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Research

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Effectiveness of community physiotherapy and enhanced pharmacy review for knee pain in people aged over 55 presenting to primary care: pragmatic randomised trial

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Abstract

Objectives To evaluate the effectiveness of two primary care strategies for delivering evidence based care to people aged 55 or over with knee pain: enhanced pharmacy review and community physiotherapy.
Design Pragmatic multicentre randomised clinical trial.
Setting 15 general practices in North Staffordshire.
Participants 325 adults aged 55 years or over (mean 68 years) consulting with knee pain; 297 (91%) reached six month follow-up.
Interventions Enhanced pharmacy review (pharmacological management in accordance with an algorithm); community physiotherapy (advice about activity and pacing and an individualised exercise programme); control (advice leaflet reinforced by telephone call).
Main outcome measure Change in Western Ontario and McMaster Universities osteoarthritis index (WOMAC) at 3, 6, and 12 months.
Results Mean baseline WOMAC pain score was 9.1 (SD 3.7), and mean baseline function score was 29.9 (SD 12.8). At three months, the mean reductions in pain scores were 0.41 (SD 2.8) for control, 1.59 (3.2) for pharmacy, and 1.56 (3.4) for physiotherapy; reductions in function scores were 0.80 (8.5), 2.61 (9.8), and 4.79 (10.8). Compared with control, mean differences in change scores for physiotherapy were 1.15 (95% confidence interval 0.2 to 2.1) for pain and 3.99 (1.2 to 6.8) for function; those for pharmacy were 1.18 (0.3 to 2.1) for pain and 1.80 (−0.8 to 4.5) for function. These differences were not sustained to six or 12 months. Significantly fewer participants in the physiotherapy group reported consulting their general practitioner for knee pain in the follow-up period, and use of non-steroidal anti-inflammatory drugs was lower in the physiotherapy and pharmacy groups than in the control group.
Conclusions Evidence based care for older adults with knee pain, delivered by primary care physiotherapists and pharmacists, resulted in short term improvements in health outcomes, reduced use of non-steroidal anti-inflammatory drugs, and high patient satisfaction. Physiotherapy seemed to produce a shift in consultation behaviour away from the traditional general practitioner led model of care.
Trial registration UK National Research Register N0286046917; Current Controlled Trials ISRCTN55376150.

Introduction

Current evidence for the primary care management of knee pain and osteoarthritis supports the use of both pharmacological and non-pharmacological approaches.[1–5] However, the traditional general practitioner led service to deliver such interventions is increasingly unsustainable, and alternative models, using the skills of other members of the primary healthcare team, have been proposed.[6] For older people with knee pain, at least two services have the potential to provide systematic, effective care. Firstly, an enhanced pharmacy review service by community pharmacists could optimise the drug management of knee pain and provide simple self help messages. Secondly, a community physiotherapy service, which promotes self management alongside an exercise based treatment package, might be a practical way of maximising the benefit of non-drug approaches. To date, the value of each of these services in implementing evidence based care packages for patients with knee pain has not been established. We therefore carried out a pragmatic randomised clinical trial to compare the clinical effectiveness, in primary care, of enhanced pharmacy review or community physiotherapy with that of a control intervention (advice leaflet reinforced by a telephone call) in the treatment of adults aged 55 years and over consulting their general practitioner with knee pain.

Methods

Study participants

We recruited participants from 15 general practices in North Staffordshire between May 2001 and March 2004. All adults aged 55 years and over who consulted their general practitioner with pain, stiffness, or both in one or both knees and who were able to give written, informed consent were invited to participate. Exclusion criteria were potentially serious pathology (such as inflammatory arthritis, acute trauma, or malignancy), previous knee replacement, being on the waiting list for knee surgery, physiotherapy for knee problems within the previous three months, or intra-articular injection to the knee in the previous six months.

We used two methods of recruitment: direct referral from general practitioners and retrospective review of records. We asked general practitioners, during a consultation for knee pain and aided by a prompt appearing on their computer screen when a knee pain related Read code was entered, to explain the trial to potential participants and give them a study information leaflet. After giving written consent for further contact,

participants were registered with the research centre by fax and telephoned by the study nurse to arrange a home visit. For the retrospective review of records, we did a monthly audit of each practice's computerised records to identify potential participants not recruited by the direct referral method. One general practitioner from each practice screened lists of potential participants, identified by Read codes, to identify those considered to be eligible. We posted an introductory letter and a study information leaflet to these patients, inviting them to return written consent for the study nurse to telephone them to arrange a home visit. For both methods of recruitment, the study nurse arranged a home visit within 10 working days of registration to gain written informed consent to randomisation and do a baseline assessment.

Procedures

We used a computerised random number generator to produce a pre-determined random allocation sequence, in blocks of six by general practice. We assigned each participant a unique study number, which corresponded with that on a sealed opaque envelope that contained information about participants' allocated treatment and was issued to the participant by the study nurse. To maintain blinding of the nurse, participants were instructed not to open the envelope in her presence. Follow-up was at 3, 6, and 12 months by postal questionnaire. Study nurses and researchers who collected, entered, and analysed data were unaware of treatment allocation. By necessity, participants and the health professionals delivering the interventions were not blind to allocation. We randomly assigned participants to enhanced pharmacy review, community physiotherapy, or standard advice and information reinforced by one telephone call.

Interventions

We gave each participant an information leaflet modelled on the Arthritis Research Campaign leaflet on knee osteoarthritis (www.arc.org.uk). Key messages included that knee pain is common and does not usually lead to severe disability; that individual patients can do a lot to help themselves; and that it is important to stay active and to pace activities throughout the day, to set realistic goals, and to maintain mobility in the knee joint. The leaflet provided advice about pain control and simple exercises. In addition, general practitioners were able to provide advice on analgesia to all patients. Each of the following interventions was delivered according to a written study protocol.

Enhanced pharmacy review—The aims of this intervention were to optimise pharmacological pain control and to reinforce self help messages contained in the advice leaflet. An experienced community pharmacist (MP) provided this service in general practice surgeries with access to patients' medical records; it was modelled on the "dependent prescriber" role outlined in the

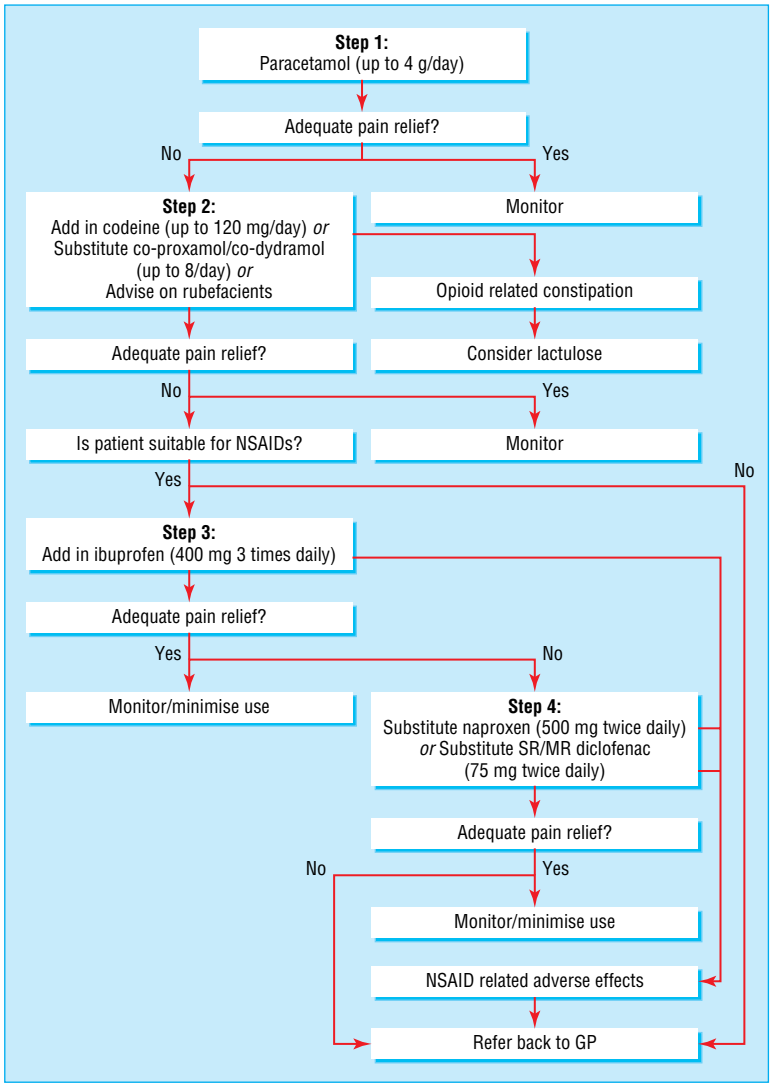

Fig 1 Pharmacy algorithm. GP=general practitioner; NSAID=non-steroidal anti-inflammatory drug; SR/MR=sustained/modified release

Crown Report.[7] MP used a pre-defined set of questions to do an initial assessment of the participants' pain control and drugs. He used standard risk factors to assess the participant's risk of adverse events from non-steroidal anti-inflammatory drugs. He changed participants' drugs according to a pre-defined algorithm (fig 1), taking into account their preferences, adherence, and potential drug interactions. The protocol permitted three to six sessions of approximately 20 minutes' duration over a 10 week period. In follow-up visits, MP monitored the effectiveness and acceptability of drugs and recommended changes as necessary. He recorded all treatment in a standardised format.

Community physiotherapy—The aim of this intervention was to encourage patients to engage in an active approach to managing knee pain through education about the safety and importance of exercise, pacing, pain relief, and coping strategies and an individualised exercise programme. Nineteen experienced musculoskeletal community physiotherapists delivered the intervention. They selected exercises from an agreed list from the computer software package PhysioTools (www.physiotools.net), including general aerobic exercise and specific muscle strengthening exercises (non-weight bearing and weight bearing) and stretching exercises to be done during treatment sessions and at home. The therapists increased the intensity of exercise in follow-up visits. The protocol permitted three to six sessions of approximately 20 minutes' duration over a 10 week period. Hydrotherapy, group based sessions, acupuncture, and intra-articular injections were not permitted. Therapists recorded all treatment in a standardised format.

Control intervention (information and advice leaflet)—Participants in the control group received the same advice and information leaflet as the other groups. It was reinforced by one telephone call from a rheumatology nurse within seven days of randomisation.

The primary outcome measures were change at 3, 6, and 12 months after randomisation in the pain and physical function subscale scores of the Western Ontario and McMaster Universities osteoarthritis index (WOMAC).[8] The psychometric properties of the WOMAC have been extensively studied in populations with knee pain in both clinical trials and postal surveys.[9–15] Secondary outcome measures included participants' global assessment of change compared with baseline (five point ordinal scale), severity of pain over the previous seven days (0-10 numerical rating scale), severity rating of patient nominated main functional problem[16] over the previous three days (0-10 numerical rating scale), participants' self efficacy (arthritis self-efficacy scale[17]), and psychological distress (hospital anxiety and depression scale[18]). At each follow-up point, we recorded participants' perceptions about the usefulness of their treatment (simple categorical data). We also recorded side effects of treatment, adverse events, and use of co-interventions (self reported consultation with the general practitioner or other health professional for knee pain; drug use).

We applied the guidelines suggested by the Outcome Measures in Rheumatology-Osteoarthritis Research Society International (OMERACT-OARSI) initiative for defining clinically significant responder criteria[19 20] to the relevant data (WOMAC pain and function scores and participants' global assessment of

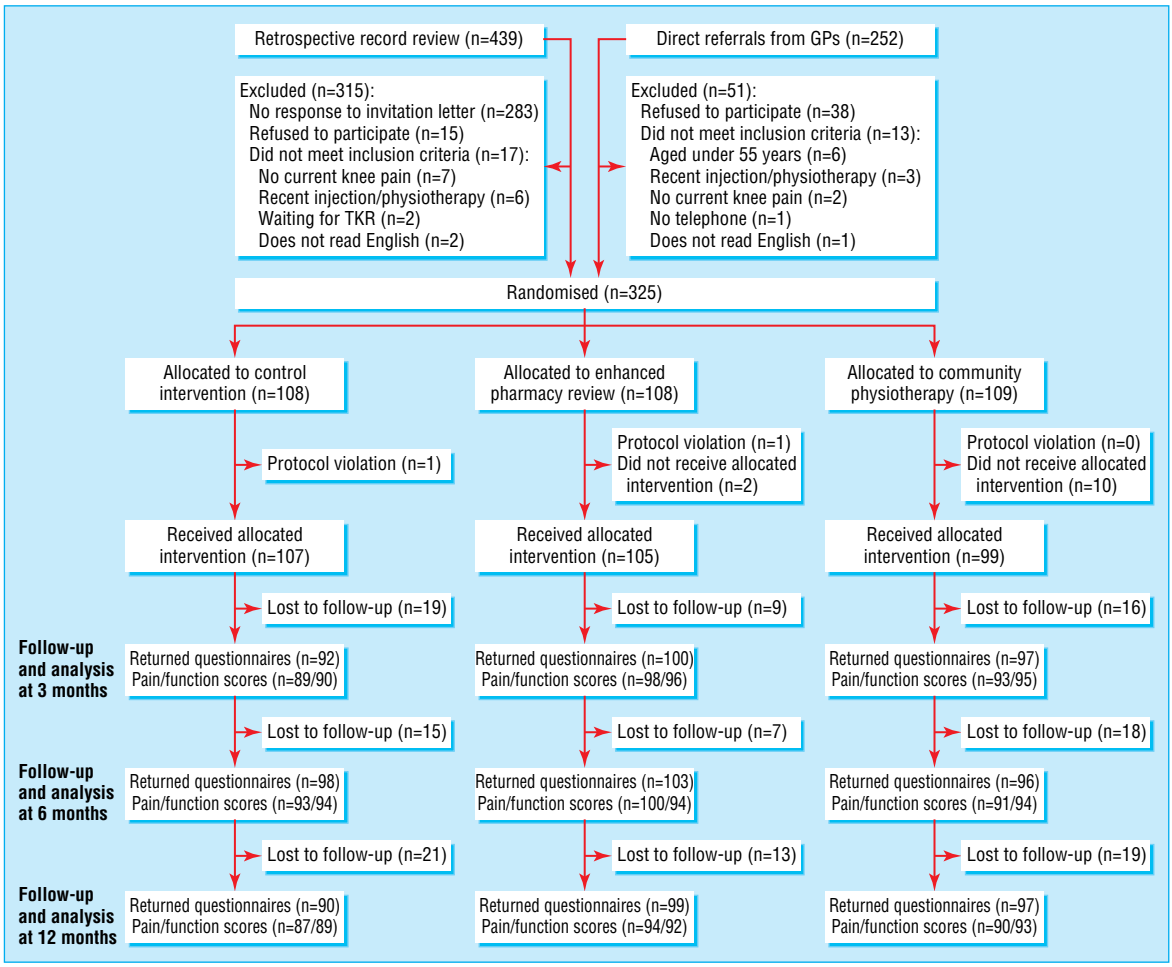

Fig 2 Trial profile. GP=general practitioner; TKR=total knee replacement

Table 1 Baseline characteristics of participants, by treatment group. Values are numbers (percentages) unless stated otherwise

Characteristics	Control intervention (n=108)	Enhanced pharmacy review (n=108)	Community physiotherapy (n=109)
Demography			
Mean (SD) age (years)	68.2 (8.0)	67.9 (8.2)	67.9 (8.5)
Female	70 (65)	68 (63)	71 (65)
Body mass index:	(n=106)	(n=106)	(n=108)
Underweight/normal (<25.0)	20 (19)	23 (22)	27 (25)
Overweight (25.0-29.9)	43 (41)	51 (48)	53 (49)
Obese (>29.9)	43 (41)	32 (30)	28 (26)
Socioeconomic classification:	(n=105)	(n=105)	(n=107)
Higher managerial/professional	3 (3)	6 (6)	7 (7)
Lower managerial/professional	16 (15)	12 (11)	15 (14)
Intermediate occupations	11 (10)	18 (17)	16 (15)
Self employed	10 (10)	14 (13)	11 (10)
Lower supervisory/technical	7 (7)	12 (11)	4 (7)
Semiroutine occupations	27 (26)	20 (19)	25 (23)
Routine occupations	31 (30)	23 (22)	29 (27)
Currently employed	20 (19)	23 (21)	22 (20)
Knee pain and function			
Mean (SD) WOMAC pain score (0-20)	9.2 (3.3)	9.1 (3.5)	9.1 (4.1)
Mean (SD) WOMAC function score (0-68)	30.6 (12.0)	29.2 (12.1)	30.0 (14.1)
Duration of pain >3 months	91 (84)	78 (72)	85 (78)
Mean (SD) pain severity in previous 7 days (NRS)	6.0 (2.3)	6.0 (2.2)	5.8 (2.3)
Mean (SD) severity of main problem (NRS)	6.1 (2.1)	6.0 (2.3)	6.3 (2.4)
Mean (SD) ASE, pain (5-50)	24.8 (8.8)	26.1 (10.1)	25.6 (9.6)
Mean (SD) ASE, other symptoms (6-60)	34.1 (12.3)	34.3 (12.2)	34.0 (12.3)
Knee injury in previous 6 months	9/107 (8)	10 (9)	14 (13)
Used drugs:			
Non-steroidal anti-inflammatory drugs	37 (34)	39 (36)	40 (37)
Analgesics	55 (51)	69 (64)	56 (51)

ASE=arthritis self-efficacy scale; NRS=numerical rating scale (0-10); WOMAC=Western Ontario and McMaster Universities osteoarthritis index.

change) collected at follow-ups to define a group of "responders."

Statistical analysis

We used the pain and function subscales of the WOMAC, at six months, for the power calculation. We based this on expected changes in pain and physical function scores of 20% between the experimental treatments and the control group, assuming that pain and physical function scores may improve by 5% in the control group.[21] On the basis of previously published data,[12 13] a minimum of 270 participants with post-randomisation outcome data at six months would be sufficient to detect these effects with 80% power and at a 5% significance level (two tailed). We therefore recruited a total of 325 participants into the study to allow for a 20% loss to follow-up at six months.

Analysis was by intention to treat. We calculated estimates of the treatment effects (control intervention minus active treatment group) with 95% confidence intervals and used *t* tests for numerical data, χ^2 tests for nominal data, and χ^2 test for trend for ordinal data for the primary and secondary outcome measures. We did two exploratory sensitivity analyses of the mean WOMAC scores. Firstly, we did analysis of covariance by using multiple linear regression with adjustment for covariates, selected according to random differences in baseline characteristics. Secondly, we did an on-treatment analysis by restricting the comparison to participants who received their allocated treatment per protocol (defined as at least one session with either a physiotherapist or pharmacist). We assessed external validity in three ways. We compared the demographic characteristics of patients obtained through direct referral from general practitioners who were not randomised in the trial with those of trial participants. Within trial participants, we made comparisons of recruitment characteristics and treatment allocation across high and low recruiting practices and participants recruited through direct referrals and review of records.

We used Stata version 7.0 for statistical analyses. We set statistical significance at the 5% level (two tailed). An independent steering and data monitoring committee monitored the trial. We did no interim analyses during the study period.

Results

General practitioners directly referred 252 patients, of whom we randomised 201 (80%) (fig 2); 13 (5%) were not eligible, and 38 (15%) did not consent. The age and sex of these last 51 patients was similar to those randomised to the trial (mean age 67 years, 65% female). In addition, we sent letters of invitation to 439 patients after the review of records: 156 responded, of whom 124 (79%) were randomised, 17 (11%) were not eligible, and 15 (10%) did not consent. Treatment allocation and baseline characteristics were similar between participants recruited directly and those recruited by record review, although the second group were less likely to report knee pain of less than three months' duration.

We randomised 325 participants to the trial: 108 to pharmacy, 109 to physiotherapy, and 108 to control. Numbers of randomised participants ranged from 1 to 88 patients per general practice. Table 1 shows the baseline characteristics of randomised participants (mean age 68 (range 55-92) years, 64% female). Recruitment characteristics were similar between treatment groups. Treatment allocation and recruitment characteristics were similar between the highest (31 or more patients recruited) and lowest (up to 30 patients recruited) recruiting practices, although patients in the lower recruiting practices were more likely to have less than three months' duration of symptoms and had higher average WOMAC pain and physical function scores. Response to follow-up questionnaires at six months was 91% (n=98) for the control group, 95% (103) for the pharmacy group, and 88% (96) for the physiotherapy group. Those lost to follow-up at six months were more likely to be male (39% (11/28) *v* 35% (105/297)), be older (mean age 69.9 *v* 67.9 years), and have higher baseline WOMAC pain and function scores (pain 9.75 *v* 9.08; function 32.8 *v* 29.7) than those who completed follow-up. Concealment of treatment from the study nurse was effective: treatment allocation was revealed to the nurse by 15 of 325 participants (seven in the control intervention and four in each treatment arm).

Treatments were in line with the study protocols, and no serious adverse events were reported. In the control arm, 103 participants were contacted by telephone and one protocol violation occurred. In the pharmacy arm, 105 attended for their intervention, of whom 101 (96%) had three or more intervention sessions (median 3, range 1-5), and one protocol violation occurred. A 70% increase in the prescribing of simple and compound analgesics occurred and a 52% reduction in the prescribing of non-steroidal anti-inflammatory drugs; 104 (99%) participants received advice reinforcing the advice leaflet. Ninety nine of 109 participants randomised to physiotherapy attended for at least one session; 83 (84%) had three or more sessions (median 4, range 1-6), 97 received a home exercise programme, and 92 received advice and information. Smaller numbers had at least one session of pain reducing modalities.

Table 2 WOMAC pain and function scores at 3, 6, and 12 months' follow-up. Values are mean (SD) unless stated otherwise

	Control intervention scores	Enhanced pharmacy review			Community physiotherapy		
		Scores	Mean difference (95% CI)*	P value†	Scores	Mean difference (95% CI)*	P value†
WOMAC pain							
3 months:	(n=89)	(n=98)			(n=93)		
Absolute score	8.99 (3.7)	7.49 (4.0)			7.36 (4.3)		
Crude change score‡	0.41 (2.8)	1.59 (3.2)	1.18 (0.3 to 2.1)	0.006	1.56 (3.4)	1.15 (0.2 to 2.1)	0.008
Adjusted change score§			1.18 (0.3 to 2.0)			1.19 (0.3 to 2.1)	
6 months:	(n=93)	(n=100)			(n=91)		
Absolute score	8.36 (3.9)	7.59 (4.1)			7.51 (4.8)		
Crude change score‡	1.05 (3.4)	1.46 (3.5)	0.41 (–0.6 to 1.4)	0.4	1.19 (3.9)	0.14 (–0.9 to 1.2)	0.7
Adjusted change score§			0.36 (–0.6 to 1.3)			0.23 (–0.8 to 1.2)	
12 months:	(n=87)	(n=94)			(n=90)		
Absolute score	8.49 (4.5)	7.60 (4.5)			7.41 (4.4)		
Crude change score‡	0.74 (4.1)	1.37 (3.9)	0.63 (–0.5 to 1.8)	0.3	1.19 (4.2)	0.45 (–0.8 to 1.7)	0.3
Adjusted change score§			0.55 (–0.6 to 1.7)			0.59 (–0.5 to 1.7)	
WOMAC function							
3 months:	(n=90)	(n=96)			(n=95)		
Absolute score	30.18 (12.8)	25.73 (13.4)			24.27 (15.2)		
Crude change score‡	0.80 (8.5)	2.61 (9.8)	1.80 (–0.8 to 4.5)	0.1	4.79 (10.8)	3.99 (1.2 to 6.8)	0.008
Adjusted change score§			2.12 (–0.5 to 4.8)			3.65 (1.0 to 6.3)	
6 months:	(n=94)	(n=94)			(n=94)		
Absolute score	28.15 (13.2)	26.82 (13.4)			25.49 (16.3)		
Crude change score‡	2.74 (10.5)	1.52 (11.4)	–1.23 (–4.4 to 1.9)	0.5	3.34 (12.2)	0.59 (–2.7 to 3.9)	0.7
Adjusted change score§			–0.96 (–4.0 to 2.1)			0.66 (–2.5 to 3.8)	
12 months:	(n=89)	(n=92)			(n=93)		
Absolute score	28.95 (14.4)	27.14 (14.6)			24.83 (15.3)		
Crude change score‡	1.65 (12.3)	1.15 (11.7)	–0.49 (–4.0 to 3.0)	0.8	4.00 (13.2)	2.35 (–1.4 to 6.1)	0.2
Adjusted change score§			–0.39 (–3.8 to 3.0)			2.41 (–1.1 to 5.9)	

WOMAC=Western Ontario and McMaster Universities osteoarthritis index.
*Difference in mean scores (control – active treatment).
†Derived from adjusted regression analysis.
‡Change in score from baseline.
§Mean difference adjusted for age, sex, baseline WOMAC pain/function score, and baseline duration of pain.

Primary outcome

At three months, significant improvements in WOMAC pain and function scores occurred in the physiotherapy group, and in pain scores in the pharmacy group, when we compared each intervention separately with control. The significant differences persisted after adjustment for sex, age, and baseline WOMAC scores and duration of pain.

No statistically significant differences existed in mean WOMAC change scores between the control group and the pharmacy or physiotherapy groups at six and 12 months (table 2). Figure 3 illustrates the changes in the WOMAC pain and function scores during the whole follow-up period. We found similar results when we did the sensitivity analysis.

Secondary outcomes

Table 3 shows participants' perceived global assessment of change in their knee problem compared with baseline. More of the pharmacy and physiotherapy groups, compared with the control group, were classified as responders according to the OMERACT-OARSI criteria at each of the three follow-up points, but the difference was statistically significant only at three months. Table 4 shows data on other secondary outcome measures.

Co-interventions

A higher proportion of participants in the control group than in the physiotherapy group reported consulting their general practitioner for knee pain during the six month follow-up (table 5). Self reported use of non-steroidal anti-inflammatory drugs and simple analgesia in the six month post-randomisation period was significantly lower in the physiotherapy group than in the control group (–15%, 95% confidence interval –2% to –28%; and –16%, –3% to –29%). In the pharmacy group, use of non-steroidal anti-inflammatory drugs was significantly lower than

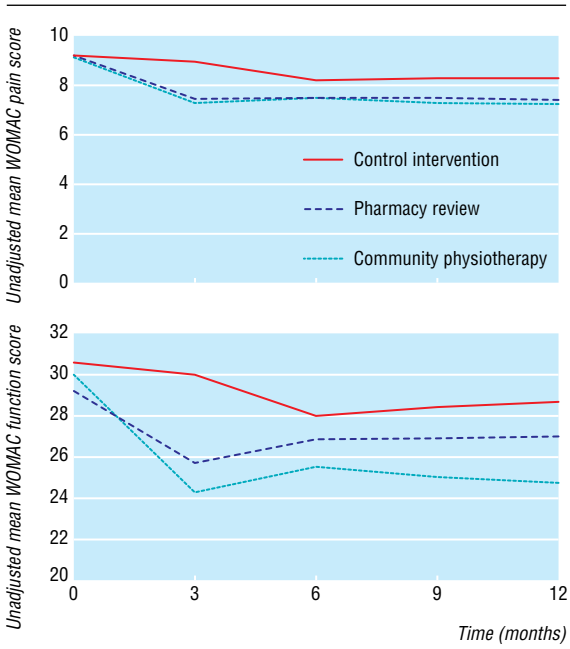

Fig 3 Mean Western Ontario and McMaster Universities osteoarthritis index (WOMAC) scores at recruitment and at 3, 6, and 12 months' follow-up. Top: WOMAC pain scores. Bottom: WOMAC function scores

Table 3 Global assessment of overall change and OMERACT-OARSI response*. Values are numbers (percentages)

	Control intervention global assessment	Enhanced pharmacy review		Community physiotherapy	
		Global assessment	P value†	Global assessment	P value†
Global assessment					
3 months:	(n=91)	(n=98)		(n=94)	
Much better	7 (8)	19 (19)		19 (20)	
Better	19 (21)	31 (32)		31 (33)	
Same	42 (46)	36 (37)	0.0002	37 (39)	<0.0001
Worse	18 (20)	12 (12)		7 (7)	
Much worse	5 (6)	0		0	
6 months:	(n=93)	(n=99)		(n=91)	
Much better	13 (14)	10 (10)		18 (20)	
Better	15 (16)	37 (37)		26 (29)	
Same	46 (49)	44 (44)	0.03	31 (34)	0.09
Worse	17 (18)	8 (8)		13 (14)	
Much worse	2 (2)	0		3 (3)	
12 months:	(n=89)	(n=94)		(n=94)	
Much better	11 (13)	13 (14)		15 (16)	
Better	11 (13)	19 (20)		13 (13)	
Same	39 (43)	37 (39)	0.2	44 (47)	0.2
Worse	22 (25)	21 (22)		20 (21)	
Much worse	6 (7)	4 (4)		2 (2)	
OMERACT-OARSI response					
3 months:					
High/improvement	6/11	18/14	0.04	19/18	0.003
Total response	17/89 (19)	32/97 (33)		37/93 (40)	
6 months:					
High/improvement	8/16	17/18	0.2	23/11	0.1
Total response	24/92 (26)	35/100 (35)		34/92 (37)	
12 months:					
High/improvement	13/11	15/10	0.8	21/11	0.3
Total response	24/86 (28)	25/93 (27)		32/89 (36)	

*Criteria suggested by the Outcome Measures in Rheumatology-Osteoarthritis Research Society International (OMERACT-OARSI) initiative for defining clinically significant response.[19 20]

†χ^2 test for trend for global assessment and χ^2 test for OMERACT-OARSI response.

for controls (−16%, −3% to −29%), but use of simple analgesia was significantly higher (15%, 0% to 28%).

Discussion

Our findings support the feasibility, acceptability, and short term clinical effectiveness of community physiotherapy and enhanced pharmacy review in the management of people aged over 55 with knee pain. Statistically significant improvements in pain scores occurred in participants allocated to enhanced pharmacy review or community physiotherapy and in function scores in those allocated to physiotherapy at three months compared with controls. These differences were not sustained to six or 12 months. To evaluate the clinical significance of the size of the differences, we applied the response criteria suggested by the OMERACT-OARSI group.[19 20] According to these rather stringent criteria, a substantially and statistically significant higher proportion of the physiotherapy group (40%) and pharmacy group (33%) than the control group (19%) were classified as responders at three months.

Effects on drug use and general practice consultations

One consistent finding, with important clinical implications, was that prescribing of non-steroidal anti-inflammatory drugs was reduced in both pharmacy and physiotherapy groups compared with control. At six months, use of non-steroidal anti-inflammatory drugs was 16% lower in the pharmacy group and 15% lower in the physiotherapy group than in the control group, with no increase in reporting of pain and high levels of patient satisfaction. This has important safety implications. Non-steroidal anti-inflammatory drugs are the most common cause of iatrogenic disease and are not recommended for long term use, particularly in elderly people, in whom the risk of complications is high. Recalled consultation with general practitioners for knee pain was significantly lower in the six month period after the physiotherapy intervention than after the control intervention.

Strengths of the trial

Importantly, this pragmatic study evaluated two approaches to delivering evidence based care for patients with knee pain (pharmacy and physiotherapy)—it did not investigate the efficacy of specific modalities (tablets and exercise). Our trial had high internal validity, shown by adequate recruitment, concealed randomisation, high follow-up rates, and effective blinding of the research team. Experienced practitioners delivered the interventions, in accordance with standardised study protocols designed to reflect evidence based practice while retaining sufficient flexibility to ensure that the therapists could develop individualised treatment plans to reflect clinical need. We deliberately chose not to restrict our trial to people with radiographically diagnosed osteoarthritis in order to reflect current clinical practice, in which treatment choices for people with knee pain seeking health care are made on the basis of presenting symptoms rather than radiographic changes.

Recruitment rate varied considerably across general practices; a single practice recruited a quarter of the study population. We found no evidence that this adversely affected the external validity of the trial or diminished the generalisability of the "usual" care given in the trial. For example, baseline use of non-steroidal anti-inflammatory drugs (a proxy measure of general practitioners' behaviour) was similar in high and low recruiting practices.

Limitations

One potential weakness of our trial is the lack of information about patients' adherence to treatment, which is likely to be an important determinant of clinical outcome.[22 23] We measured adherence in a limited fashion by the number of sessions attended rather than the actual level of ongoing participation in, for example, home exercises in the physiotherapy group or numbers of tablets taken in the pharmacy group. Adherence may have decreased over time, as has been shown in other studies,[22] and this may be one explanation for the lack of a long term superior clinical effect of the pharmacy and physiotherapy interventions over control in our trial. A further explanation may lie in the "dosage" of our interventions. The interventions were based on recommendations from international guidelines for the management of osteoarthritis of the knee.[24 25] The exact content was drawn up in collaboration with general practitioners, pharmacists, and physiotherapists to reflect current UK primary care practice and was agreed with the treating clinicians in two workshops before the trial began. Although the protocols permitted up to six sessions with a physiotherapist or pharmacist, the interventions were actually delivered in fewer sessions (equating to a median of 53 minutes of contact time in the pharmacy group and 80 minutes in the physiotherapy group). More intensive initial treatment[26] or systematic approaches to follow-up, including "top-up" treatments or open access to practitioners to manage flares of symptoms, might have improved long term outcomes.

Table 4 Secondary outcome measures at 3, 6, and 12 months' follow-up, by treatment

End point	Control intervention measurement	Enhanced pharmacy review			Community physiotherapy		
		Measurement	Difference* (95% CI)	P value†	Measurement	Difference* (95% CI)	P value†
Knee pain and function (mean (SD))							
Change in pain severity‡ (numerical rating scale):							
3 months	0.54 (2.2)	1.34 (2.5)	−0.72 (−1.4 to −0.1)	0.04	1.40 (2.3)	−0.84 (−1.5 to −0.2)	0.01
6 months	0.84 (2.5)	1.37 (2.4)	−0.41 (−1.1 to 0.3)	0.3	1.22 (2.4)	−0.34 (−1.1 to 0.4)	0.4
12 months	0.80 (2.8)	1.25 (2.8)	−0.32 (−1.2 to 0.5)	0.5	0.58 (2.8)	0.01 (−0.8 to 0.9)	0.9
Change in severity of main problem‡ (numerical rating scale):							
3 months	0.03 (2.2)	0.50 (2.5)	−0.46 (−1.2 to 0.3)	0.2	1.20 (2.7)	−1.06 (−1.8 to −0.3)	0.005
6 months	0.00 (2.3)	0.48 (2.5)	−0.39 (−1.1 to 0.3)	0.3	1.31 (3.0)	−1.22 (−2.0 to −0.4)	0.002
12 months	0.29 (2.7)	0.34 (3.1)	−0.01 (−0.9 to 0.9)	0.9	0.70 (3.3)	−0.40 (−1.3 to 0.5)	0.4
Psychological measures (mean (SD))							
Change in arthritis self-efficacy scale, pain‡:							
3 months	−1.87 (9.9)	−1.16 (9.5)	−0.88 (−3.8 to 2.0)	0.6	−4.62 (9.5)	2.67 (−0.3 to 5.6)	0.07
6 months	−1.91 (9.1)	−1.25 (9.6)	−1.08 (−3.9 to 1.7)	0.4	−3.24 (12.5)	1.29 (−2.1 to 4.6)	0.5
12 months	−3.20 (10.1)	0.38 (10.5)	−3.58 (−6.7 to −0.4)	0.03	−4.38 (12.7)	1.31 (−2.3 to 4.9)	0.5
Change in arthritis self-efficacy scale, other symptoms‡:							
3 months	−1.47 (12.3)	−2.03 (9.9)	0.53 (−2.8 to 3.8)	0.8	−4.33 (10.3)	2.55 (−0.7 to 5.8)	0.1
6 months	−2.15 (10.4)	−1.87 (10.2)	−1.30 (−4.3 to 1.7)	0.4	−3.42 (13.4)	1.30 (−2.3 to 4.9)	0.5
12 months	−3.31 (12.6)	−0.24 (12.7)	−3.44 (−7.3 to 0.5)	0.08	−4.49 (13.7)	1.48 (−2.5 to 5.4)	0.5
Change in hospital anxiety and depression scale, depression‡:							
3 months	−0.28 (2.0)	0.22 (2.2)	−0.55 (−1.2 to 0.1)	0.08	0.14 (2.0)	−0.40 (−1.0 to 0.2)	0.2
6 months	−0.32 (2.3)	0.18 (2.2)	−0.46 (−1.1 to 0.2)	0.2	0.10 (2.8)	−0.37 (−1.1 to 0.4)	0.3
12 months	−0.24 (2.2)	−0.27 (2.1)	0.01 (−0.7 to 0.7)	0.9	0.02 (2.8)	−0.27 (−1.1 to 0.5)	0.5
Change in hospital anxiety and depression scale, anxiety‡:							
3 months	−0.17 (2.5)	0.22 (2.6)	−0.46 (−1.2 to 0.3)	0.2	0.59 (2.6)	−0.66 (−1.4 to 0.01)	0.09
6 months	0.24 (2.5)	0.15 (2.6)	0.10 (−0.6 to 0.8)	0.8	0.81 (3.1)	−0.53 (−1.4 to 0.3)	0.2
12 months	−0.28 (2.8)	0.05 (2.8)	−0.23 (−1.1 to 0.6)	0.6	0.50 (2.9)	−0.69 (−1.5 to 0.2)	0.1
Treatment usefulness and satisfaction (No (%))							
Treatment useful for reducing knee pain:							
3 months	27/89 (30)	45/97 (46)	−16% (−29 to −2)	0.02	57/90 (63)	−33% (−46 to −19)	<0.0001
6 months	22/89 (23)	37/93 (40)	−17% (−29 to −3)	0.02	47/87 (54)	−31% (−43 to −16)	<0.0001
12 months	19/82 (23)	36/91 (40)	−17% (−30 to −3)	0.02	43/93 (46)	−23% (−36 to −9)	0.001
Treatment useful for helping to return to usual activities:							
3 months	20/87 (23)	38/96 (40)	−17% (−29 to −3)	0.01	45/90 (50)	−27% (−40 to −13)	<0.0001
6 months	21/89 (24)	30/94 (32)	−8% (−21 to 5)	0.2	40/87 (46)	−22% (−35 to −8)	0.002
12 months	18/78 (23)	29/91 (32)	−9% (−22 to 4)	0.2	35/90 (39)	−16% (−29 to −2)	0.03
Treatment useful in giving practical advice:							
3 months	46/88 (52)	71/96 (74)	−22% (−34 to −8)	0.002	77/90 (86)	−33% (−45 to −20)	<0.0001
6 months	46/88 (52)	62/94 (66)	−14% (−27 to 0.1)	0.06	69/85 (81)	−29% (−41 to −15)	<0.0001
12 months	29/80 (35)	55/91 (60)	−24% (−38 to −9)	0.002	59/90 (66)	−29% (−43 to −14)	<0.0001
Satisfied with received treatment:							
3 months	41/88 (46)	64/96 (67)	−20% (−33 to −6)	0.006	67/90 (74)	−28% (−47 to −14)	<0.0001
6 months	37/86 (42)	53/93 (57)	−14% (−28 to 1)	0.06	60/86 (70)	−27% (−40 to −12)	<0.0001
12 months	27/82 (33)	47/91 (52)	−19% (−32 to −4)	0.01	51/91 (56)	−23% (−37 to −8)	0.002

*Difference (control – active treatment): derived from adjusted regression (age, sex, baseline WOMAC pain/function score, and baseline duration of pain) for numerical outcomes.
†Derived from adjusted regression analysis for numerical outcomes and χ^2 test for categorical outcomes.
‡Change in scores from baseline.

Implications for practice

Physiotherapists working in community settings are ideally placed to deliver a package of care that incorporates self help messages into an exercise based treatment programme and to shift the management of chronic musculoskeletal problems away from the general practitioner.[27] Although exercise based interventions have shown beneficial effects for older adults with knee pain, effect sizes are small, at best, and are short lived.[28] Similarly, community pharmacists in the United Kingdom have been linked with a new role as "supplementary prescribers,"[7] which allows them to review and, if necessary, prescribe certain drugs within an agreed clinical management plan for patients whose condition has been assessed by an independent prescriber (such as the general practitioner). Interventions by pharmacists have been shown to favourably influence prescribing to reduce adverse drug reactions, improve the appropriateness of drug use, reduce drug costs, and improve compliance in a range of conditions.[29–34] Our trial adds to this evidence by showing that evidence based care for adults over 55 with knee pain, delivered by primary care pharmacists and physiotherapists, results in short term improvements in health outcome, reduction in use of non-steroidal anti-inflammatory drugs, and high patient satisfaction. Community physiotherapy also seemed to effect a long term shift in consultation behaviour away from the traditional general practitioner led model of care. The challenge posed by these results is to investigate how the early clinical benefits seen might be enhanced in the longer term and whether potential reductions in use of health care make these interventions cost effective as first line primary care management strategies.

Table 5 Self reported consultations with healthcare practitioners and drug use at six month follow-up. Values are numbers (percentages) unless stated otherwise

	Control intervention co-interventions (n=100)	Enhanced pharmacy review (n=104)			Community physiotherapy (n=101)		
		Co-interventions	Difference (%) (95% CI)	P value	Co-interventions	Difference (%) (95% CI)	P value
Consulted with healthcare practitioner							
General practitioner	25 (25)	21 (20)	5 (–7 to 16)	0.4	10 (10)	15 (5 to 25)	0.005
Osteopath	2 (2)	0	2 (–2 to 7)	0.2	0	2 (–2 to 7)	0.2
Chiropractor	1 (1)	1 (1)	0 (–4 to 5)	1.0	0	1 (–3 to 6)	0.3
Pharmacist*	3 (3)	1 (1)	2 (–3 to 8)	0.3	0)	3 (–1 to 9)	0.08
Rheumatologist	5 (5)	1 (1)	4 (–1 to 10)	0.09	1 (1)	4 (–1 to 10)	0.1
Physiotherapist*	8 (8)	4 (4)	4 (–3 to 12)	0.2	0	8 (3 to 15)	0.004
Orthopaedic consultant	5 (5)	3 (3)	2 (–4 to 9)	0.4	3 (3)	2 (–4 to 9)	0.5
Acupuncturist	4 (4)	0	4 (0 to 10)	0.04	1 (1)	3 (–2 to 9)	0.2
Used drugs							
Non-steroidal anti-inflammatory drugs	44 (44)	29 (28)	16 (3 to 29)	0.02	29 (29)	15 (2 to 28)	0.02
Analgesics	58 (58)	76 (73)	–15 (–28 to 0)	0.02	42 (42)	16 (3 to 29)	0.02

*Contacts do not include those as part of trial interventions.

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What is already known on this topic

Current guidelines for the primary care management of knee pain and osteoarthritis emphasise the importance of non-pharmacological approaches such as education and exercise

The traditional general practitioner led service to deliver evidence based interventions is increasingly unsustainable, and alternative models are needed

What this study adds

Enhanced pharmacy review and community physiotherapy resulted in short term, clinically significant improvements compared with control in people aged 55 or over with knee pain

Both interventions were associated with high patient satisfaction and resulted in a substantial reduction in use of non-steroidal anti-inflammatory drugs

Community physiotherapy effected a shift in care away from the traditional general practitioner led model

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