Effects of Training on General Practitioners' Management of Pain in Osteoarthritis: A Randomized Multicenter Study

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ABSTRACT. ***Objective.*** To evaluate the effects of a short interactive training program for general practitioners (GP) on pain management in patients with osteoarthritis (OA).

Methods. A multicenter, parallel-group study. GP were randomized to receive training on relationships and communication, pain evaluation, prescription, and negotiation of a patient contract or to a control group receiving a presentation about obtaining consent in trials. Outcomes were patient assessments of pain and functional ability. We invited 1500 GP to take part in the study. Those who volunteered to receive the training recruited outpatients from May 2001 to April 2002. Patients participating in the evaluation of the effects of the general practitioners' training had lower limb OA and pain on motion [≥ 40 mm on a visual analog scale (VAS)] and had indications for treatment with acetaminophen. The primary endpoint: sum of patient pain relief based on the daily VAS self-evaluation during the 2 weeks of the trial.

Results. In total, 180 GP (84 trained, 96 nontrained) enrolled 842 patients (414 and 428, respectively). Mean baseline VAS pain was 63 ± 14 mm. Patients in the trained-GP group had better overall pain relief (316 ± 290 mm·day vs 265 ± 243 mm; $p < 0.0001$), greater improvement in Lequesne and WOMAC scores ($p < 0.0001$), and better overall perception of treatment ($p = 0.002$). Acetaminophen use was slightly higher in the trained group; however, the difference in pain relief remained statistically significant ($p = 0.0003$) after adjustment for this difference.

Conclusion. This is the first study to demonstrate a positive effect of physician training on patients with a painful condition. (First Release May 15 2006; J Rheumatol 2006;33:1827–34)

Key Indexing Terms:
CONTINUING MEDICAL EDUCATION GENERAL PRACTICE
PAIN OSTEOARTHRITIS ACETAMINOPHEN RANDOMIZED TRIAL

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Practitioners are offered various continuing medical education (CME) formats, mainly formal lectures or interactive sessions on current recommendations and practice guidelines. However, the effectiveness of guidelines and recommendations in changing physicians' behavior remains the subject of debate[1-5]. Similarly, little rigorous research has been done to determine whether acquiring knowledge and skills during CME sessions results in better health outcomes, and the little research that does exist points to equivocal results[6-10].

Given that Canadian and British general practitioners (GP) spend, on average, 90 hours[11] and 50 hours[12] a year on CME training, respectively, Davis, *et al*[13] published a review on the available evidence concerning CME effectiveness. Their aim was to answer 3 questions: What is the overall impact of CME? Under what conditions is CME effective? What CME formats are most likely to change physicians' performance and improve the health outcomes of their patients? A literature search identified only 14 randomized controlled trials of formal didactic and/or interactive CME interventions in which at least 50% of the participants were practicing physicians. It was concluded that, overall, no significant effect of these educational methods could be detected. Didactic interventions (i.e., formal presentations, predominantly lectures with mini-

mal audience participation) appeared to be even less effective in changing physicians' performance than interactive interventions using techniques to enhance physicians' participation[13]. Further, the effects of training have usually been evaluated in terms of physicians' performance rather than on health outcomes for patients.

Pain relief has become one of the major goals of physicians, especially in the growing context of chronic diseases. Management of pain is a complex issue and medical knowledge alone is not enough. Communication skills and patient-physician relationships are essential to identify the patient-related factors (e.g., belief, knowledge, coping) that influence the patient's behavior toward pain and its treatment. We performed a literature search (Medline, Embase, Excerpta Medica) at the beginning of the project, using the following key words: CME, pain, chronic pain, osteoarthritis [OA], evaluation, and randomization. We found no published studies on the evaluation of CME focused on the management of patients suffering from chronic pain. We therefore developed an educational program to improve general practitioners' behavioral skills and attitudes to pain management. One preliminary issue for a successful and relevant CME training was to define physicians' needs, the barriers that prevent changes in their clinical practice, and patients' expectations and behaviors[4,14-18]. The design of the training was based on several national and international guidelines on pain and OA[19-21], on the biopsychosocial model of chronic pain[22,23], and on evidence-based educational strategy[13,24].

The e.Dol study [e.Dol: éducation Douleur (pain education)] we conducted next aimed to discover whether this training could improve pain management for patients with OA.

MATERIALS AND METHODS

A randomized, parallel-group, multicenter study design was used. We invited 1500 randomly selected GP to take part. GP who agreed were randomized to receive the CME training (trained group) or to be in the control group. Randomization was stratified according to practice location and date of qualification.

Course content and delivery. The CME course on chronic pain management was developed by academics and GP with expertise in pain management, rheumatology, and clinician-patient communications. The course content was based on 2 surveys of the beliefs, knowledge, and behaviors of patients with pain and of the educational needs of GP[25,26]. It was also based on national and international published recommendations on pain and OA[19-21]. The training was designed to be pragmatic, interactive, centered on the patient-physician relationship[13,24], and based on the specific biopsychosocial model of chronic pain[22,23]. The training focused on 3 themes (Table 1). Workshop 1 dealt with the patient-physician relationship. Workshop 2 covered the analysis and evaluation of pain. Workshop 3 was dedicated to prescribing and the negotiation of a therapeutic contract with the patient. Videos of consultations and clinical situations were used to generate reactions and reflection from participants.

The training was delivered to GP during a 4-hour meeting by 3 pairs of trainers acting as facilitator and expert. Each pair trained a group of 36 GP, who discussed issues in groups of 6. Each group discussed pain evaluation and management in patients with OA and was asked to make 10 recommendations to improve pain management. The trainers had to ensure that recommendations proposed by GP were in line with the 10 items worded by the authors (Table 2). After the training, 8 reminders emphasizing these recommendations and including national guidelines on chronic pain management[21] were mailed to the participants. GP were also asked to give their patients a list of 5 statements about pain relief (Table 3).

The control group attended the same meeting but received a presentation about patient recruitment and obtaining consent in clinical trials. Both groups of GP then recruited patients for our e.Dol study. After the study, the 2 GP groups were offered the alternative training.

Patients. Patients over 49 years of age could enter the study if they had radiographic confirmation of OA of the knee or hip for at least 6 months; had pain intensity on motion ≥ 40 mm on a 100 mm visual analog scale (VAS) the day before inclusion; and were suitable for treatment with acetaminophen. Patients were not included in the study if they had an acute painful onset of OA; were prescribed a non-opioid analgesic [acetaminophen, acetylsalicylic acid, low-dose nonsteroidal antiinflammatory drug (NSAID)] within 24 hours of the study; required a weak or strong opioid analgesic (codeine or dextropropoxyphen, tramadol, morphine) during the 2 previous weeks; had started treatment with a NSAID within 2 weeks of the study or were likely to need a change of NSAID during the study; had started antidepressant treatment within 2 months or were likely to need a change in prescription during the study; had received a corticosteroid either orally or injected into the affected joint within the 2 previous months, or injected into another joint in the previous week; had undergone surgery of the joint under study within 3 months; or had recently received other treatments such as calcitonin, hyaluronic acid, or physiotherapy.

Patients received written information about the study and gave informed consent to participate in the study. The protocol was approved by an independent institutional review board. All patients received 64 effervescent tablets of acetaminophen 1000 mg (Doliprane®, Laboratories Sanofi-Aventis) for pain relief, to be taken according to the GP's prescription, allowing a maximum dose of 4 g per day for 16 days. This first visit was the one occasion in the study schedule for GP in the trained group to relay the information they wished to convey.

Patients were assessed at the first visit (baseline), then after 2 weeks. Pain intensity on motion, OA severity, and functional disability were assessed at each visit using respectively a VAS, the Lequesne index, and the Western Ontario and McMaster Universities OA index (WOMAC). Patients also completed a daily diary, recording average pain intensity on motion using a VAS. Patients reported their global perception of change at the end of the study using a 7-point Likert scale, ranging from much better to much worse. For patients with more than one affected joint, assessments were made on the most painful joint.

Outcomes. The primary endpoint was the change from baseline in the intensity of pain on motion as measured on a 100 mm VAS ranging from 0 (no pain) to 100 (worst possible pain) over the 2 weeks of the study. This was expressed as the sum of the pain intensity differences (SPID), which corresponds to the area under the curve (AUC) of pain intensity differences over time. The AUC was calculated using the trapezoidal method and is expressed in mm per day. Secondary endpoints were the differences between baseline and study end for VAS pain intensity, Lequesne index score, WOMAC scores, global perception of change, acetaminophen use, and percentage of patients requiring supplementary analgesia.

Statistical analysis. Our hypothesis was that pain relief would be greater among patients whose GP received training. The sample size was calculated to detect a difference of 5 mm on the pain intensity VAS between trained GP and control groups, with a standard deviation of 20 mm, an alpha error set at 0.05, a beta error set at 0.06, and using a 2 tailed test. This gave a sample size of 400 patients per group. Anticipating that 10% of patients would not complete the study, we aimed to recruit 880 patients.

Analysis was performed on an intent-to-treat basis, including all patients with at least one assessment after baseline. Quantitative data were analyzed using fixed-effect models of analysis of covariance (ANCOVA), with baseline scores as covariable and the randomization group as explicative variable. Missing diary data were replaced using the last observation carried forward method. A sensitivity analysis was carried out for the primary efficacy para-

Table 1. Content of training course. During the training, GP were divided into 3 groups, each led by a pair of facilitator and expert. Each group was then divided into 6 small groups* of about 6 GP.

1. Relationships and communication
After watching a video showing a patient consultation:
Two groups* discussed the GP's and patient's attitude during the visit
Two groups discussed the effect of the visit on the patient's anxiety
Two groups discussed the patient's comprehension of issues
2. Pain evaluation
Participants then used various tools to evaluate experimental acute pain using themselves as subjects. After this:
Two groups discussed methods of pain evaluation and available tools
Two groups discussed the limitations of pain evaluation
Two groups discussed how existing tools could be improved
3. Prescription and negotiating an agreement on therapy
After watching another video of a consultation:
Two groups discussed the effects of choice of words during prescribing
Two groups discussed how to improve compliance with longterm prescriptions and when treatments need to vary according to the course of the disease or the patient's physical activity (typical in OA)
Two groups discussed how to negotiate a therapeutic contract with a patient

Table 2. Ten recommendations to improve pain management.

1. I show my patient that I believe his/her pain is genuine
2. I explain the mechanisms of pain and reassure him/her about the causes
3. I describe the likely evolution of his/her pain
4. I ask him/her to quantify his/her pain using self-rating scales
5. I ask him/her to observe and to express his/her pain using these self-rating scales
6. I explain the need for symptomatic treatment
7. I explain the rationale for the choice of drug, particularly the effectiveness/safety ratio
8. I explain the way in which the drug should be taken and the frequency of dosing
9. I make sure that the patient has said everything he/she wants to
10. I propose the idea of a therapeutic partnership with my patient

Table 3. Written statements given to patients by the trained GP.

The keys for pain relief—
Did you know?
1. You are the expert on your pain!
2. Learning how to evaluate your pain so you can explain it to your doctor will lead to better care.
3. Improved communication with your doctor will help you understand the cause of your pain and its treatment.
4. Better understanding about your treatment will make sure you take it correctly and get the best from it.
5. You and your doctor are partners in the treatment of your pain.

meters, adjusting the effect of the randomization group with the amount of acetaminophen tablets taken, to check whether any difference was due to difference in acetaminophen consumption. Patients' global perceptions were compared using the Wilcoxon signed-rank test. The need for rescue treatment was analyzed using Fisher's exact test. A 2 tailed significance level of 0.05 was used for all comparisons.

A per-protocol analysis was performed and yielded similar results compared to ITT. These data are therefore not shown here.

RESULTS

Of the 1500 general practitioners contacted, 350 expressed an interest in the study and 232 attended the meeting and were randomized. Of those who did not attend, 43 were unavailable at the time of the CME session and 75 gave other reasons such as lack of time, current participation in another trial in OA, and anticipated problems with recruitment. After the meeting, 19 GP chose not to take part in the study and 33 did not recruit any patients. Thus, 180 GP recruited at least one patient. Of these, 84 received the CME training and 96 were in the control group (Figure 1). Their median age was 47 years, with 19 years' post-registration experience. During the study period (May 2001–April 2002) GP enrolled 842 patients (414 in the trained group, 428 in the control group). Baseline patient characteristics were comparable (Table 4). The patients, primarily women (65%), were aged from 41 to 92 years, and 83% were receiving treatment for at least one concomitant disease at baseline. Overall, 10.5% had a current prescription for analgesics or NSAID, the proportion being slightly higher in the control group (12.1% vs 8.7%). The most painful joint was the knee, in 73% of patients. The mean pain intensity on motion at baseline was 63.2 ± 13.6 mm. About 13% of patients had a

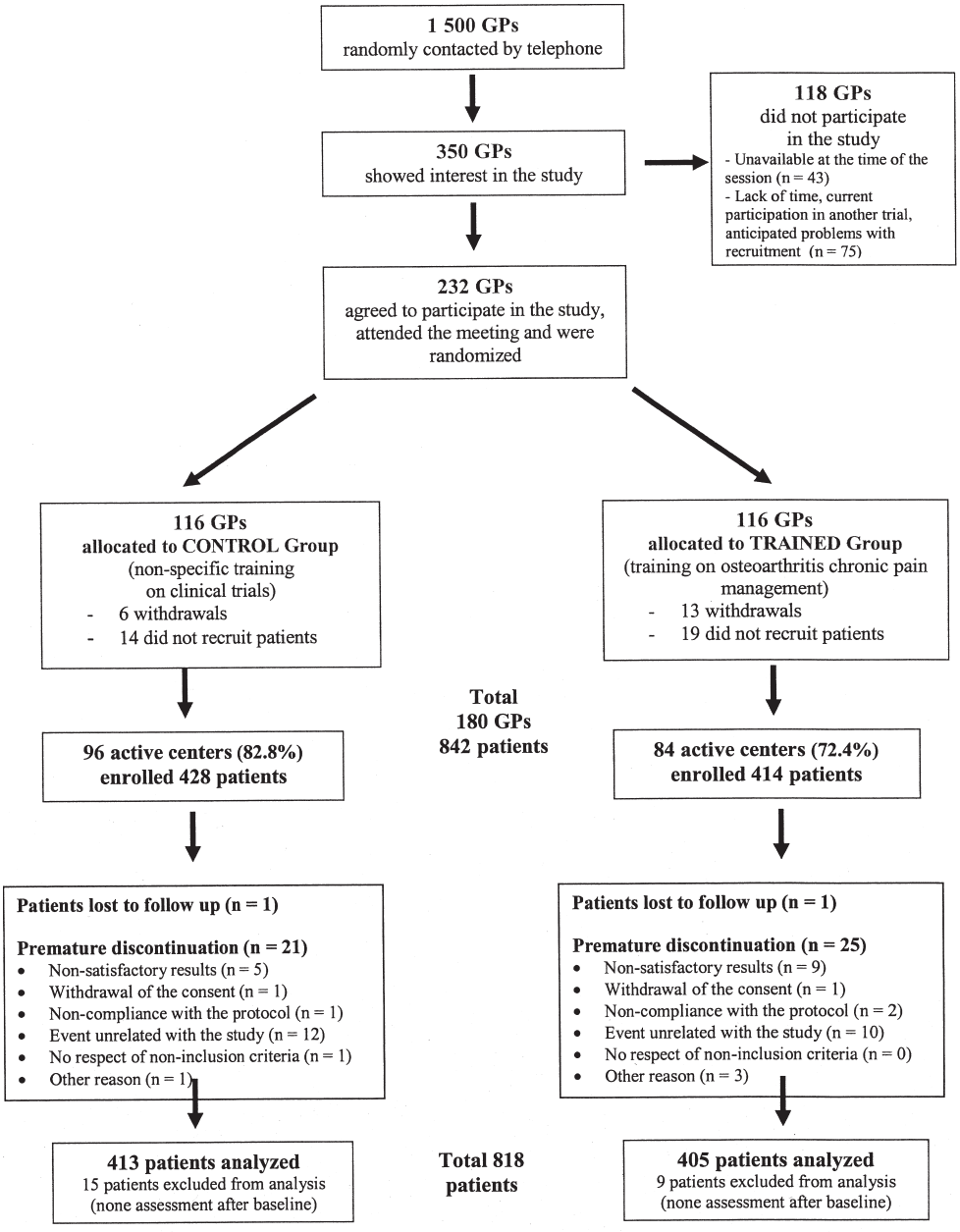

Figure 1. Progress of general practitioners (GP) and patients through each stage of the e.Dol study.

baseline pain score over 80 mm. Only 5 patients had a baseline score below 40 mm. The mean baseline Lequesne index score for the most painful joint was 9.5 ± 3.1 (the threshold for hip replacement is usually 10–12, with a maximum of 24). The total score was below 10 for 63.6% of the patients (a higher score reflects greater severity). The global WOMAC score at baseline was 45.5 ± 13.5 (the maximum is 96 and a higher score represents greater impairment). The average length of followup was 15.6 ± 5.2 days. Forty-eight patients (6%) withdrew prematurely, but reasons for withdrawals were mainly unrelated to the study and were similar in both groups. Twenty-four patients did not provide any assessment after baseline, leaving 818 patients who provided data on the primary endpoint (SPID; Figure 1).

Primary endpoint. Pain relief as measured by the AUC of VAS change from baseline over 2 weeks (SPID) was significantly greater in the trained group (n = 405), with a SPID value of 316 ± 290 mm·day, versus 265 ± 243 mm·day in patients from the control group (n = 413) ($p < 0.0001$; Table 5). Since patients are clustered within GPs, an ANCOVA analysis taking into account the center effect was carried out (actually the center-nested within-group effect). It shows a significant center-nested within-group effect ($p < 0.0001$). This means that the center effect (i.e., the effect of the investigator on

Table 4. Baseline patient characteristics.

	Trained GP Group, n = 414	Control Group, n = 428
Female, %	60.4	68.5
Age, mean yrs ± SD	68.9 ± 9.8	69.3 ± 9.8
OA of the hip (%)	142 (34.3)	139 (32.5)
OA of the knee (%)	309 (74.6)	333 (77.8)
OA of both hip and knee (%)	37 (8.9)	44 (10.3)
Most painful joint (%)		
Hip	122 (30)	107 (25)
Knee	292 (71)	321 (75)
Intensity of pain on motion on VAS, mm, mean ± SD	63.7 ± 13.8	62.8 ± 13.5
Lequesne index, n = 841*, mean ± SD	9.2 ± 2.9	9.8 ± 3.2
Patients with knee OA, n = 612*	9.3 ± 2.9	9.9 ± 3.3
Patients with hip OA, n = 229	9.0 ± 2.9	9.6 ± 2.9
WOMAC index, mean ± SD		
Pain, n = 836*	9.3 ± 3.0	9.6 ± 2.8
Stiffness, n = 836*	4.1 ± 1.4	4.0 ± 1.4
Physical function, n = 830*	31.2 ± 10.9	32.8 ± 9.5
Global score, n = 830*	44.6 ± 14.4	46.4 ± 12.5

* Some missing data explains the slight differences in the number of patients. Differences between the groups were not statistically significant.

Table 5. Pain and disability assessments.

	Trained GP Group, mean ± SD	Control Group, mean ± SD	p	Mean of Difference (95% CI)
Pain relief (SPID), n = 818	315.6 ± 289.5	264.7 ± 242.9	< 0.0001	50.9 (14.2, 87.6)
Change in scores between baseline and study end				
VAS, mm, n = 817	–29.0 ± 23.1	–24.8 ± 21.1	0.01	–4.5 (–7.5, –1.5)
Lequesne Index, n = 811	–2.5 (2.5)	–2.0 (2.4)	< 0.0001	–0.5 (–0.8, –0.2)
WOMAC Index				
Pain, n = 800	–2.9 ± 3.4	–2.2 ± 2.9	< 0.0001	–0.7 (–1.1, –0.3)
Stiffness, n = 802	–1.2 ± 1.6	–0.8 ± 1.4	0.0004	–0.4 (–0.6, –0.2)
Physical function, n = 790	–8.7 ± 10.7	–6.1 ± 8.8	< 0.0001	–2.6 (–3.8, –1.4)
Global score, n = 788	–12.9 ± 14.8	–9.2 ± 12.2	< 0.0001	–3.7 (–5.6, –1.8)
Acetaminophen consumption, mg/day	3400 ± 800	2900 ± 900	< 0.0001	500 (378, 622)

* Differences in patient numbers due to missing data.

her/his patients' outcome) depends significantly on the group to which the investigator belongs (i.e., whether the investigator has or has not attended the training). Thus, the difference is then 19.2% in favor of the trained group. The difference between the 2 groups remained highly significant even after adjustment for the amount of acetaminophen taken (p = 0.0003). The difference was apparent by the first day of treatment and the benefit was maintained for 2 weeks. Comparison of mean VAS values showed a similar pattern (Figure 2).

Secondary endpoints. Patients in the trained GP group reported a greater reduction in pain intensity from baseline to end of study, and greater improvement in the Lequesne index and in the WOMAC scores than the control group (Table 5). There was no difference in the use of rescue treatment between the groups, with 7% requiring an additional analgesic and 4% a NSAID. However, mean consumption of acetaminophen was higher in the trained group. Patients' global perception of change was also significantly better in the trained group than the controls, with 81% versus 75% of patients considering themselves slightly to much better and 16% versus 24% unchanged (p = 0.002 for overall comparison). Similar proportions of patients reported adverse events in the 2 groups (9% in the trained group vs 10% in the control group).

DISCUSSION

Our study suggests that a short interactive training session on pain management given to general practitioners can improve pain and functioning in patients with OA.

Few previous CME programs have employed methods permitting the evaluation of their effects on patients' health[13,14]. Thus, although physicians' performance may appear to be improved, studies showing improvements in patient-centered outcomes are less common[7-10,26]. Showing that physicians' skill or knowledge improves after a CME session does not

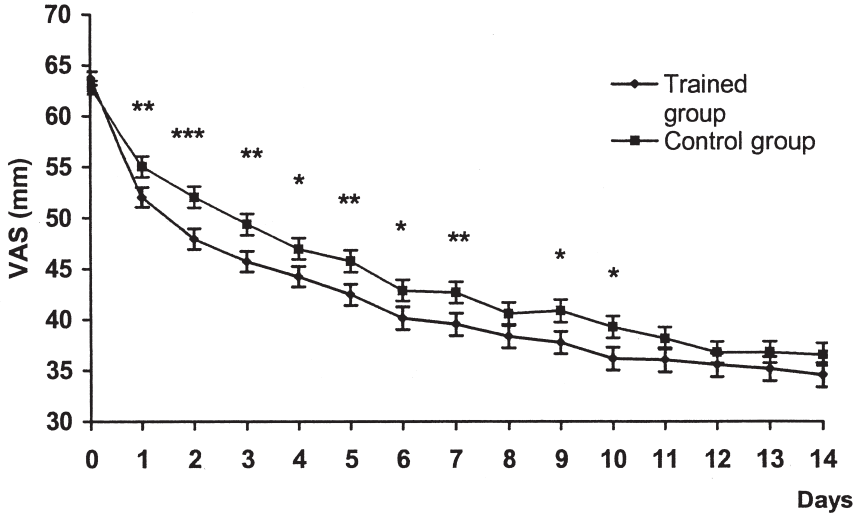

Figure 2. Pain intensity (mean VAS scores) over the 2 weeks of the e.Dol study. *p < 0.05; **p < 0.01; ***p < 0.001. Bars represent standard deviations.

necessarily mean that they will change their everyday practice. Rigorous randomized trials have more often shown no effect of the CME intervention[6,27-29] than positive results[30].

In the field of pain management, studies of CME have used noncomparative designs[31], or simple assessment of physicians' satisfaction or knowledge[32,33]. Glazier, *et al*[34] therefore concluded that weak methodology made it impossible to draw firm conclusions about the effectiveness of CME for primary care physicians in rheumatic diseases.

The success of our CME program might be due to several factors. It used an evidence-based strategy with small-group, interactive sessions[13,24] focusing on previously identified training needs and the beliefs and knowledge of patients[25,26]. The content was based on published guidelines and recommendations[19-21], adapted according to evidence-based practice[15]. It focused on issues that are specific to primary care, and was based on the biopsychosocial model of chronic pain[22,23]. Further, we measured effects on patient-centered outcomes in a randomized trial, rather than relying on judgments of physician's performance. To our knowledge, a positive effect of a CME on pain management has not been previously demonstrated.

However, some limitations of our study should be noted. The effect of training GP has been shown only for the short-term management of patients with OA. Further investigation of the persistency of these effects over the longer term would be of interest. However, the 2-week duration of the e.Dol trial is relevant and usual in the context of short-term pain management in OA[35].

The actual GP participation rate was 10.4% lower in the trained versus the control group (Figure 1). The "dropout" general practitioners may have been those who disagreed with or were uncomfortable with the approach advocated in the training program. This differential dropout rate may have introduced a bias in favor of that trained group producing positive outcomes. However, considering that our statistical significances are relatively large ($p < 0.001$) and that the difference in dropout rate is only 10% between groups, it is most probable that most of the recorded changes are related to the intervention.

Although reminders were sent to general practitioners throughout the study period, direct training took place only during a single session. It is possible that repeated sessions would produce an even greater effect[13,14]. Nevertheless, with a single CME session delivered to GP, we were able to show an improvement in the pain of patients with OA.

Our study allowed GP only one visit to relay messages about pain management to patients. However, the primary care setting has the advantage that the GP already knew their patients, thus allowing more time during the visit for enhancing the patient-physician relationship. Despite this relatively brief interaction with the patient, we were still able to show a statistically significant difference between the trained GP group and the control group.

Although all patients received the same number of acetaminophen tablets, those in the trained GP group used on average 500 mg more acetaminophen per day than the control group. This difference could have explained the difference in pain scores between the 2 groups. However, when the analysis was adjusted to take account of acetaminophen consumption, the difference in pain relief remained highly significant ($p = 0.0003$). This confirms that the CME session, which covered aspects from assessment to treatment, dealt with multiple factors involved in the process of the management of chronic pain, and not only on the prescription of drugs. Moreover, if the training did improve analgesic prescribing by improving the explanation of the prescription to patients, and therefore patient compliance with the doctor's intentions, then these

results are relevant and the goal of the CME has still been achieved.

We powered our study to detect a 5 mm difference in VAS score. No regulatory guideline defines currently what is the minimal clinically relevant difference between pain scores[36,37], and the threshold is still under debate[38-40], but a 5 mm difference has been exploited in some comparative trials of analgesics. Some minimal clinically important improvement level (MCII) has been proposed. Tubach, *et al*, using an anchoring method based on patient's opinion, showed that the MCII for pain (VAS) after 4 weeks of treatment was –19.9 mm for knee and –15.3 mm for hip OA in a cohort study of 1362 patients[41]. Our results reach beyond this threshold, as the mean improvement of pain over 2 weeks was –24.8 in the control group and –29.0 in the trained GP group. But the MCII, which corresponds to an improvement over time within patients, may not be similar to the minimal important difference between treatment groups. The fact that we also observed consistent statistically significant improvements in functioning and other endpoints lends strength to the argument that the observed changes were clinically significant. Moreover, a 20% difference in SPID came out favoring the trained group.

The open design of this study and the effect of recruiting patients into it may have affected the behavior of the control group and reduced our ability to observe an effect of training, since GP in the control group, knowing they were taking part in a study, may have enhanced their usual practice. Since the control group received training about recruiting patients to clinical trials this might have improved their performance as investigators. However, recruitment rates were similar in the 2 groups and it seems unlikely that this nonspecific presentation would have enhanced the general practitioners' management of chronic pain.

General practitioners' attendance at our interactive training on chronic pain management was associated with improved health outcomes for patients with OA at 2 weeks. We cannot be sure of the reasons for this. The training may have improved patient-doctor relations, pain assessment, and the prescription of analgesics. It may also have resulted in better patient compliance with treatment, leading to greater relief of pain. The longer-term effects of training need to be assessed as well as the possible benefits of multiple sessions. However, the process of developing, delivering, and evaluating the CME training package as in this study may usefully be applied to other painful conditions.

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