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RESEARCH

ARTIST (osteoarthritis intervention standardized) study of standardised consultation versus usual care for patients with osteoarthritis of the knee in primary care in France: pragmatic randomised controlled trial

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ABSTRACT

Objective To evaluate the impact of standardised consultations on patients with osteoarthritis of the knee.

Design Open pragmatic cluster randomised controlled trial.

Setting Primary care in France.

Participants 198 primary care rheumatologists, each of whom had to include two consecutive patients who met the American College of Rheumatology criteria for osteoarthritis of the knee.

Interventions Standardised consultation was provided during three goal oriented visits (education on osteoarthritis and treatment management; information on physical exercises; information on weight loss) or usual care.

Main outcome measures Change in body weight and in time spent on physical exercises (Baecke index) at four months.

Results 336 patients were included (154 allocated to standardised consultation and 182 to usual care). Nine patients were excluded because of lack of baseline data (standardised consultation, n=8; usual care, n=1). At four months, taking into account the clustering effect, the decrease in weight was greater in the standardised consultation group than in the usual care group (mean −1.11 (SD 2.49) kg *v* −0.37 (2.39) kg; P=0.007). The physical activity score was higher for the standardised consultation group than for the usual care group (mean 0.20 (0.65) *v* 0.04 (0.78); P=0.013). The standardised consultation and usual care groups did not differ in secondary outcomes, except for global assessment of disease activity (0-10 numeric scale: mean −1.66 (2.26) *v* −0.90 (2.48); P=0.003) and pain level (0-10 numeric scale: mean −1.65 (2.32) *v* −1.18 (2.58); P=0.04).

Conclusions A structured consultation programme for patients with osteoarthritis of the knee resulted in short term improvement in weight loss and time spent on physical activity.

Trial registration Clinical trials NCT00462319.

INTRODUCTION

Osteoarthritis is a major source of morbidity, disability, and loss of function in the general population.[1] In an ageing population, osteoarthritis of the knee is likely to be of increasing concern. The guidelines for treatment of osteoarthritis of the knee from the National Institute for Health and Clinical Excellence, the American College of Rheumatology, and the European League Against Rheumatism recommend non-drug treatments,[2-5] including education of patients, social support, physical exercises, and weight loss.[6] However, despite these recommendations, such non-drug treatments are not systematically offered to patients in clinical practice. For example, less than half of obese patients with osteoarthritis of the knee have been advised by a healthcare professional to lose weight.[7-9]

Managing a chronic disease such as osteoarthritis requires a modification of patients' behaviour; patients need to be educated about the disease and to understand the purpose of the treatment proposed. However, providing such complex interventions is time consuming and difficult to do in the context of short consultations.[10-12] The lack of implementation of guidelines for treating osteoarthritis is probably linked to difficulties in providing information to patients on all these important matters during a single consultation.

We aimed to test whether a new standardised programme of goal oriented visits would give better results in terms of weight management and physical activity than would usual care among patients with osteoarthritis of the knee.

METHODS

Design

We designed a multicentre pragmatic cluster randomised controlled trial. The unit of randomisation was care providers (rheumatologists), and the unit of analysis was patients. This design allowed us to avoid the risk of contamination that can occur in trials assessing participative interventions such as education

if healthcare providers are doing both experimental and control interventions.[13-17] This study report followed the guidelines of the CONSORT statements for cluster randomised controlled trials and non-drug treatments.[18-20]

Participants

Care providers were primary care rheumatologists who, in France, are specialist doctors whom patients can consult directly without referral. We recruited rheumatologists by mail, sending them an invitation to participate in the trial. If they were interested, they responded by mail, and we then contacted them by phone and gave them a more detailed explanation. Each rheumatologist had to include the first two patients who complied with the inclusion criteria.

Patients had to meet the following criteria: outpatient aged 45-75 years consulting a rheumatologist, diagnosis of osteoarthritis of the knee according to the American College of Rheumatology clinical and radiological definition,[21] knee pain rated between 30 mm and 70 mm on a numerical scale and necessitating treatment with non-steroidal anti-inflammatory drugs, body mass index ≥25 and <35, and able to understand and speak French and to answer questions over the phone. These patients were consulting a rheumatologist for the first time or were already consulting a rheumatologist.

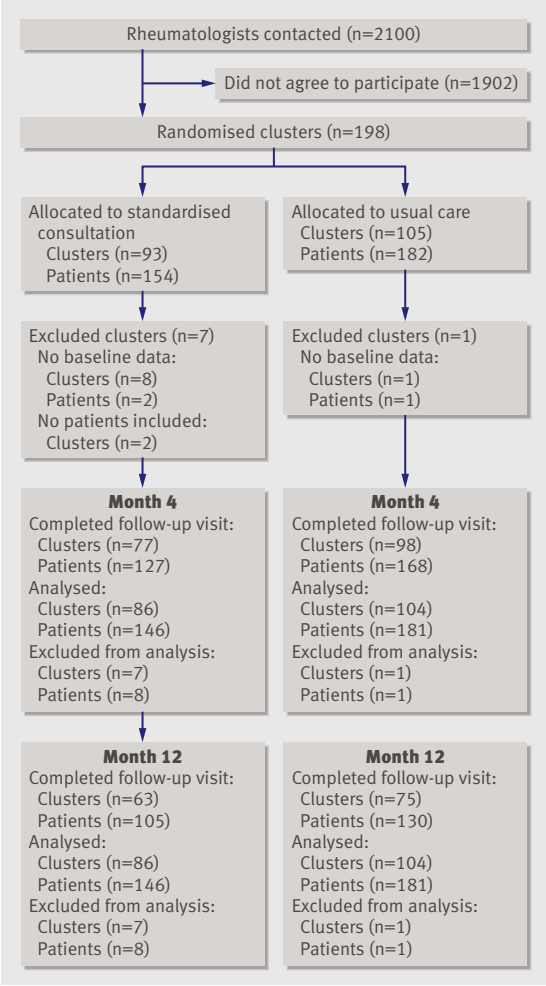
We excluded patients who needed to have a surgical procedure in the next six months; had a chronic disease such as coronary disease, severe hypertension, stroke, congestive heart failure, chronic obstructive pulmonary disease, type 1 diabetes mellitus, or renal or hepatic diseases; were unable to walk without aid; were participating in another programme with nutritional education; had an electronic implantable device (pacemaker); or were already participating in a clinical trial.

Allocation sequence generation

We randomly assigned rheumatologists who agreed to participate to the intervention they had to provide: usual care or standardised consultation. A statistician at the department of epidemiology biostatistics and clinical research, Hospital Bichat, who was not involved in the conduct of the study, used a computer generated process to randomise rheumatologists; randomisation was stratified by region. If several rheumatologists were working in the same clinic, they were randomised to the same arm.

Allocation concealment

We based allocation on clusters rather than individuals and concealed the sequence until interventions were assigned. However, rheumatologists recruited patients after knowing the treatment assignment. To limit the risk of selection bias, we asked rheumatologists to include the first two patients who met the selection criteria. Furthermore, we investigated the risk of selection bias and took it into account in the statistical analyses.



Flow diagram of participants in the trial

Intervention

In each arm, interventions were provided at the individual level. A group of rheumatologists and epidemiologists developed and defined the experimental intervention after iterative discussion sessions.[22] The group defined the key components of the intervention, the potential barriers to changing practice, the main methods to overcome these barriers, and the main management strategies to be conveyed to the patients.[23]

The background behind the intervention was briefly as follows. Education about osteoarthritis, exercise regimens, and weight loss has been independently evaluated in randomised controlled trials (mainly explanatory randomised controlled trials) and shown to improve the condition of patients with osteoarthritis. Educating patients about these different components in clinical practice is recommended. However, these recommendations are difficult to implement because this is a complex intervention that is time consuming for physicians and supposes a high level of understanding and adherence by the patient. To overcome these problems, we aimed to develop an intervention that would be easy to implement for physicians and that could improve patients' adherence.

Our intervention is drawn in part from an intervention intended to limit the number of actions per visit to a physician and has previously been tested in a randomised controlled trial. This trial, done in Harare (Zimbabwe), tested the hypothesis that a programme consisting of few but more oriented visits in the field of antenatal care would give better results than the standard programme.[24]

To improve physicians' adherence to the guidelines, we proposed to overcome the constraint of consultation time, the main obstacle to effective patient-provider communication. For this purpose, we proposed three goal oriented visits, with one component of the complex intervention being implemented at each visit. We standardised the content of each visit by providing a clear description of the content on the case report form.

To improve patients' adherence, our theoretical background was as follows. The first visit aimed at informing patients about the disease and treatment. In fact, properly informed patients are more likely to adhere to treatment plans and lifestyle changes. The next two visits focused on only one component each (exercise and weight loss). This focus allowed for a simplification of the message to improve patients' comprehension and recall of information. Finally, we implemented tailored counselling of patients to increase the odds of achieving modification of behaviour: the exercise programme took into account patients' preferences, and the strategy for losing or maintaining weight varied according to patients' readiness to change.

Experimental intervention

Rheumatologists randomised to the experimental arm had to provide a programme of three goal oriented standardised consultations for each included patient.

Identification, evaluation, and treatment of overweight and obesity in adults

1) Assess obesity risk—Physicians should assess their patients' risk of obesity related conditions and identify obesity related comorbidities and risk factors for cardiovascular disease

2) Ask about readiness to lose weight—Rather than assuming that all overweight patients are motivated to begin a weight loss programme, clinicians should determine whether their patients are motivated to lose weight

3) Advise about designing a weight control programme—Clinicians should advise patients who are ready and motivated to lose weight about designing a weight control programme individually suited to their needs. For patients who are not ready or motivated, clinicians should provide counselling to maintain weight

4) Assist in establishing appropriate intervention—A comprehensive lifestyle modification programme with decreased energy intake through diet and increased energy expenditure through physical activities constitutes an integral part of all intervention programmes for weight loss

To help the physician to implement the intervention, the case report form fully described all information necessary for each of the standardised consultations (including the key messages to tell the patient). The physician had to follow the case report form step by step.

During the first visit (day 0), rheumatologists provided education and advice related to osteoarthritis and its treatment. During the second visit (day 15), rheumatologists informed patients about how to protect joints (movements to avoid) and the need for physical exercise. They proposed a progressive exercise regimen consisting of three sessions of 30 minutes a week progressively increased to three sessions of 60 minutes a week of rapid walking or cycling depending on the patient's preference.

During the third visit (day 30), rheumatologists educated patients about body weight and its influence on osteoarthritis of the knee and proposed a strategy for losing or maintaining weight. They told patients that excess weight would influence their knee pain and the progression of osteoarthritis, that the area of the joint contact was approximately 3 cm^2 (1 cm^2 in cases of meniscectomy), and that the force applied to the joint when walking is equivalent to three times the person's weight. In the case of osteoarthritis of one knee, with excess weight the risk of developing osteoarthritis of the other knee at two years is 54%; otherwise, the risk is 14%. The risk of worsening bilateral osteoarthritis of the knee is threefold that without excess weight. Finally, rheumatologists had to implement the US National Institutes of Health evidence based guidelines for management of obesity, a practical patient centred tool for organising information for weight loss counselling.[25] This tool considers particularly the patient's state of readiness to change and intentions regarding implementation. The tool is available at www.nhlbi.nih.gov/guidelines/obesity/prctgd_c.pdf and is summarised in the box.

In addition, specific documents provided to patients included information on osteoarthritis and a booklet to record weight and physical activities each week. To ensure consistency in delivery and content of the intervention, rheumatologists had to use a pre-printed data collection form following algorithms proposed in the National Institutes of Health guidelines to provide this standardised programme, use similar language and explanations at each step of the programme, and provide specific leaflets to patients.

Control group

In France, patients with osteoarthritis of the knee usually visit their rheumatologists every six or 12 months. In this trial, we asked rheumatologists randomised to the control arm to provide usual care to their patients during three consecutive visits (the same number of visits as the experimental group). At the end of the study, we made all documents used in the experimental arm available to these rheumatologists.

Co-interventions

We left the prescription of paracetamol or non-steroidal anti-inflammatory drugs, as well as all other co-interventions, to the care providers' decision.

Outcomes

To assess outcomes, rheumatologists evaluated all patients who agreed to participate during clinical visits at baseline and at days 15, 30, and 120. An independent data collector evaluated patients' satisfaction and knowledge during a phone interview before the clinical visits at day 120. An independent data collector evaluated long term outcomes at 12 months during a phone interview.

Short term outcomes (four months)

We evaluated the primary short term outcomes at four months at the level of the patient. These included patients' weight measured on a specific weighing machine provided to the rheumatologists and time spent on physical exercises as measured by the physical exercise in leisure subscale of the Baecke index (0-5 scale).[26-28]

Secondary outcomes evaluated during the follow-up visits to the rheumatologist were pain on movement during the 48 hours before the visit measured on a 0-10 numerical scale; score on the French-Canadian version of the Western Ontario and McMaster Universities osteoarthritis index (WOMAC) physical function subscale (17 items, five point Likert-type scale version, total score ranging from 0 to 68; high scores indicate a high degree of functional impairment); global assessment of disease activity as measured on a 0-10 numerical scale; and physical and mental scores on the Medical Outcomes Survey short form 12 (SF-12), a generic quality of life questionnaire.[29] Rheumatologists asked patients to complete questionnaires, including WOMAC, the Baecke index, and the SF-12, in the seven days after the visit and to return them in a stamped envelope to an independent structure in charge of the trial. Secondary outcomes evaluated during a standardised phone interview by an independent data collector were patients' satisfaction with and knowledge of with their treatment as evaluated on a 0-10 numerical scale.

Long term outcomes (12 months)

At 12 months, the patients' outcomes collected by an independent data collector by phone interview concerned self reported weight, time spent on physical exercises during the previous three months as measured by the physical exercise in leisure subscale of the Baecke index,[27 28] pain on movement during the 48 hours before the contact as measured on a 0-10 numerical scale, score on the French-Canadian version of the WOMAC physical function subscale, global assessment of disease activity as measured on a 0-10 numerical scale, and SF-12 score.[29] Measurement of patients' weight at 12 months was self reported and not standardised, whereas measurement of the primary outcome (weight at four months) was standardised by the use of identical weighing machines provided to rheumatologists.

Adverse events

Physicians systematically recorded all adverse events and classified severity according to the World Health Organization classification. The investigators systematically reported all severe adverse events and assessed the relation between intervention and adverse events.

Sample size

The main objective of this study was to evaluate the impact of a programme of standardised consultation on the two main outcomes: change in patients' body weight and change in time spent on physical exercises as measured by the physical exercise in leisure subscale of the Baecke index at four months.

We took into account the cluster randomisation in the sample size calculation by using the intracluster correlation coefficient. Because we had two main outcomes, α was 0.025. We lacked data on possible intracluster correlation in this specific area, so we assumed an intracluster correlation of ρ=0.05, which is compatible with intracluster correlation coefficients seen for patients' self reported outcomes in other studies of chronic conditions and is probably conservative.[30] We fixed the cluster size to two patients recruited by each rheumatologist.

For change in patients' weight, we anticipated a power of 90% to detect an expected absolute variation of mean change in weight of 2 (SD 7.4) kg between the usual care and standardised consultation groups with α=0.025, so 362 rheumatologists would be needed. For time spent on physical activities (the physical exercise in leisure subscale of the Baecke index), we expected a

Table 1 | Demographic and clinical characteristics of patients with knee osteoarthritis at baseline according to group. Values are mean (SD) unless stated otherwise

Characteristics	All patients (n=327)	Standardised consultation (n=146)	Usual care (n=181)
Age (years)	64.3 (8.3)	63.9 (8.1)	64.6 (8.3)
No (%) male	83 (25.4)	34 (23.3)	49 (27.1)
Weight (kg)	82.6 (13.3)	84.1 (12.9)	81.4 (13.6)
Body mass index	30.7 (3.7)	31.2 (3.5)	30.2 (3.8)
PEL (0-5)	2.2 (0.9)	2.2 (0.8)	2.2 (0.9)
Median (interquartile range) delay since beginning of pain (years)	4 (1-10)	5 (2-10)	4 (1-7)
Age at beginning of pain (NS 0-10)	57.9 (10.5)	56.5 (10.5)	59.1 (10.4)
Pain (NS 0-10)	5.6 (1.3)	5.5 (1.2)	5.6 (1.3)
Global assessment of disease status (NS 0-10)	5.6 (1.5)	5.6 (1.5)	5.6 (1.5)
WOMAC physical function subscale (0-100)	30.1 (12.1)	30.3 (11.8)	29.9 (12.4)
SF-12 physical function subscale (n=276)	35.2 (7.2)	35.5 (7.1)	35.0 (7.4)
SF-12 mental function subscale (n=276)	42.4 (10.6)	43.3 (10.7)	41.6 (10.4)

NS=numerical scale; PEL=physical exercises in leisure subscale of Baecke index; SF-12=Medical Outcomes Survey short form 12; WOMAC=Western Ontario and McMaster Universities osteoarthritis index.

Table 2 | Characteristics of treatments used by patients with knee osteoarthritis at baseline according to group. Values are numbers (percentages)

Characteristics	All patients (n=327)	Standardised consultation (n=146)	Usual care (n=181)
Drug treatments			
Current use of analgesics	224/325 (68.9)	95/145 (65.5)	129/180 (71.7)
NSAIDs	184/326 (56.4)	90 (61.6)	94/180 (52.2)
Current use of NSAIDs	143/184 (77.7)	70/90 (77.8)	73/94 (77.7)
SYSADOA	142/326 (43.6)	68 (46.6)	74/180 (41.1)
Current use of SYSADOA	136/139 (97.8)	67/68 (98.5)	69/71 (97.2)
Intra-articular treatment	60 (18.3)	29 (19.9)	31 (17.1)
Non-drug treatments			
At least one non-drug treatment	180/325 (55.1)	71 (48.6)	109/179 (60.2)
Diet	80 (24.5)	31 (21.2)	49 (27.1)
Consultation with a dietitian	19 (5.8)	7 (4.8)	12 (6.6)
Physical exercises at home	71 (21.7)	27 (18.5)	44 (24.3)
Physiotherapy	47 (14.4)	17 (11.6)	30 (16.6)
Knee orthosis	32 (9.8)	11 (7.5)	21 (11.6)
Insoles	35/326 (10.7)	11 (7.5)	24/180 (13.3)
Walking stick	23/325 (7.1)	10 (6.8)	13/179 (7.3)

NSAIDs=non-steroidal anti-inflammatory drug; SYSADOA=systematic slow acting drug for osteoarthritis.

mean change in score of 0.25 (SD 0.46) between the groups. A total of 92 rheumatologists, with 184 patients, would be needed. To take into account these two aims and the risk of imbalanced clusters, we proposed to sample 400 rheumatologists for this study. Each rheumatologist had to include two patients, for a sample size of 800 patients.

Blinding

We could not completely blind patients and care providers to the intervention allocated, and nor could outcome assessment be blind. However, patients were blinded to the study hypothesis. Patients were informed that they were participating in a trial comparing different forms of consultations. They were informed about the content of the consultations to which they were assigned but not the consultation programme the other arm received. Data collectors interviewing patients during the phone visits were independent and blinded to treatment. However, rheumatologists evaluating weight were not blinded to treatment assignment.

Statistical methods

A blinded statistician at the Department of Epidemiology Biostatistics and Clinical Research, Hospital Bichat did the statistical analysis with SAS 9.1. Analyses followed a pre-specified plan based on the principle of modified intent to treat (that is, all participants are included in the group to which they were assigned, regardless of whether they completed the intervention given to the group). However, if no baseline data were recorded, we excluded the patients from the analyses. Missing data were supplied by the last observation carried forward procedure.

We analysed all outcomes in the framework of a marginal model analysis, comparing changes in means of variables in each group. We adjusted all comparisons for the baseline value of the considered outcome and, except for weight, for the baseline value of the body mass index. For the primary outcomes, we considered a P value ≤ 0.025 to be statistically significant. For secondary outcomes, we considered a P value ≤ 0.05 to be statistically significant. We restricted investigation of patients' satisfaction and knowledge at week four to patients who answered the phone interview satisfaction questions.

We also did a propensity score analysis. For each patient, we calculated the conditional probability that a patient received a particular treatment on the basis of pre-treatment variables. The objective was to balance the treatment groups so as to reduce bias from cluster randomisation. We then derived a propensity score weight: each patient was weighted with the inverse of the propensity score in the intervention group and with the inverse of one minus the propensity score in the control group. A propensity score weighted marginal model was thus fitted to compare groups for each outcome.[31]

For each outcome measure, we estimated the intracluster correlation coefficient and derived an approximate 95% confidence interval by using formulas for the balanced case.[32]

RESULTS

Participants

The figure shows the flow of clusters and individual participants through each stage. Because of difficulties in recruitment, we included and randomised only 198 rheumatologists between May 2005 and June 2006; 137 rheumatologists included two patients, and 53 included only one patient. (We excluded six

rheumatologists (who included nine patients: eight in the standardised consultation group and one in the usual care group) because they did not complete the baseline data for their patients and two because they did not include any patients). Consequently, at four months, data were available for analysis for 327 patients—146 in the standardised consultation group and 181 in the usual care group.

Tables 1 and 2 summarise the baseline characteristics of patients in each group. The groups seemed to be similar. However, the standardised consultation group had a higher mean body mass index and longer delay from the beginning of pain linked to osteoarthritis of the knee. Patients in the usual care group were more often treated with non-drug treatments. More than 95% of patients in the intervention group and 96% of patients in the control group attended all three consultations.

Outcomes

Table 3 gives the results for the primary and secondary outcome measures during follow-up. At four months, according to a modified intent to treat analysis taking into account the clustering effect, the decrease in measured weight was greater in the standardised consultation group than in the usual care group (mean −1.11 (SD 2.49) kg *v* −0.37 (2.39) kg; P=0.007). The proportion of patients who lost more than 2 kg was 28.1% (41/146) in the standardised consultation group and 16.0% (29/181) in the usual care group (P=0.01).

The increase in time spent on physical exercises as measured by the physical exercise in leisure subscale of the Baecke index was greater in the standardised consultation group than in the usual care group (mean 0.20 (0.65) *v* 0.04 (0.78); P=0.013). When we applied propensity methods in the primary analyses, the differences seen were also significant. The standardised consultation and usual care groups did not differ in secondary outcomes, except for pain (0-10 numerical scale: mean −1.65 (2.32) *v* −1.18 (2.58); P=0.04) and global assessment of disease activity (0-10 numerical scale: mean −1.66 (2.26) *v* −0.90 (2.48); P=0.003). The intracluster correlation coefficients varied from 0.00 to 0.315 according to the outcome measure chosen and are detailed in table 3.

Satisfaction

At four months, we evaluated patients' satisfaction with and knowledge of osteoarthritis of the knee and its management for 272 patients. Patients in the

Table 3 | Mean change between baseline and four months for patients receiving standardised consultation and usual care (n=327)

	Mean	SD	Intracluster correlation coefficient (95% CI)	P value*	P value†
Weight (kg)					
Standardised consultation	−1.11	2.49	0.006 (0.000 to 0.144)	0.007	0.005
Usual care	−0.37	2.39	0.000 (0.000 to 0.101)		
PEL (0-5)					
Standardised consultation	0.20	0.65	0.000 (0.000 to 0.357)	0.013	0.025
Usual care	0.04	0.78	0.244 (0.000 to 0.483)		
Pain (NS 0-10)					
Standardised consultation	−1.65	2.32	0.315 (0.084 to 0.535)	0.041	0.020
Usual care	−1.18	2.58	0.161 (0.000 to 0.383)		
WOMAC physical function subscale (0-100)					
Standardised consultation	−5.74	10.66	0.079 (0.000 to 0.267)	0.199	0.121
Usual care	−4.03	11.35	0.000 (0.000 to 0.184)		
Global assessment of disease status (NS 0-10)					
Standardised consultation	−1.66	2.26	0.008 (0.000 to 0.298)	0.003	0.002
Usual care	−0.90	2.48	0.281 (0.068 to 0.487)		
Body mass index					
Standardised consultation	−0.37	1.14	0.069 (0.000 to 0.204)	0.124	0.095
Usual care	−0.16	0.92	0.000 (0.000 to 0.116)		
SF-12 physical function subscale (n=276)					
Standardised consultation	3.02	6.97	0.000 (0.000 to 0.200)	0.109	0.203
Usual care	1.83	7.39	0.001 (0.000 to 0.276)		
SF-12 mental function subscale (n=276)					
Standardised consultation	0.36	8.91	0.000 (0.000 to 0.177)	0.890	0.665
Usual care	0.86	9.51	0.082 (0.000 to 0.286)		

NS=numerical scale; PEL=physical exercises in leisure subscale of Baecke index; SF-12=Medical Outcomes Study short form 12; WOMAC=Western Ontario and McMaster Universities osteoarthritis index.
*Comparisons were adjusted for baseline value and for baseline value of body mass index for all variables except weight.
†Comparisons were adjusted for baseline value and for baseline value of body mass index for all variables except weight and used a propensity score weight method.

Table 4 | Patients' knowledge about osteoarthritis and care and satisfaction with knowledge. Values are numbers (percentages) unless stated otherwise

	All patients (n=272)	Standardised consultation (n=126)	Usual care (n=146)	P value
Information obtained on (yes)				
Knee osteoarthritis	223 (82.0)	108 (85.7)	115 (78.8)	0.117
Drug treatments	153 (56.2)	75 (59.5)	78 (53.4)	0.322
Need for regular exercise	212 (77.9)	117 (92.9)	95 (65.1)	<0.001
Need to lose weight	227 (83.5)	116 (92.1)	111 (76.0)	0.001
Level of satisfaction related to the information obtained (very satisfied)				
Knee osteoarthritis (n=223)	72/223 (32.3)	41/108 (38.0)	31/115 (27.0)	0.299
Drug treatments (n=155)	49/155 (31.6)	22/75 (29.3)	27/80 (33.7)	0.579
Need for regular exercise (n=213)	86/213 (40.4)	50/117 (42.7)	36/96 (37.5)	0.574
Need to lose weight (n=229)	97/229 (42.4)	53/116 (45.7)	44/113 (38.9)	0.252
Documents obtained on (yes)				
Knee osteoarthritis	139 (51.1)	99 (78.6)	40 (27.4)	<0.001
Exercise	106 (39.0)	93 (73.8)	13 (8.9)	<0.001
Weight loss	102 (37.5)	80 (63.5)	22 (15.1)	<0.001
Patients' knowledge assessment				
Exercise is always bad for knee osteoarthritis (wrong)	172/271 (63.5)	89 (70.6)	83/145 (57.2)	0.024
Walking, cycling, or swimming is good for knee osteoarthritis (right)	224/271 (82.7)	109 (86.5)	115/145 (79.3)	0.132
Knee osteoarthritis is not related to weight (wrong)	165/271 (60.9)	82 (65.1)	83/145 (57.2)	0.201
Losing weight can improve knee osteoarthritis (right)	231/271 (85.2)	114 (90.5)	117/145 (80.7)	0.031

standardised consultation group were more likely than those in the usual care group to have obtained information about the need for regular exercises and to lose weight and to have obtained documents on osteoarthritis of the knee, exercise, and weight loss (table 4). Their knowledge about management of osteoarthritis of the knee did not differ substantially from that of the usual care group, except for knowledge about losing weight.

Adverse events

No adverse events were reported during the study.

One year follow-up

A total of 235 of the 327 patients randomised agreed to complete the one year follow-up phone interview. The standardised consultation and usual care groups did not differ in self reported weight (mean −2.85 (4.76) *v* −2.07 (4.37); P=0.20). The proportion of patients who lost more than 2 kg was 44.5% (65/146) in the standardised consultation group and 39.2% (71/181) in the usual care group (P=0.36). The standardised consultation group showed better scores than did the usual care group for physical activity (mean 0.23 (0.72) *v* 0.08 (0.85); P=0.024), pain level (n=145, mean −1.35 (2.48) *v* n=181, −0.86 (2.59); P=0.03), WOMAC function score (n=144, mean −8.67 (12.05) *v* n=176, −5.44 (12.97); P=0.02), global assessment of disease activity (n=146, mean −1.40 (2.56) *v* n=181, −0.51 (2.59); P<0.001) and SF-12 physical component score (n=129, mean 5.23 (8.18) *v* n=147, 2.97 (7.72); P=0.003).

DISCUSSION

The results from this large, pragmatic, community based cluster randomised controlled trial show that with a programme of standardised consultations given by rheumatologists to patients with osteoarthritis of the knee such patients can reduce their body weight, increase the time they spend on physical activity, and show improved pain level and global measures of disease activity at four months compared with patients given usual care. However, disability at four months did not differ between the groups. At 12 months, the two groups did not differ in self reported weight, but the standardised consultation group showed greater improvement in physical activities, pain level, and function than did the usual care group.

Specific interventions aimed to increase physical activities, decrease weight, or improve patients' education about osteoarthritis have shown efficacy.[33] Exercise has been shown to improve pain and physical function among people with osteoarthritis of the knee.[34-37] However, most studies evaluating the impact of these beneficial non-drug treatments have focused on the efficacy of a single component. The overall success of a healthcare programme is separate from that of its individual components. The main contribution of

WHAT IS ALREADY KNOWN ON THIS TOPIC

Non-drug treatments, including education of patients, social support, physical exercises, and weight loss, are widely recommended for management of osteoarthritis of the knee

However, such non-drug treatments are rarely proposed to patients in clinical practice

The lack of implementation of these guidelines may be linked to difficulties in providing information to patients on all these important matters during a single consultation

WHAT THIS STUDY ADDS

A programme of three goal oriented standardised consultations was useful for patients with osteoarthritis of the knee

This programme led to increased weight loss and physical activity at four months and improved patients' function and pain at four months and at one year

this trial is to propose a global practical way to improve the implementation of counselling about lifestyle changes for patients with osteoarthritis.

Our results have high applicability because we recruited rheumatologists in primary care settings, the inclusion and exclusion criteria were not too stringent, and the intervention, although complex, is easy to reproduce. However, these results occurred in the French healthcare system, in which patients have direct access to rheumatologists, and we cannot exclude that they may be different in other systems of care. In other fields, such interventions are often done by nurses rather than physicians. Nurses could help physicians to do this intervention, although the prime effect of advice from a physician as a catalyst for changing patients' behaviour should not be underestimated.[38]

In trials assessing participative interventions such as education, physiotherapy, and counselling, the risk of contamination is high if physicians do both interventions. One physician cannot counsel one patient to lose weight and take physical exercise and not counsel others in a similar way. Consequently, the use of a cluster randomised controlled trial design avoids contamination. In cluster randomised controlled trials, observations for individual participants in the same cluster tend to be correlated. We controlled for the effect of clusters in the sample size calculation and statistical analyses. Nevertheless, such a trial implies risk of selection bias because, for our trial, we randomised rheumatologists to trial arms before they included patients, and they were consequently aware of the treatment they had to provide to the included patients. Knowledge of assignment could lead to the exclusion of certain patients depending on their prognosis because they could have been allocated to the perceived inappropriate group.[39 40] Therefore, we used propensity scores to deal with potential confounders and imbalance to confirm our results.

A challenge in assessing non-drug treatments is related to difficulties of blinding. To limit the risk of bias, patients were blinded to the study hypothesis (that is, they were not informed of the content of the treatment provided in the other group), as has been proposed in other trials.[41] Furthermore, patients in each arm had the same number of visits. Consequently, the control arm is not really a "usual care" arm, because the follow-up of patients in the usual care and standardised consultation groups differed greatly from the usual care currently provided to patients with osteoarthritis in France. Usually, patients with osteoarthritis visit their rheumatologists every six or 12 months. This modification in visits could favour the usual care group and potentially underestimate the treatment effect. In the same way, the effects of the intervention could have been reduced in part because the percentage of patients in the control group who said they received information about exercise was very high.

In terms of clinical relevance of the modifications we saw, the mean weight reduction at four months was limited (approximately 1 kg). However, some consider that a 1 kg weight loss is associated with a 4 kg reduction in knee load per step.[42] Therefore, for a person who loses 1 kg in weight, each knee would be subjected to 4800 kg less in compressive load for each mile walked (assuming 1.2 strides/mile).[42] In addition, we found no difference in patients' self reported weight loss at one year but a significant improvement in pain and physical function. Such improvement in a large population of patients could have public health implications.[43]

This study has several limitations. Firstly, we did not achieve the expected sample size because of logistic difficulties in recruiting rheumatologists. However, our significant differences and the risk of false positive results are reduced because the standard deviations and intracluster correlation coefficients seen were lower than the values assumed for the sample size calculation. Secondly, the cluster randomised controlled design we chose may have implied baseline differences, which are a particular concern in such trials. The baseline data of patients showed a higher mean weight for the standardised consultation than for the usual care group. To take this into account, we did marginal model analyses adjusted for baseline values, as well as propensity score analysis. Thirdly, we excluded nine randomised patients from the analysis because we did not have any data (even baseline data) for them, which precluded any analysis or adjustment. The fourth limitation is the partial lack of blinding, and we cannot exclude the possibility that subjective outcomes could be influenced despite our attempt to limit the risk of bias by blinding the patients to the study hypothesis.

Conclusions

Our study shows that rheumatologists offering a programme of standardised consultations about non-drug treatment for osteoarthritis of the knee could be useful for patients with osteoarthritis of the knee. Such a programme led to weight loss, increased physical activity, and improved pain after four months and improved patients' physical activity, pain, and function at one year. This programme of standardised consultation should help rheumatologists to follow international guidelines for care of patients with

osteoarthritis of the knee. Further studies in different settings are needed to confirm these results.

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