Feasibility and efficacy of a multidisciplinary health care programme for patients with knee osteoarthritis

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Abstract

Objective

To examine the feasibility and efficacy of a multidisciplinary health care programme for patients with knee OA.

Methods

A 12-month follow-up care programme for knee OA, based on clinical evidence and expert opinion was implemented in primary care settings. It included recommendations on diagnosis, management and follow-up. Consecutive patients with knee OA and pain were included, classified into mild (21–39 score), moderate (40–69 score), severe disease (70–100 score) in WOMAC pain subscale, and managed according to the programme. Data were recorded using electronic devices or internet at each visit. Primary end points were: OMERACT-OARSI responder criteria; 70% compliance rate of the recommendations.

Results

We included 226 patients, 75% women, mean age 63 years, mean disease duration of 2.4 years, 76% reported Kellgren-Lawrence grade 3-4, and were classified as mild: 17%, moderate: 54% and severe disease: 29%. At the end of the study, 78% of patients achieved pain relief of ≥20 points in the WOMAC pain subscale, and 80% OMERACT-OARSI response criteria. Almost 90% of physicians followed the recommendations. WOMAC and SF-36 subscales/dimensions improved ($p<0.050$), 14% remained classified as moderate or severe disease, 85% of patients attended the exercise training course, and more than 80% of patients and professionals were satisfied with the programme. Compared to usual care the programme seems to use fewer resources.

Conclusions

The implementation of multidisciplinary health care programmes could be very effective and viable for the management of knee OA, could increase patients' and health professional's satisfaction, and optimise health care resources use.

Key words

osteoarthritis, critical pathway, exercise therapy, analgesic

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Introduction

Knee osteoarthritis (OA) is a chronic and worldwide prevalent disease (1-3) with huge impact for patients, society and health systems (4-7).

Knee OA treatment consists of pharmacological and non-pharmacological interventions (8-10), which have been extensively and critically analysed and exposed in clinical guidelines and other documents (11-13). Although these have shown to be effective, there might be some barriers in daily practice such us variability (14), attitudes and beliefs (15-17), lack of knowledge (18), short consultations (19), lack of communication and coordination between health professionals and with patients (20), health care organisation, etc., which may limit their effectiveness. This may explain, at least in part, that success in implementing guidelines is varied (21) and may not be sustained (22). But most importantly, quality of care of these patients could not be completely guaranteed, and we could even be generating health inequities.

Four key success factors have been suggested which are strongly associated with a decision support system's ability to improve clinical practice. These include the automatic provision of decision support as a part of physicians workflow, provision at the point of decision making, support in the form of clear recommendations and the use of computerised systems (23, 24).

In this context, the ARTROACAS programme was design to improve knee OA patient's quality of care. Based on scientific evidence and the consensus of a multidisciplinary panel of experts, patient-centered recommendations on diagnosis and management were developed. When designing this programme, the characteristics and the different care levels of the Spanish health system were taken into account to achieve an appropriate and rational use of human and material resources.

Moreover, electronic tools and devices were used in order to facilitate the programme goals and data collection. Finally, it was implemented in a primary care setting which is most often the first health contact in Spain for patients, and therefore, a real scenario which allows the programme to be reproducible in other areas.

The aim of this study was to evaluate whether this programme, integrated into daily practice could improve knee OA outcomes and increase the satisfaction of patients and professionals.

Methods

Study design

A 12-month follow-up multidisciplinary health care programme for patients with knee OA was designed. The programme was based on best clinical evidence and expert opinion and consensus (11-13, 25-27), and consisted of recommendations (regarding patients and disease features) about knee OA: diagnosis, management including pharmacological treatment and an education and exercise programme, tests, visits schedule, and referral to specialists (Figs. 1, 2).

The education and exercise programme included: knee OA disease information, specific recommendations on healthy lifestyle, weight loss, gait modifications and walking aids for off-loading, relevant data within the constructs of self-management, and a home based exercise training programme. This programme was delivered by physiotherapists. It was implemented in primary care settings in 4 health areas in Spain. Before the start of the programme, explanatory meetings were held with the 32 physicians involved in it (15 primary care physicians, 8 rheumatologists, 6 physiatrists, and 3 orthopaedic surgeons) to guarantee acknowledgment and agreement with the study protocol and to homogenise criteria and processes. This programme was approved by the ethics committee of the Institut Municipal d'Assistencia Sanitaria.

Patient selection

To estimate the study sample size a 45% reduction in Western Ontario McMaster University Osteoarthritis Index (WOMAC) pain subscale was used. And assuming an alpha and beta error of 0.005 and 0.20, respectively, and losses to follow-up of 20%, the final estimated sample size was 268 patients. Consecutive patents with knee OA and pain without pharmacological

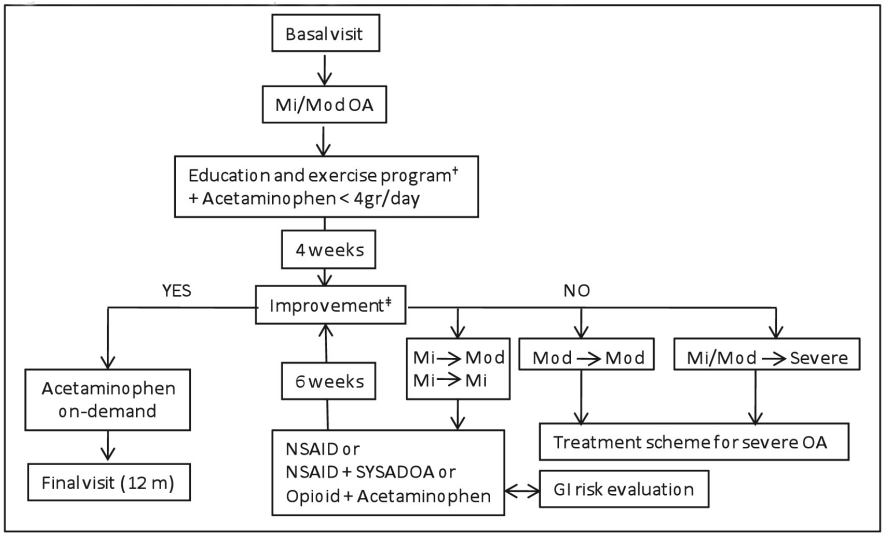

Fig. 1. Treatment scheme for patients with mild or moderate OA*.
gr: grame; Mi: Mild OA; Mod: Moderate; OA: osteoarthritis; NSAID: non-steroidal anti-inflammatory drugs; SYSADOA: symptomatic slow acting drug; m: month; GI: gastrointestinal.
*Mild OA (21-39 score), moderate OA (40-69 score), or severe OA (70–100 score) according to WOMAC pain subscale.
†Education and exercise programme: knee OA disease information, specific recommendations on healthy lifestyle, weight loss, gait modifications and walking aids for off-loading, relevant data within the constructs of self-management, and a home based exercise training programme. This programme was delivered by physiotherapists.
‡Improvement: 45% reduction [absolute change ≥20 normalised units (NU)] in WOMAC pain subscale or 2 of the following: a) 15% reduction (absolute change ≥10 NU) in pain, b) 30% reduction (absolute change ≥15 NU) function, c) 35% reduction (absolute change ≥10 NU) in patient global assessment.

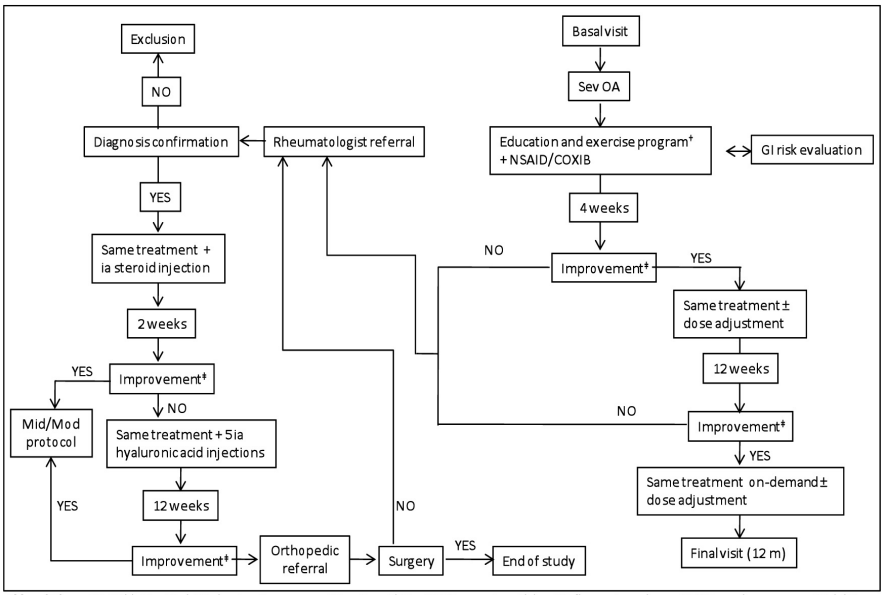

Fig. 2. Treatment scheme for patients with severe OA*.
Mi: Mild OA; Mod: Moderate; Sev: severe; OA: osteoarthritis; NSAID: non-steroidal anti-inflammatory drugs; COXIB: cyclooxygenase-2 inhibitors; m: month; GI: gastrointestinal; ia: intra-articular.
*Mild OA (21-39 score), moderate OA (40-69 score), or severe OA (70–100 score) according to WOMAC pain subscale.
†Education and exercise programme: knee OA disease information, specific recommendations on healthy lifestyle, weight loss, gait modifications and walking aids for off-loading, relevant data within the constructs of self-management, and a home based exercise training programme. This programme was delivered by physiotherapists.
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treatment within the previous 15 days were eligible for inclusion. In the case that both knees were eligible, patients were asked to indicate the most symptomatic one which was then the target knee for the rest of the study. Knee OA was defined if it fulfilled the following criteria with 94% sensitivity and 88% specificity (28) (1+2 or 1+3+5+6 or 1+4+5+6): 1) Knee pain; 2) Radiological osteophytes 3) OA synovial fluid of the knee; 4) Age 40 years to 75 years; 5) Morning stiffness <30 minutes; 6) Knee crepitus. The exclusion criteria were: 1) Patients with functional disability unable to self-care; 2) Knee inflammatory arthritis; 3) Acute knee locking; 4) Pain at rest and night; 5) Inflammatory knee pain; 6) Lack of knee OA signs on x-rays; 7) Kellgren-Lawrence grade IV knee OA; 8) Pain and general status impairment: malaise, asthenia, anorexia, weight lost, irritability; 8) Patients who require supervised rehabilitation for a long time; 9) Treatments: use of symptomatic slow-acting drugs for osteoarthritis (SYSADOAs) or knee injections (steroids or hyaluronic acid) within the previous three months, long acting non-steroidal anti-inflammatory drugs (NSAIDs) as those of the oxicam class within the previous 15 days, other NSAIDs (including cyclooxygenase-2 inhibitors, COXIBs) in the previous week, analgesic in the previous 3 days; 10) Patients who, according to physicians, were not likely to comply with the programme requirements including medication and exercise scheme; 11) Patients with an elective total knee replacement during the programme.

Primary care physician identified eligible patients through reviewing the medical history and according to current symptoms and physical examination, and the coordinators of the programme in each health area checked the inclusion and exclusion criteria. If necessary, x-rays and/or blood analyses were requested. Positive cases were informed about the aims and characteristic of the programme, and were invited to participate. A new appointment (basal visit) was given to those who agreed, in which patients were classified into mild OA (21–39 score), moderate OA (40–69 score), or severe OA

(70-100 score) according to WOMAC pain subscale. Then, depending on the OA status a specific treatment and visits schedule was established (Figures 1 and 2). Apart from the pre-established appointment schedule, patients were allowed to ask for extra appointments during the study period if they considered necessary. At least two visits were mandatory (basal and final visit at the end of the programme).

Data acquisition

Data were collected at each visit using electronic devices (Personal Digital Assistant, PDA) or internet following a standardised electronic questionnaire. Recommendations on patient data protection regarding electronic data management were followed. In the basal visit sociodemographics, clinical variables and use of health resources were registered. At the final visit (1 year after the basal visit), clinical, programme compliance and satisfaction variables and use of health resources. Finally, in the case of extra visits, clinical and programme compliance variables were registered. These electronic devices also provided the management scheme. In the case that physicians changed the protocol, explanations were given and recorded.

Variables

The primary outcome measures were: 1) OARSI responder criteria (27) from baseline to month 12: 45% reduction (absolute change ≥20 normalised units (NU)) in WOMAC pain subscale or 2 of the following: a) 15% reduction (absolute change ≥10 NU) in pain, b) 30% reduction (absolute change ≥15 NU) function, c) 35% reduction (absolute change ≥10 NU) in patient global assessment; 2) 70% compliance rate of the programme recommendations (29, 30).

Secondary outcome measures were: 1) OMERACT-OARSI responder rate: high improvement in pain or in function ≥50% and absolute change ≥20% (27, 31); 2) improvements in WOMAC subscales and 36-item Short Form (SF-36) domains, 3) improvements in visual analogue scale (VAS) of pain, 4) changes in OA classification, 5) rate of adherence to the education self-management programme, 6) patients' and health professionals' satisfaction (assessed with structured questionnaires), and 7) use of health care resources as visits to primary care physicians, specialists, emergency room (ER), blood analyses, images, drugs, hospitalisations, days of hospitalisation, and the use of analgesics, NSAIDs, SYSADOAs, steroids, hyaluronic acid injections, gastroprotective drugs. Other variables assessed were: a) sociodemographics (sex, age, educational level, employment status); b) clinical variables including body mass index (BMI), comorbidities, age at knee OA onset, disease duration, radiographic OA severity according to Kellgren-Lawrence grades 0 to III, patient global disease assessment.

Statistical analyses

We analysed the subjects' sociodemographic and clinical characteristics and use of health resources by the measures of central tendency appropriate for the distribution of each variable. The results are described using summary statistics including means, standard devistion (SD), frequencies, and percentages. Mean differences between basal and final visits were calculated using paired *t*-test. These results are expressed as difference (diff) ±SD. To assess the efficacy of the programme regarding health care resources, we compared their use in the ARTROACAS study with those from the ArtRoCad study (4). Briefly, ArtRoCad was a cross-sectional study (2003) which included patients aged 50 or older with symptomatic and radiological knee and/or hip OA, who attended primary care centres in all the provinces of Spain, following standard care. Information on demographics, health status, comorbidities, clinical (WOMAC) and radiological OA severity (Kellgren/Lawrence), data related to OA health resources utilisation (medical and non-medical), and subjects' and carers' expenses for losses of time in the previous 6 months were collected.

Table I. Baseline sociodemographic and clinical characteristics of study patients*.

	Study population n=226	Mild OA n=39	Moderate OA n=121	Severe OA n=66
Age† (years)	63 ± 8	64 ± 8	63 ± 8	64 ± 8
Sex (women)	75%	67%	79%	74%
Educational level				
No studies,	2%	5%	2%	1%
Elementary school,	81%	77%	80%	85%
High school, and	15%	13%	16%	14%
Post high school	2%	5%	2%	0%
Employment status				
Housewife	39%	36%	45%	30%
Work disability	2%	0%	2%	3%
Retired	34%	49%	25%	41%
Active worker	1%	0%	0	3%
Unemployed	24%	15%	28%	23%
BMI† (kg/m^2)	30 ± 4	30 ± 5	30 ± 5	30 ± 5
Affected knee (right)	52%	46%	49%	62%
Knee OA duration† (years)	2 ± 2	2 ± 2	2 ± 2	2 ± 2
Previous surgeries				
None	97%	100%	97%	97%
Meniscectomy	1%	0%	1%	3%
Contralateral TJR	1%	0%	1%	0%
Others	1%	0%	1%	0%
Kellgren-Lawrence grade				
0	4%	5%	4%	3%
1	20%	33%	18%	14%
2	46%	46%	51%	38%
3	30%	16%	27%	45%

*Results are expressed as percentage otherwise is indicated.
†Mean ± standard deviation.
BMI: body mass index; kg: kilogramme; m^2: square metre; TJR: total joint.

Table II. Changes in clinical variables*.

	Study population		Mild OA		Moderate OA		Severe OA	
	Diff	*p*-value	Diff	*p*-value	Diff	*p*-value	Diff	*p*-value
WOMAC subscales								
Pain	-25.7	<0.001	-8.6	0.002	-25.5	<0.001	-36.5	<0.001
Stifness	-24.6	<0.001	-12.6	<0.001	-21.2	<0.001	-37.9	<0.001
Physical functioning	-29.1	<0.001	-17.3	<0.001	-28.0	<0.001	-38.1	<0.001
SF-36 domains								
Physical activities	13.1	<0.001	17.2	<0.001	11.7	<0.001	13.3	<0.001
Social activities	4.4	0.026	5.6	0.180	3.3	0.309	5.8	0.105
Physical health problems	15.3	<0.001	6.6	0.344	19.7	<0.001	12.4	0.059
Emotional problems	8.1	0.032	-2.7	0.635	10.3	0.039	10.3	0.194
General mental health	4.6	0.001	4.2	0.116	5.2	0.010	3.8	0.197
Vitality	6.4	<0.001	4.3	0.137	8.1	<0.001	4.5	0.097
Bodily pain	11.6	<0.001	11.8	0.010	10.8	<0.001	12.8	<0.001
General health	3.8	0.001	1.1	0.623	4.9	0.003	3.5	0.094
Physical activities	13.1	<0.001	17.2	<0.001	11.7	<0.001	13.3	<0.001
Social activities	4.4	0.026	5.6	0.180	3.3	0.309	5.8	0.105
Physical health problems	15.3	<0.001	6.6	0.344	19.7	<0.001	12.4	0.059
Emotional problems	8.1	0.032	-2.7	0.635	10.3	0.039	10.3	0.194

*Differences from basal visit to final visit.
OA: osteoarthritis; Diff: difference; WOMAC: Western Ontario; McMaster University Osteoarthritis Index; SF-36: 36-item Short Form Questionnaire.

Patients with knee OA meeting ARTROACAS inclusion criteria were selected from ArtRoCad study. Besides, in order to reach as much homogeneity as possible, only patients aged 50 to 70 years from both populations were included for this analysis. Differences were tested using paired *t*- test. All statistical analyses were made using Stata, version 10 (StataCorp, College Station, TX).

Results

Study population

We included 249 patients of whom 23 withdrew during follow-up (6 did not attend the basal visit, 5 changed address, 4 physician decision, 4 patient decision, 1 did not meet inclusion criteria, 3 others). Thus, a total of 226 patients (84% of the estimated sample size) with knee OA were analysed and classified as mild: 17%, moderate: 54% and severe OA: 29%. Most of them were middle age women, retired or housewives. Only 8% of the study population had a normal body mass index (18.5–24.9), 45% presented arterial hypertension and 41% dyslipidemia. We also found that 9% of patients had knee OA for more than 5 years, 3% reported a previous knee surgery and 46% had Kellgren-Lawrence grade 2 knees. For more details see Table I.

Health care programme results

Regarding the primary end points, 87.6% of the patients achieved OARSI responder criteria from baseline to month 12 (67%, 92% and 97% in the mild, moderate and severe OA subgroups, respectively). However, 16 of 25 patients who did not respond showed a mean improvement in the VAS pain score of -9.2±5.9. Moreover, almost 90% of physicians followed the programme recommendations.

Following with the secondary end points, 80% of patients met OMERACT-OARSI responder criteria (67%, 82% and 85% in the mild, moderate and severe OA subgroups).

Table II depicts differences from baseline to month 12 in quality of life assessed with WOMAC subscales and SF-36 domains in the study population, and according to OA subgroups.

The VAS pain score clearly improved in the study population (diff= -35.1±23.7, $p<0.001$) and in the OA subgroups (diff= -9.7±16.7, $p=0.001$ in mild subgroup; diff= -33.9±17.3, $p<0.001$ in moderate subgroup, diff= -52.2±23.4, $p<0.001$ for severe subgroup). A total of 173 patients (76.5%) improved in the OA classification. At the end of the study, 86% were classified as mild OA. On the other hand, 22.2% remained in their subgroup and 3% impaired. We found that 84% of study patients attended the education self-management programme, of whom 94% followed given recommendations. According to the satisfaction questionnaire, 73% of patients considered the information given during the programme as very positive, 94% that it was feasible and 81.4% exposed that this care programme was better compared with the care provided before it. Regarding physicians, 100% were pleased with the programme and considered it useful.

Moreover, we compared the use of health care resources between ARTROACAS (n=158) and ArtRoCad (n=201) subpopulations. There were no statistically significant differences between groups regarding age, sex, BMI, mean VAS pain score and previous surgeries. However, the mean OA duration was 7 years in the ArtRoCad study group compared with 2 years in the current study ($p<0.001$). Besides, OA radiographic severity (according to Kellgren-Lawrence grades) was higher in patients from the ArtRoCad study group, in which 72% reported grade 3, in contrast with patients from the ARTROACAS where 45% of them had grade 2 knees, $p<0.001$. When health care resources use was compared between studies subpopulations, we found that, although the time used to collect

Table III. Use of health care resources in the ARTROACAS and ARTROCAD OA subpopulations*.

	ARTROACAS (n=158)	ARTROCAD (n=201)	*p*-value
Primary care physician visits†	3.4±0.6	5.3±4.3	<0.001
Specialist visits	17 (11%)	85 (42%)	<0.001
ER visits	2 (1.3%)	13 (6.5%)	0.014
Hospitalisation	2 (1.3%)	9 (4.5%)	0.149
Hospitalisation days†	0.1±1.6	0.2±1.3	0.121
Blood analyses	1±0.2	0.5±0.6	<0.001
Use of drugs			
Analgesics	133 (84%)	118 (59%)	<0.001
NSAIDs	54 (34%)	146 (73%)	<0.001
SYSADOAs	14 (9%)	34 (17%)	0.028
Steroids	5 (3%)	1 (0.5%)	0.061
Hyaluronic acid injections	1 (0.6%)	8 (4%)	0.041
Gastroprotective drugs	56 (35%)	120 (60%)	<0.001

*Results are expressed as number and percentage (%) otherwise is indicated.
†Mean ± standard deviation.
OA: osteoarthritis; ER: emergency room; NSAID: non-steroidal anti-inflammatory drugs; SYSADOA: symptomatic slow acting drug.

data was double in the ARTROACAS study (1 year *vs*. 6 months), there were less visits to primary care physiscians, specialists and ER, and less blood analyses (Table III).

Interestingly, the use of analgesics was higher in the ARTROACAS population ($p<0.001$), but the prescription of NSAIDs, SYSADOAs, hyaluronic acid injections, and gastroprotective drugs was statistically higher in the ArtRoCad group.

No relevant problems or major difficulties were reported during the study.

Discussion

The implementation of the ARTROACAS health care programme for patients with knee OA led to clinical improvement in terms of pain, function and quality of life, and was feasible and well-considered by patients and physicians. Besides, when compared to usual care, it seemed to optimise health care resources. And although cost analysis is beyond the scope of this study, it is reasonable to expect that costs will have clearly decreased with the implementation of the programme.

One of the strengths of this project was the development of the programme itself. Following best practice suggestions (23, 24) and the best evidence available (11-13, 25-27), a multidisciplinary expert panel was set up which established diagnosis and management recommendations for patients with knee OA. The aim was to give patients the care they want and need exactly when they want and need it, but also considering a rational use of health care resources. Therefore, rapid cycle processes and clinical care pathways where developed according to disease features and evolution. This included explicit indications regarding treatments to reduce clinical uncertainty and related to specialist consultations to facilitate delivery and improve outpatient referral appropriateness, which may shown deficiencies (15, 32, 33).

Regarding pharmacological recommendations, different schemes on effective therapies (34-39) were proposed that could also satisfy patients and specialist preferences.

The non-pharmacological treatment included advice, education and an exercise training programme which was delivered by physiotherapists in the primary care facilities. Thus, primary care physicians this did not increase their workload and patients could attend it in the same place where they receive usual care.

Other strong point was the use of electronic tools and devices which have been shown to be very useful in the decision making process (23, 24). Moreover, physicians did not have problems or difficulties with them.

Finally, the programme was implemented in primary care settings, following the care process that patients usually follow in Spain and specific diagnostic criteria (28). Therefore, it could be reproducible in other parts of the country and similar results could also be expected. However, further studies in different settings are needed to confirm these hypotheses.

On the other hand, the success of the programme was evaluated by comparing differences between the first visit with the final one, one year later. The goal was to analyse the efficacy of the programme from different perspectives. As a result, patients, health professionals but also health organisation outcomes were assessed (including the recommended standardised core set of outcome measures for osteoarthritis (27)). The analyses revealed that patients with knee OA improved in terms of pain, function and quality of life. Besides, along with the clinical results, we would like to point out that most of them considered this better than what had been provided before (usual care).

Regarding physicians, apart from the high rate of satisfaction reported, we are convinced that the programme has also provided important benefits by improving communication and collaboration with different health professionals involved in knee OA patients care. This could be a good starting point to achieve the highest standards of care in knee OA.

This study also found some limitations. One of the main limitations is related to the analysis of health care resources use and the comparison we made with the ArtRoCad study (4), which showed that in the ARTROACAS programme fewer resources were used. However, as depicted in the results section, subpopulations from both studies were not the same; those from ArtRoCad had longer and more severe disease. This can explain the fact that the use of resources was higher. Therefore, these results should be considered carefully because the effect of the programme could be overestimated. However, in our opinion, the magnitude of some of these differences, such as the number of visits to the specialist, may reflect that the programme is really optimis-

ing care resources (probably to a lesser extent, though).

In line with the above, another methodological limitation is that we did not establish a control group that followed usual care, which would probably help demonstrate definitively the effectiveness of the programme. However, on the other hand, it has been published that the implementation of best practices guidelines may lead to better outcomes (21, 29). Thus, taken all into account, we are confident that the programme is really superior to usual care.

There have been different multidisciplinary programmes published on management of patients with knee OA (33, 40). However, to our knowledge, this is the first one that combines best evidence, care providers and care levels and explicit clinical pathways which cover knee OA patient processes and needs, and which has been also implemented in daily practice as a part of it.

Currently there is a need to provide physicians with the best evidence for informed decision-making regarding diseases diagnosis and treatment options. The implementation in daily practice of a multidisciplinary care programme for patients with knee OA in a busy clinical practice setting demonstrated a considerable improvement in disease clinical outcomes, patient and physician satisfaction, and probably in terms of health care resources use and costs. Using this approach, we are now able to give and guarantee the patient appropriate care at a time they need it, contributing to the sustainability of the health systems.

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