

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

The traditional general practitioner led service to deliver interventions for management of knee pain is increasingly unsustainable.¹ For older people with knee

pain, 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. Secondly, a community physiotherapy service could promote self management alongside an exercise based treatment package. The value of each of these services has not yet been established. We carried out a pragmatic randomised clinical trial to compare the clinical effectiveness of enhanced pharmacy review or community physiotherapy with that of a control intervention in the primary care treatment of knee pain in adults aged 55 years and over.

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 were invited to participate. We used two methods of recruitment: direct referral from general practitioners and retrospective review of records.

Procedures

Follow-up was at 3, 6, and 12 months by postal questionnaire. Study nurses and researchers were blinded to treatment allocation. 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). The leaflet provided advice about pain control and simple exercises. In addition, general practitioners were able to provide advice on analgesia.

Enhanced pharmacy review—The aims were to optimise pharmacological pain control and to reinforce self help messages contained in the advice leaflet. An experienced community pharmacist provided this service in general practice surgeries with access to patients' medical records.² The pharmacist made an initial assessment of the participants' pain control and drugs. He changed participants' drugs according to a pre-defined algorithm. The protocol

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BMJ 2006;333:995–8



This is the abridged version of an article that was posted on bmj.com on 20 October 2006: <http://bmj.com/cgi/doi/10.1136/bmj.38977.590752.0B>

Table 1 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.

permitted three to six sessions of approximately 20 minutes' duration over a 10 week period.

Community physiotherapy—Nineteen experienced musculoskeletal community physiotherapists delivered the intervention. They selected exercises including general aerobic exercise and specific muscle strengthening and stretching exercises to be done during treatment sessions and at home. The protocol permitted three to six sessions of approximately 20 minutes' duration over a 10 week period.

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.

Outcome measures—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).³ Secondary outcome measures included participants' global assessment of change compared with baseline, severity of pain over the previous seven days, severity rating of patient nominated main functional problem⁴ over the previous three days, participants' self efficacy,⁵ and psychological distress.⁶ We applied the guidelines suggested by the Outcome Measures in Rheumatology-Osteoarthritis Research Society International (OMERACT-OARSI) initiative for defining clinically significant responder criteria.^{7, 8}

Statistical analysis

Analysis was by intention to treat. We calculated estimates of the treatment effects. We assessed external validity (see bmj.com).

Results

General practitioners directly referred 252 patients, of whom we randomised 201 (80%); 13 (5%) were not eligible, and 38 (15%) did not consent. 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. We randomised 325 participants to the trial: 108 to pharmacy, 109 to physiotherapy, and 108 to control (mean age 68 (range 55-92) years, 64% female). Recruitment characteristics were similar between treatment groups. 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.

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

Table 2 Global assessment of overall change and OMERACT-OARSI response*. Values are numbers (percentages)

Global assessment	Control intervention global assessment	Enhanced pharmacy review		Community physiotherapy	
		Global assessment	P value†	Global assessment	P value†
3 months:	(n=91)	(n=98)		(n=94)	
Much better	7 (8)	19 (19)	0.0002	19 (20)	<0.0001
Better	19 (21)	31 (32)		31 (33)	
Same	42 (46)	36 (37)		37 (39)	
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)	0.03	18 (20)	0.09
Better	15 (16)	37 (37)		26 (29)	
Same	46 (49)	44 (44)		31 (34)	
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)	0.2	15 (16)	0.2
Better	11 (13)	19 (20)		13 (13)	
Same	39 (43)	37 (39)		44 (47)	
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.

and the pharmacy or physiotherapy groups at six and 12 months (table 1).

Secondary outcomes—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 2). See bmj.com for other secondary outcome data.

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 (see bmj.com). 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 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. One consistent finding was that prescribing of non-steroidal anti-inflammatory drugs was reduced in both pharmacy and physiotherapy groups compared with control. 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. 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 and limitations

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. We deliberately chose not to restrict our trial to people with radiographically diagnosed osteoarthritis in order to reflect current clinical practice.

Recruitment rate varied considerably across general practices; a single practice recruited a quarter of

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

the study population. We found no evidence that this adversely affected the external validity of the trial or diminished generalisability. 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.^{9 10} We measured adherence by the number of sessions attended rather than the actual level of ongoing participation. Adherence may have decreased over time, as has been shown in other studies,⁹ 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. 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 treatment¹¹ might have improved long term outcomes.

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.¹² Although exercise based interventions have shown beneficial effects for older adults with knee pain, effect sizes are small, at best, and are short lived.¹³ Similarly, community pharmacists in the United Kingdom have been linked with a new role as "supplementary prescribers."²² 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.

We thank the following organisations and people directly involved with the study for their support: the rheumatology

nurses; the community physiotherapists and physiotherapy managers; the North Staffordshire GP Research Network and all the general practitioners who referred patients to the trial; the health informatics team, administration team, Peter Croft, Rhian Hughes, and Panos Barlas from the Primary Care Musculoskeletal Research Centre; members of the independent Data Monitoring and Ethics Committee; and the members of the public who took part in the study.

Contributors: See bmj.com.

Funding: Arthritis Research Campaign, North Staffordshire Primary Care Research Consortium, and the Department of Health National Co-ordinating Centre for Research Capacity Development. NEF is funded by a primary care career scientist award from the Department of Health and NHS R&D. The sponsors of the study had no role in the study design, data collection, data analysis, data interpretation, or writing of the report.

Competing interests: None declared.

Ethical approval: North Staffordshire local research ethics committee.

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doi 10.1136/bmj.38977.590752.0B

Endpiece

A trouble shared is a trouble halved

Everyone who tries to encourage a despondent friend or to reassure a panicky child practices psychotherapy.

Alexander F. *Psychoanalysis and Psychotherapy*. London: George Allen and Unwin, 1957

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