 (+24)	79 (+15)	0.6 (0.2, 1.8)	p = 0.325
12-months (change)	74 (+28)	68 (+6)	2.2 (0.7, 6.7)	p = 0.158
Fulfilled physical activity recommendations†, %				
Baseline	51	48		
3-months (change)	78 (+27)	44 (−4)	29.3 (9.0, 95.3)	p < 0.001
6-months (change)	67 (+16)	45 (−3)	10.1 (3.2, 31.6)	p < 0.001
9-months (change)	58 (+7)	51 (+3)	3.1 (1.0, 9.6)	p = 0.055
12-months (change)	67 (+16)	56 (+8)	4.0 (1.3, 12.6)	p = 0.018
Overweight/obesity, %				
Baseline	73	67		
3-months (change)	71 (−2)	68 (+1)	1.1 (0.02, 1.47)	p = 0.456
6-months (change)	69 (−4)	63 (−4)	1.3 (0.77, 2.11)	p = 0.350
9-months (change)	71 (−2)	68 (+1)	1.6 (0.92, 2.68)	p = 0.096
12-months (change)	69 (−4)	63 (−4)	1.2 (0.69, 2.05)	p = 0.535
Satisfied or very satisfied with the provided care, %				
Baseline	32	31		
3-months (change)	71 (+39)	35 (+4)	17.0 (6.5, 44.3)	p < 0.001
6-months (change)	73 (+41)	33 (+2)	23.2 (8.7, 61.6)	p < 0.001
9-months (change)	66 (+34)	37 (+6)	10.1 (3.9, 26.6)	p < 0.001
12-months (change)	64 (+32)	40 (+9)	7.2 (2.8, 18.6)	p < 0.001
Referred to physiotherapy, Yes %				
Baseline	52	48		
3-months (change)	36 (−16)	25 (−23)	2.5 (1.1, 5.5)	p = 0.030
6-months (change)	21 (−31)	30 (−18)	0.7 (0.3, 1.5)	p = 0.303
9-months (change)	15 (−37)	26 (−22)	0.4 (0.2, 1.0)	p = 0.043
12-months (change)	15 (−37)	17 (−31)	0.8 (0.3, 1.9)	p = 0.538
Referred to CRG, Yes %				
Baseline	33	34		
3-months (change)	11 (−22)	22 (−12)	0.4 (0.2, 0.9)	p = 0.031
6-months (change)	8 (−25)	13 (−21)	0.7 (0.2, 1.6)	p = 0.354
9-months (change)	10 (−23)	8 (−26)	1.4 (0.5, 4.0)	p = 0.473
12-months (change)	8 (−25)	10 (−24)	0.8 (0.3, 2.1)	p = 0.659
Referred to MRI, Yes %				
Baseline	26	27		
3-months (change)	10 (−16)	14 (−13)	0.5 (0.5, 1.7)	p = 0.262
6-months (change)	5 (−21)	8 (−19)	0.4 (0.1, 1.7)	p = 0.229
9-months (change)	7 (−19)	3 (−24)	2.4 (0.4, 12.5)	p = 0.311
12-months (change)	3 (−23)	1 (−26)	2.6 (0.2, 28.9)	p = 0.436
Referred to orthopedic surgeon, Yes %				
Baseline	9	6		
3-months (change)	4 (−5)	10 (+4)	0.2 (0.1, 0.7)	p = 0.015
6-months (change)	6 (−3)	13 (+7)	0.2 (0.1, 0.8)	p = 0.019
9-months (change)	8 (−1)	8 (+2)	0.6 (0.2, 2.6)	p = 0.508
12-months (change)	8 (−1)	6 (0)	1.2 (0.3, 5.0)	p = 0.837
Joint replacement surgery, %				
3-months	0.4	3.7	−1.6 (−2.7, −0.6)	p = 0.002
6-months	1.1	3.0	−1.5 (−2.5, −0.5)	p = 0.004
9-months	1.1	2.8	−1.5 (−2.6, −0.5)	p = 0.003
12-months	1.4	1.8	−1.6 (−2.7, −0.5)	p = 0.005

Data are proportions of binary secondary outcomes by groups and time point and adjusted odds ratio.
CI: confidence interval, CRG: conventional radiographs, MRI: magnetic resonance imaging, OARSI: Osteoarthritis Research Society International, OMERACT: Outcome Measures in Rheumatology

* From logistic multilevel mixed longitudinal models adjusted for patient age, sex, BMI (except for the analysis of proportions with overweight/obesity), and time trends (number of months between study start date and the patients' inclusion date).

† To fulfill the physical activity recommendations, the patients had to report moderate-intensity activity for 150 min or 60 min of vigorous intensity per week, or a combination of these.

Table III

Study outcomes for categorical data.

	EQ-5D-5L utility index over 12-months follow-up	Costs over 12 months follow-up	ICER	Probability of cost-effectiveness at € 27,500	Net monetary benefit
	QALY (95% CI)	€ per patient (95% CI)	€/QALY	%	€/QALY gained (95% CI)
Intervention group	0.78 (0.76, 0.80)	1247 (865, 1629)			
Control group	0.76 (0.73, 0.80)	3183 (1951, 4414)			
Incremental effect/cost	0.02 (−0.08, 0.12)	-1936 (−3225, −658)	- 96,788	99%	2020 (611, 3492)

CI: confidence interval, EQ-5D-5L: EuroQol 5 Dimension with 5 levels, ICER: incremental cost-effectiveness ratio, QALY: quality-adjusted life-year

Table IV Osteoarthritis and Cartilage

Cost-effectiveness analyses over 12 months.

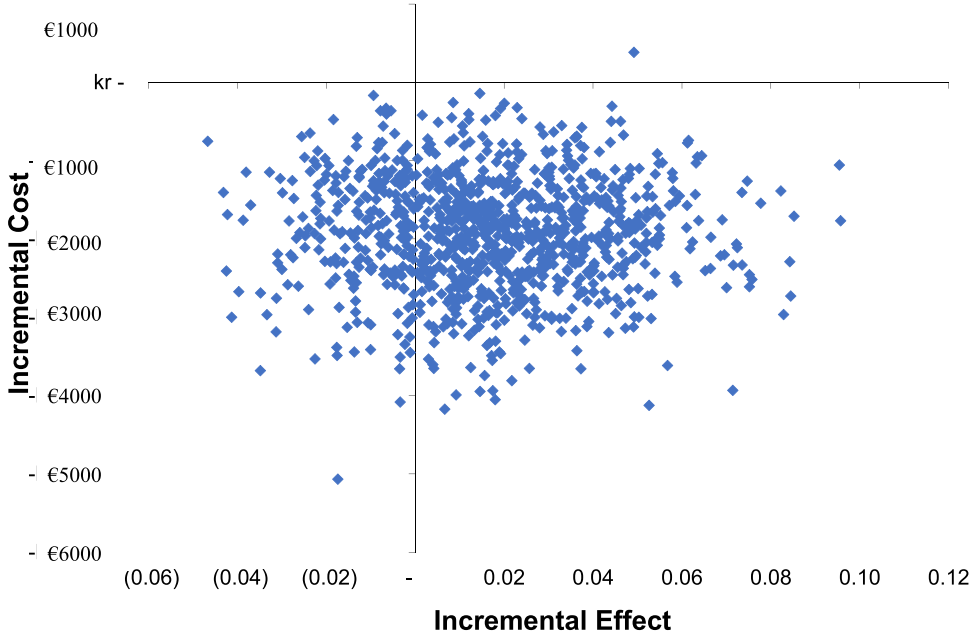

Fig. 4 Osteoarthritis and Cartilage

Cost-effectiveness plane for the comparison of implementation of the SAMBA model of care for OA (intervention group) and usual care (control group).

the main difference between the two groups was the proportion of joint replacements, which is associated with high costs. Since the control group had a higher proportion of joint replacements, this was the main driver for the costs and the reason that the study intervention with the structured model of OA care was deemed to have lower costs than usual care.

Study strengths include the high-quality design, the pragmatic approach, large number of patient participants, and patient and public involvement in the design and interpretation of the results. Another strength is the collection of patient-reported outcomes every third month to limit recall bias and the use of national register data, which means that we could extract data on secondary healthcare, including joint surgery, for all patients including non-responders to follow-ups. Due to the nature of the study intervention, it was impossible to blind the patients or health professionals for study arm allocation, which represents a limitation of the study. The study may be slightly underpowered since there were 98 respondents in the control group at the 12-month follow-up, but 104 were needed to have 80% power. Since the initial instructions in the OA-QI questionnaire refer to the time frame “past 12 months”, we cannot exclude that the responses at the longer-term follow-ups may mirror post-intervention responses. The self-reporting body weight may have induced a response bias leading to inaccuracy in body weight measures. The higher loss to follow-up in the intervention group as compared to the control group may have introduced bias in the self-reported effectiveness outcomes. Since those lost to longer-term follow-up had more pain and worse self-reported function at baseline compared to the completers, this may indicate a non-random drop-out and a potential overestimation of the effects in the intervention group at the longer-term follow-ups. Whereas for cost-effectiveness, the loss to follow-up may have led to an underestimation of primary healthcare costs in the intervention

group, but not for surgery and other secondary healthcare procedures since this was extracted from national registers for all included patients. While the patient study sample is comparable to the OA population in other countries, the generalizability of this study's results may depend on differences in the healthcare systems in other countries, but similar OAMPs have been implemented in other countries.[48]

In conclusion, our results indicate that implementing core recommendations through a structured model of care for OA in primary healthcare may improve quality of care and is a cost-effective alternative compared to usual care for people with hip and knee OA.

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Data availability

Due to ethical approval and requirements of the data protection legislation, the statistical code and data set will only be made available after January *2024* on a restricted basis according to the data sharing policies (https://nds.no/nsddata/utlaansrutiner_en.html) at the Norwegian Centre for Research Data (www.nsd.no). Applications for access to anonymized data can be found at: https://nds.no/.

Declaration of Competing Interest

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Author contributions

Conception and design: NØ, TM, BN, JHR, KD, LvBV, TVV, KBH. Obtaining of funding: NØ, BN, JHR, KD, LvBV, TVV, KBH. Data curation: NØ, EAA, TM, OF, AMF. Drafting of the article: NØ. Critical revision of the article for important intellectual content: EAA, TM, BN, JHR, KD, LvBV, TVV, OF, AMF, KBH. Final approval of the article: EAA, TM, BN, JHR, KD, LvBV, TVV, OF, AMF, KBH.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.joca.2023.10.003.

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