

Acupuncture as an adjunct to exercise based physiotherapy for osteoarthritis of the knee: randomised controlled trial

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doi:10.1136/bmj.39280.509803.BE

ABSTRACT

Objective To investigate the benefit of adding acupuncture to a course of advice and exercise delivered by physiotherapists for pain reduction in patients with osteoarthritis of the knee.

Design Multicentre, randomised controlled trial.

Setting 37 physiotherapy centres accepting primary care patients referred from general practitioners in the Midlands, United Kingdom.

Participants 352 adults aged 50 or more with a clinical diagnosis of knee osteoarthritis.

Interventions Advice and exercise (n=116), advice and exercise plus true acupuncture (n=117), and advice and exercise plus non-penetrating acupuncture (n=119).

Main outcome measures The primary outcome was change in scores on the Western Ontario and McMaster Universities osteoarthritis index pain subscale at six months. Secondary outcomes included function, pain intensity, and unpleasantness of pain at two weeks, six weeks, six months, and 12 months.

Results Follow-up rate at six months was 94%. The mean (SD) baseline pain score was 9.2 (3.8). At six months mean reductions in pain were 2.28 (3.8) for advice and exercise, 2.32 (3.6) for advice and exercise plus true acupuncture, and 2.53 (4.2) for advice and exercise plus non-penetrating acupuncture. Mean differences in change scores between advice and exercise alone and each acupuncture group were 0.08 (95% confidence interval -1.0 to 0.9) for advice and exercise plus true acupuncture and 0.25 (-0.8 to 1.3) for advice and exercise plus non-penetrating acupuncture. Similar non-significant differences were seen at other follow-up points. Compared with advice and exercise alone there were small, statistically significant improvements in pain intensity and unpleasantness at two and six weeks for true acupuncture and at all follow-up points for non-penetrating acupuncture.

Conclusion The addition of acupuncture to a course of advice and exercise for osteoarthritis of the knee delivered by physiotherapists provided no additional improvement in pain scores. Small benefits in pain intensity and unpleasantness were observed in both acupuncture groups, making it unlikely that this was due to acupuncture needling effects.

Trial registration Current Controlled Trials
ISRCTN88597683.

INTRODUCTION

Knee pain in older adults is a common disabling problem, managed in the United Kingdom mostly within primary care.¹ Osteoarthritis is the most likely underlying diagnosis and has been shown by radiography to be present in 70% of community dwelling adults aged 50 or more with knee pain.² Structural changes before radiography are common in the remainder.³ Practice guidelines from the United Kingdom and mainland Europe emphasise the role of education, exercise, and drugs.⁴⁻⁶ The recommendations for exercise are underpinned by clinical trials.⁷⁻⁹ A recent best evidence summary of systematic reviews concluded that exercise therapy (strengthening, stretching, and functional exercises) compared with no treatment is effective for patients with knee osteoarthritis.¹⁰ Long term use of oral non-steroidal inflammatory drugs is discouraged¹¹ and studies show that patients generally do not like taking drugs.¹² People with knee osteoarthritis want non-pharmacological options for pain relief¹³ and often choose complementary medicine.¹⁴

The concept of integrated health care that incorporates conventional and complementary therapies has been promoted.¹⁵ Between 30% and 40% of general practices in England provide access to some form of complementary therapy for their patients,¹⁶ and acupuncture is one of the most popular options. Each week about 10% of general practitioners refer patients to acupuncture, or practise it themselves.¹⁶ More than 10% of chartered physiotherapists in the United Kingdom (n=4300) are members of an acupuncture group (personal communication, business manager of the Acupuncture Association of Chartered Physiotherapists, January 2007). Despite growing enthusiasm to provide complementary therapy within the UK National Health Service framework and the positive consensus statement from the National Institutes of Health,¹⁷ the place of acupuncture within mainstream health care remains controversial. Clinical trials of acupuncture have been criticised for small sample sizes, inadequate blinding, and lack of credible sham

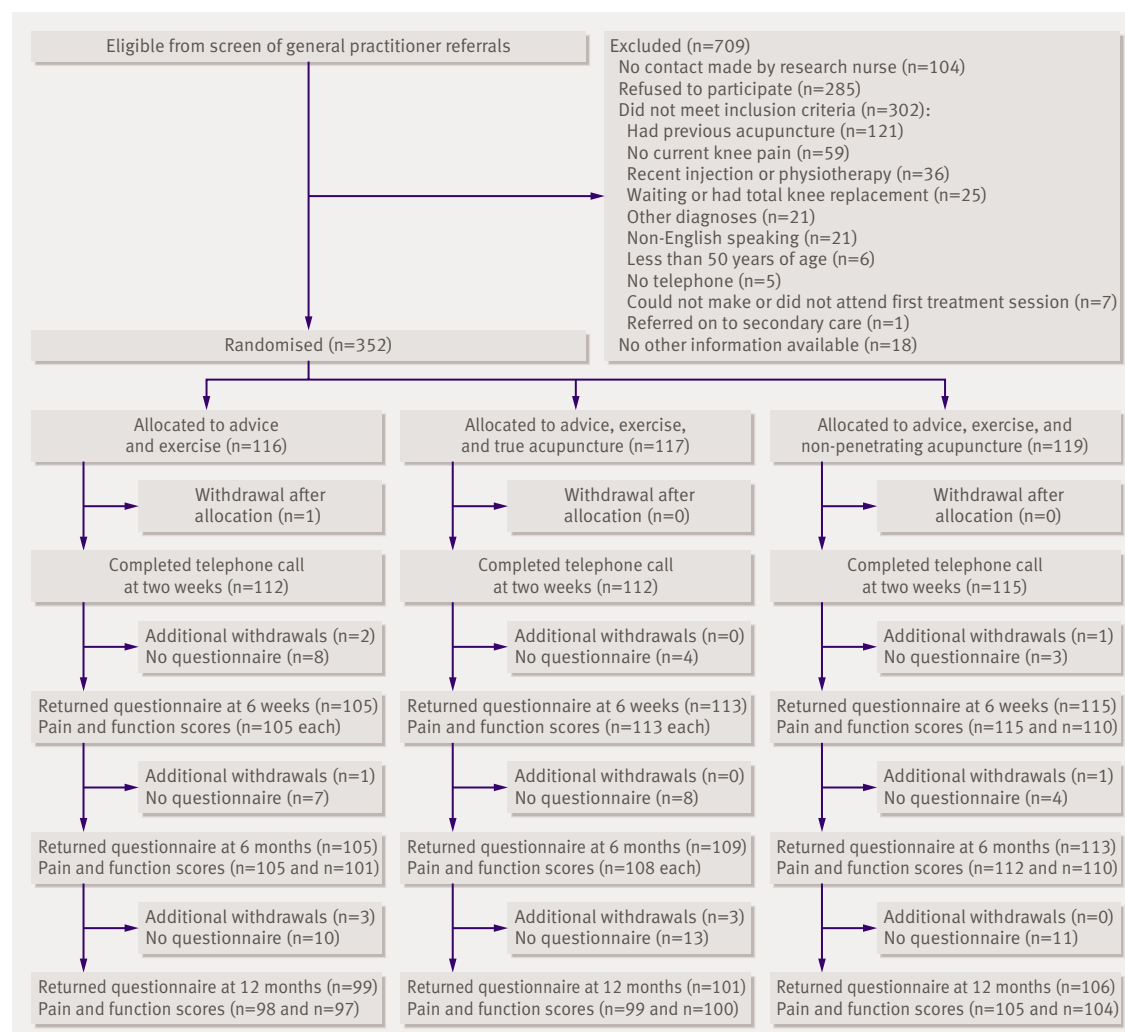
controls and long term follow-up.¹⁸⁻²¹ Recent trials have gone some way to tackling these limitations²²⁻²⁶ and systematic reviews conclude that acupuncture is more effective than placebo for osteoarthritis of the knee.^{20,21} However, questions about the benefit of adding acupuncture to mainstream, recommended treatments for this population remain unanswered. We have shown that exercise based physiotherapy is more effective than usual primary care for older adults with knee pain,⁹ but no high quality trial has investigated the additional benefit of integrating acupuncture with a recommended treatment such as exercise based physiotherapy for this population. Since physiotherapists, in addition to providing exercise and advice, are one of the largest groups of acupuncture providers within the National Health Service, they are an appropriate group with whom to investigate the effectiveness of integrating acupuncture into mainstream health care.

We carried out a prospective randomised controlled trial within primary care to investigate whether acupuncture is a useful adjunct to exercise based physiotherapy for knee pain in older adults.

METHODS

Full details of the methods, recruitment, and outcome measures have been published.²⁷ Participants were recruited from 37 NHS physiotherapy centres providing services for general practices within the Midlands and Cheshire regions of the United Kingdom between November 2003 and October 2005. Adults aged 50 years or more with knee pain and a clinical diagnosis of knee osteoarthritis were invited to participate. They were referred to physiotherapy by their general practitioner between November 2003 and October 2005 and they had not had acupuncture previously.

We screened referral letters and sent potential participants information leaflets about the study by post. They were subsequently telephoned to make an appointment, further explain the study, confirm eligibility, and obtain consent to participate. The leaflet explained that participants would receive physiotherapy advice and exercise and “may receive acupuncture, using one of two different types of acupuncture needle” without specifying the needles’ mode of action (penetrating compared with



Flow of participants through trial

non-penetrating) to maximise the effectiveness of blinding. After consent had been obtained the study nurse carried out a baseline research assessment. Participants then received an initial physiotherapy assessment during which affected knees were examined and conditions other than osteoarthritis (for example, referred pain from the hip or back) were ruled out. Potential acupuncture points were selected and recorded on a form. The first session of advice and exercise was delivered. After this the physiotherapist telephoned an administrator at the research centre to record the selected acupuncture points and to receive a computer generated

randomisation group for the patient. This process ensured that the selection of initial acupuncture points, the assessment, and the first advice and exercise session were carried out blind to subsequent treatment allocation.

Using random permuted blocks of 12 (blocked by treatment centre) the participants were randomised to advice and exercise, advice and exercise plus true acupuncture, or advice and exercise plus non-penetrating acupuncture. Researchers who collected, entered, and analysed data were unaware of treatment allocation. By necessity the physiotherapists delivering the interventions were not blind to allocation.

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

Variables	Advice and exercise (n=116)	Advice, exercise, and true acupuncture (n=117)	Advice, exercise, and non-penetrating acupuncture (n=119)
Personal details			
Mean (SD) age (years)	63.8 (8.3)	63.1 (8.7)	62.8 (9.4)
Women	79 (68)	71 (61)	66 (55)
Body mass index:			
Underweight or normal (<25.0)	26 (22)	25 (22)	22 (18)
Overweight (25.0-29.9)	55 (47)	54 (47)	49 (41)
Obese (>29.9)	35 (30)	35 (31)	48 (40)
Socioeconomic classification*:			
Higher managerial or professional	9 (9)	11 (10)	9 (9)
Lower managerial or professional	19 (18)	20 (18)	18 (16)
Intermediate occupations	22 (21)	15 (14)	20 (17)
Self employed	5 (5)	10 (9)	8 (7)
Lower supervisory or technical	3 (3)	6 (5)	11 (10)
Semiroutine occupations	23 (22)	29 (26)	29 (25)
Routine occupations	24 (23)	19 (17)	20 (17)
Currently employed	37 (32)	53 (45)	48 (40)
Knee pain and function			
Mean (SD) pain score†	9.1 (3.7)	9.3 (4.0)	8.9 (3.3)
Mean (SD) function score†	29.0 (12.9)	30.8 (13.9)	31.1 (12.8)
Total duration of knee pain (years):			
<1	47 (41)	53 (45)	48 (40)
1 to <5	38 (33)	41 (35)	35 (29)
5 to <10	14 (12)	8 (6)	18 (15)
≥10	17 (15)	15 (13)	18 (15)
Onset of current problem:			
Sudden	54 (47)	51 (44)	55 (46)
Gradual	62 (53)	66 (56)	64 (54)
Mean (SD) pain severity in past 7 days‡	5.6 (2.2)	6.0 (2.3)	6.1 (2.1)
Mean (SD) pain unpleasantness in past 7 days‡	5.6 (2.3)	6.0 (2.4)	6.2 (2.2)
Mean (SD) severity of main problem‡	6.3 (2.1)	6.3 (2.1)	6.5 (2.0)
Self efficacy and drugs			
Mean (SD) pain§	29.0 (9.4)	27.2 (8.6)	27.3 (9.0)
Mean (SD) other symptoms§	36.3 (10.5)	34.5 (10.8)	33.7 (9.9)
Used drugs:			
Non-steroidal anti-inflammatory drugs	55 (47)	57 (49)	63 (53)
Analgesia	49 (42)	49 (42)	49 (41)

Not all numbers add up to totals owing to missing data.

*Office for National Statistics.^{39 40}

†Western Ontario and McMaster Universities osteoarthritis index.

‡Numerical rating scale (0-10).

§Arthritis self efficacy scale.

Interventions

Interventions were delivered within 10 working days of randomisation by 67 physiotherapists trained in acupuncture to at least minimum national standards for membership of the Acupuncture Association of Chartered Physiotherapists. Two thirds of the physiotherapists had been qualified for more than 10 years and over half had been using acupuncture for more than three years. The treatment procedures were agreed and the use of the non-penetrating needle²⁸ standardised during training before the trial.

Advice and exercise

Participants allocated to the advice and exercise group received advice supplemented by a leaflet modelled on the Arthritis Research Campaign leaflet on knee osteoarthritis (www.arc.org.uk). Participants who were receiving non-steroidal anti-inflammatory drugs were permitted to continue with their stable dose. The advice and exercise package was developed from reviews of best evidence, clinical guidelines, a survey

of physiotherapy practice for knee pain,²⁹ and a consensus workshop. Exercises were individualised using PhysioTools (www.physiotools.net), oriented towards lower limb strengthening, stretching, and balance. This could include concentric, eccentric, and isometric exercise; non-weight bearing exercise; and weight bearing exercise plus a home exercise programme. Intensity was progressed, when appropriate, at each supervised exercise session. The package consisted of up to six sessions of 30 minutes (including the prerandomisation session) over six weeks. Data on participants' self reported adherence to exercise were collected.

Advice and exercise plus true acupuncture

Participants allocated to advice and exercise plus true acupuncture received acupuncture on traditional Chinese acupuncture points. The acupuncture protocol was based on the concept of adequacy of treatment,²¹ survey results,³⁰ a consensus workshop, and recommendations from traditional Chinese protocols. We did not

Table 2 | Outcome and credibility of treatment* at two weeks. Values are numbers (percentages) of participants

Patient's response	Advice and exercise (n=112)	Advice, exercise, and true acupuncture (n=112)	P value (χ^2 test for trend)†	Advice, exercise, and non-penetrating acupuncture (n=115)	P value (χ^2 test for trend)‡
Confident that treatment can help problem?:					
Very	26 (23)	27 (24)	0.01	38 (33)	0.0001
Quite	44 (39)	64 (57)		60 (53)	
Neither	18 (16)	12 (11)		10 (9)	
Not very	21 (19)	7 (6)		5 (4)	
Not at all	3 (3)	2 (2)		1 (1)	
Missing data	0	0		1	
Recommend treatment to friend with similar knee problem?:					
Very confident	29 (26)	34 (30)	0.2	41 (36)	0.03
Quite confident	61 (54)	58 (52)		62 (54)	
Neither	8 (7)	15 (13)		4 (4)	
Not very confident	12 (11)	5 (4)		5 (4)	
Not at all confident	2 (2)	0 (0)		2 (2)	
Missing data	0	0		1	
Does treatment make sense to you?:					
Very logical	46 (41)	32 (29)	0.006	45 (39)	0.4
Quite logical	53 (47)	54 (48)		51 (45)	
No opinion	5 (4)	6 (5)		4 (4)	
Not very logical	7 (6)	18 (16)		13 (11)	
Not at all logical	1 (1)	2 (2)		1 (1)	
Missing data	0	0		1	
Do you think treatment would be successful in treating other problems?:					
Very	17 (15)	17 (15)	0.3	29 (25)	0.03
Quite	61 (55)	68 (61)		56 (49)	
No opinion	27 (24)	25 (22)		29 (25)	
Not very	5 (5)	1 (1)		0 (0)	
Not at all	2 (2)	1 (1)		0 (0)	
Missing data	0	0		1	

*Adapted from Vincent and Lewith.³⁶

†Advice and exercise compared with advice, exercise, and true acupuncture.

‡Advice and exercise compared with advice, exercise, and non-penetrating acupuncture.

allow moxibustion, cupping, herbs, or electroacupuncture. For each individualised treatment session between six and 10 acupuncture points from 16 commonly used local and distal points were selected. Local points were Sp 9, Sp 10, St 34, St 35, St 36, Xiyan, Gb 34, and trigger points. Distal points were LI 4, TH 5, Sp 6, Liv 3, St 44, Ki 3, BI 60, and Gb 41. Sterilised disposable steel needles (30×0.3 mm) were used; the depth of insertion was between 5 mm and 25 mm, depending on the points selected. Needles were manipulated to achieve the de qi sensation (for example, aching, warm or tingling sensation) and the therapists recorded the sensations that patients reported. The protocol permitted 25 to 35 minutes between insertion of the last needle and stopping treatment. The therapists revisited and manipulated the needles as appropriate. If the de qi sensation was no longer present the therapists were expected to use stronger manipulation, either rotation or thrust and withdraw techniques, to elicit it. In addition to the prerandomisation advice and exercise session the package consisted of up to six treatment sessions over three weeks, during which both the true acupuncture and the advice and exercise treatments were delivered.

Advice and exercise plus non-penetrating acupuncture

Participants randomised to receive advice and exercise plus non-penetrating acupuncture²⁸ had acupuncture delivered through needles with a blunt tip. The shaft of these needles collapses into the handle, creating an illusion of insertion. They meet the recommendations for acceptable controls for acupuncture research¹⁸ and have been used in previous trials.^{22,31} Some authors believe that a small acupressure effect may be induced by this method.³¹ The same protocol was used as for true acupuncture, thus all criteria for harnessing non-specific effects were included (same contact time and interaction between therapist and patient, manual contact during the search for acupuncture points, and attention to elicited sensations). No attempt was made to elicit the de qi sensation but participants were told they may experience sensations and to report what they felt. In addition to the prerandomisation advice and exercise session the package consisted of up to six treatment sessions over three weeks, during which

both the non-penetrating acupuncture and the advice and exercise treatments were delivered.

Outcomes

Full details of the outcome measures are published elsewhere.²⁷ Follow-up was at two weeks (by telephone), six weeks, and six and 12 months (by postal questionnaire) after randomisation. The primary outcome measure was change at six months in the pain subscale score of the Western Ontario and McMaster Universities osteoarthritis index (Likert 3.0).³² This subscale has been shown to be reliable for use within postal surveys.³³ Secondary outcomes at six months included the function subscale score of the Western Ontario and McMaster Universities osteoarthritis index, participants' global assessment of change compared with baseline, pain severity and unpleasantness, severity of patient nominated main functional problem, arthritis self efficacy, satisfaction with care, and adherence with exercises, and all measures at six weeks and 12 months. Side effects of treatment, adverse events, and use of cointerventions were also recorded. We identified the proportion of each group who achieved a clinically significant response according to criteria from the outcome measures in Rheumatology and Osteoarthritis Research Society international initiative (OMERACT-OARSI).^{34,35}

Physiotherapists recorded the number and duration of treatment sessions, the exercises prescribed, the location and number of acupuncture points (when applicable), and any adverse reactions. In the acupuncture groups, therapists recorded the sensations that participants reported. This information was subsequently categorised by four acupuncture experts (three independent of the study team), blinded to treatment allocation, to identify those most likely to represent the de qi sensation. Acceptability and credibility of the intervention groups were evaluated during a telephone call two weeks after the start of treatment and at six weeks by questionnaire, using items adapted from previous literature.³⁶

Statistical analysis

We assumed a 45% improvement in pain measured by the pain subscale at six months in participants

Table 3 | Compliance with exercise at two weeks. Values are numbers (percentages) of participants unless stated otherwise

Variable	Advice and exercise (n=112)	Advice, exercise, and true acupuncture (n=112)	P value* (χ ² test for trend)	Advice, exercise, and non-penetrating acupuncture (n=115)	P value† (χ ² test for trend)
I have been doing my exercises as often as advised:					
Strongly agree	35 (32)	41 (37)		44 (39)	
Agree	34 (31)	37 (33)		27 (24)	
Not sure	0 (0)	2 (2)	0.2	0 (0)	0.7
Disagree	40 (36)	31 (28)		41 (36)	
Strongly disagree	2 (2)	1 (1)		2 (2)	
Missing data	1	0	—	1	—

*Advice and exercise compared with advice, exercise, and true acupuncture.

†Advice and exercise compared with advice, exercise, and non-penetrating acupuncture.

randomised to the advice and exercise group. The sample size calculation was based on the ability to detect a 65% improvement in the two groups also receiving acupuncture (an additional improvement of 20%).³⁷ A minimum of 270 participants with data at six months would be sufficient to detect these effects with 80% power at a 5% significance level (two tailed).³⁸ To allow for dropouts we inflated this value by 30% and hence aimed to randomise 350 participants.

Analysis was by intention to treat. Estimates of the treatment effects for numerical data are presented as difference in mean change, with 95% confidence intervals (advice and exercise plus acupuncture groups minus advice and exercise alone group) and χ^2 tests (heterogeneity test for binary data or linear trend test for ordinal data). We carried out exploratory sensitivity analyses of the mean pain subscale scores

by adjusting for baseline characteristics using multiple linear regression. A priori subgroup analyses included comparing those participants in the advice and exercise plus true acupuncture group who had 50% or more treatment sessions in which the de qi sensation was elicited with those with less than 50%, and comparing the effect of treatment in those who had severe knee pain or disability at baseline. External validity was assessed by comparing demographic characteristics of patients not randomised with those of participants and the participants' recruitment characteristics and treatment allocation across high and low recruiting centres.

ET carried out statistical analyses using Stata 7.0. The trial was monitored by an independent steering and data monitoring committee and no interim analyses were undertaken.

Table 4 | Change in pain and function scores.* Values are means (standard deviations) unless stated otherwise

	Advice and exercise	Advice, exercise, and true acupuncture	Mean difference† (95% CI)	P value‡	Advice, exercise, and non-penetrating acupuncture	Mean difference† (95% CI)	P value‡
Pain							
Six weeks:							
No analysed	105	113			115		
Absolute score	6.86 (4.2)	6.38 (4.1)			5.98 (4.3)		
Crude change score§	2.10 (3.5)	2.83 (4.0)	0.74 (-0.3 to 1.7)	0.1	3.02 (3.6)	0.93 (0.0 to 1.9)	0.05
Adjusted change score¶			0.69 (-0.2 to 1.6)	0.1		0.88 (0.0 to 1.8)	0.06
Six months:							
No analysed	105	108			112		
Absolute score	6.78 (4.5)	7.07 (4.4)			6.50 (4.8)		
Crude change score§	2.28 (3.8)	2.32 (3.6)	0.04 (-1.0 to 1.0)	0.9	2.53 (4.2)	0.25 (-0.8 to 1.3)	0.6
Adjusted change score¶			-0.08 (-1.0 to 0.9)	0.9		0.25 (-0.8 to 1.3)	0.6
12 months:							
No analysed	98	99			105		
Absolute score	6.29 (4.7)	6.84 (4.7)			6.16 (4.8)		
Crude change score§	2.57 (4.3)	2.37 (4.2)	-0.20 (-1.4 to 1.0)	0.7	2.82 (4.1)	0.25 (-0.9 to 1.4)	0.7
Adjusted change score¶			-0.42 (-1.5 to 0.7)	0.5		0.23 (-0.9 to 1.3)	0.7
Function							
Six weeks:							
No analysed	105	113			110		
Absolute score	22.34 (14.9)	22.38 (14.5)			22.14 (15.7)		
Crude change score§	6.21 (11.4)	8.18 (11.5)	1.97 (-1.1 to 5.0)	0.2	9.32 (11.4)	3.11 (0.0 to 6.2)	0.05
Adjusted change score¶			1.46 (-1.5 to 4.4)	0.3		2.49 (-0.6 to 5.5)	0.1
Six months:							
No analysed	101	108			110		
Absolute score	24.36 (15.6)	24.93 (16.0)			23.83 (16.9)		
Crude change score§	4.60 (11.4)	6.25 (12.1)	1.66 (-1.5 to 4.9)	0.3	7.13 (13.1)	2.54 (-0.8 to 5.9)	0.1
Adjusted change score¶			0.92 (-2.2 to 4.0)	0.6		2.39 (-0.9 to 5.6)	0.2
12 months:							
No analysed	97	100			104		
Absolute score	23.16 (15.8)	23.83 (16.5)			22.47 (16.7)		
Crude change score§	5.36 (11.9)	6.61 (13.8)	1.24 (-2.3 to 4.5)	0.5	8.24 (13.5)	2.87 (-0.7 to 6.4)	0.1
Adjusted change score¶			0.23 (-3.2 to 3.6)	0.9		2.52 (-0.9 to 6.0)	0.2

*Scores on Western Ontario and McMaster Universities osteoarthritis index.

†Difference in mean scores (advice and exercise plus acupuncture group minus advice and exercise group).

‡Derived from linear regression.

§Change in score from baseline.

¶Mean difference adjusted for recruitment age, sex, duration of pain, and scores for pain or function.

RESULTS

Overall, 1061 potentially eligible participants were identified, of whom 709 (66.8%) were ineligible or did not want to participate (figure). In total 352 (33.2%) patients were randomised: 116 to advice and exercise, 117 to advice and exercise plus true acupuncture, and 119 to advice and exercise plus non-penetrating acupuncture. Thirty seven physiotherapy centres recruited at least one patient (maximum 29 per site). Baseline characteristics of participants (mean age 63 years, 61% women) were similar between the groups (table 1).

Those patients who were screened but not randomised (n=709) were slightly older than those randomised (65 v 63 years), but both groups had 61% of women. Treatment allocation and recruitment characteristics were similar between the higher (≥ 18 patients; n=177 patients) and the lower (≤ 17 patients; n=175 patients) recruiting centres (data not shown).

Four participants in the advice and exercise group and two in the advice and exercise plus non-penetrating

acupuncture group withdrew permission for further contact in the period up to the six months' follow-up. In the 346 eligible for contact at six months the response rate was 94% for advice and exercise, 93% for advice and exercise plus true acupuncture, and 97% for advice and exercise plus non-penetrating acupuncture. Nineteen participants did not return the questionnaire at six months. Non-responders were more likely to be men (47% v 39%), to be younger (mean age 60 v 63 years), and to have slightly lower baseline scores for pain and function (pain: 8.7 v 9.2, function: 27.8 v 30.5).

Treatments were in line with the study protocols. A few participants violated the protocol: three in the advice and exercise group and two in the advice and exercise plus non-penetrating acupuncture group. No adverse events occurred in the advice and exercise group or in the advice and exercise plus non-penetrating acupuncture group. Five adverse events were reported for participants receiving true acupuncture (pain, sleepiness, fainting, nausea, and swelling around the treated knee).

Table 5 | Global assessment at follow-up. Values are numbers (percentages) of participants unless stated otherwise

Variables	Advice and exercise	Advice, exercise, and true acupuncture	P value* (χ^2 test for trend)	Advice, exercise, and non-penetrating acupuncture	P value† (χ^2 test for trend)
Two weeks:					
Much better	14 (13)	25 (22)	0.02	29 (25)	0.008
Better	55 (49)	58 (52)		53 (46)	
No change	34 (30)	25 (22)		28 (25)	
Worse	7 (6)	2 (2)		4 (4)	
Much worse	2 (2)	2 (2)		0 (0)	
Missing data	0	0		1	
Six weeks:					
Complete recovery	4 (4)	1 (1)	0.3	4 (4)	0.2
Much better	25 (24)	33 (30)		42 (37)	
Better	42 (40)	52 (46)		36 (32)	
No change	24 (23)	23 (21)		25 (22)	
Worse	8 (8)	2 (2)		5 (4)	
Much worse	1 (1)	1 (1)		2 (2)	
Missing data	1	1	1		
Six months:					
Complete recovery	4 (4)	3 (3)	0.9	6 (5)	0.2
Much better	24 (23)	23 (21)		38 (34)	
Better	28 (27)	33 (31)		23 (21)	
No change	33 (31)	33 (31)		29 (26)	
Worse	12 (11)	12 (11)		13 (12)	
Much worse	4 (4)	4 (4)		3 (3)	
Missing data	0	1	1		
12 months:					
Complete recovery	11 (11)	4 (4)	0.7	5 (5)	0.8
Much better	19 (19)	20 (20)		31 (29)	
Better	21 (21)	39 (39)		26 (25)	
No change	30 (30)	15 (15)		25 (24)	
Worse	12 (12)	17 (17)		14 (13)	
Much worse	6 (6)	6 (6)		5 (5)	
Missing data	0	0	0		

*Advice and exercise compared with advice, exercise, and true acupuncture.

†Advice and exercise compared with advice, exercise, and non-penetrating acupuncture.

Table 6 | Response to criteria from the outcome measures in Rheumatology and Osteoarthritis Research Society international initiative at follow-up. Values are numbers (percentages) of participants unless stated otherwise

Variables	Advice and exercise	Advice, exercise, and true acupuncture	P value* (χ^2 test for trend)	Advice, exercise, and non-penetrating acupuncture	P value† (χ^2 test for trend)
Six weeks:					
High	30	39	0.1	51	0.1
Improvement	24	31		20	
Total response	54 (51)	70 (62)		71 (62)	
Six months:					
High	31	29	0.4	38	0.2
Improvement	14	26		21	
Total response	45 (43)	55 (50)		59 (52)	
12 months:					
High	37	31	0.6	41	0.3
Improvement	11	22		18	
Total response	48 (48)	53 (52)		59 (56)	

*Advice and exercise compared with advice, exercise, and true acupuncture.

†Advice and exercise compared with advice, exercise, and non-penetrating acupuncture.

The median (range) number of treatment sessions was in line with the study protocols: 6 (1-9) in the advice and exercise group, 7 (4-9) in the advice and exercise plus true acupuncture group, and 7 (1-8) in the advice and exercise plus non-penetrating acupuncture group. In both acupuncture groups the acupuncture treatment was used in a median of six sessions. The de qi sensation was reported at least once for 95 (83%) participants receiving true acupuncture and 65 (55%) receiving non-penetrating acupuncture. Of these, 67 (71%) and 29 (45%) reported de qi during at least half of their treatment sessions.

Intervention credibility and exercise compliance

Table 2 summarises treatment credibility two weeks after treatment started. Participants receiving either acupuncture intervention were significantly more confident that treatment could help their knee problem than those receiving advice and exercise alone.

Most participants had treatment sessions that included supervised exercises (85% for advice and exercise, 77% for advice and exercise plus true acupuncture, and 78% for advice and exercise plus non-penetrating acupuncture) and a home exercise programme (89%, 91%, and 95%). Self reported compliance with exercise at two weeks was 63%, 70%, and 64% (table 3). Compliance remained above 50% in each group over the 12 months' follow-up.

Outcome measures

At six months no statistically significant differences were found in change on the pain subscale from baseline between the groups receiving acupuncture in addition to advice and exercise compared with the group receiving advice and exercise alone (table 4).

At six weeks the advice and exercise plus non-penetrating acupuncture group reported small but significantly greater improvements in pain than did the advice and exercise group (mean difference 0.88,

95% confidence interval 0.0 to 1.8). At 12 months no statistically significant differences were found between the groups (table 4). At two weeks statistically significant trends were found in favour of better global outcome for each of the acupuncture groups compared with the advice and exercise alone group (table 5).

No other statistically significant differences were found in the changes in function scores, global assessment, or response status according to the OMERACT-OARSI criteria between the three groups at any follow-up points, or in the adjusted analyses (tables 5 and 6).

Statistically significant differences were found between the groups in pain intensity and unpleasantness (table 7). The results at two and six weeks for pain intensity and at six weeks for change in pain unpleasantness favoured both groups receiving acupuncture. The results at six and 12 months for both pain intensity and pain unpleasantness favoured the group receiving advice and exercise plus non-penetrating acupuncture. Satisfaction with care was significantly greater for participants receiving advice and exercise plus non-penetrating acupuncture than for those receiving advice and exercise alone (table 8). No statistically significant differences were seen between advice and exercise plus true acupuncture and advice and exercise plus non-penetrating acupuncture for any other of the outcomes measured (data not shown).

Exploratory subgroup analyses showed no significant differences in change scores for pain or function between participants in the advice and exercise plus true acupuncture group reporting de qi during more than 50% of treatment sessions compared with those who reported de qi less often. Those with severe pain or disability at baseline showed similar change scores in each of the treatment groups (data not shown). No significant differences were found between groups in the number of reported general practitioner consultations over six months (advice and exercise

25%, advice and exercise plus true acupuncture 19%, and advice and exercise plus non-penetrating acupuncture 20%) or in the use of non-steroidal anti-inflammatory or simple analgesics.

DISCUSSION

Acupuncture delivered by physiotherapists as part of an integrated package of health care with advice and exercise, for older adults with osteoarthritis of the knee, provided no additional improvement in pain scores compared with advice and exercise alone measured on the Western Ontario and McMaster Universities osteoarthritis index at six and 12 months. Small benefits were shown for pain intensity and unpleasantness but these effects were greater and sustained for longer in the group receiving non-penetrating acupuncture than in the group receiving true acupuncture. This finding makes it unlikely that the observed effects were due to needling effects of needle penetration, manual stimulation throughout treatment, and elicitation of the de qi sensation.

Comparison with other studies

Our trial is important for two reasons. Firstly, it provides new information on the effectiveness of acupuncture for knee osteoarthritis in older adults, delivered in addition to an evidence based package of physiotherapy care within mainstream health care. Previous trials of acupuncture for knee osteoarthritis have compared true acupuncture with sham acupuncture (including off-point needling),²² ongoing stable medication,⁴¹ waiting list controls,²⁴ or education alone.²³ We decided not to include a no treatment group as this would be difficult to justify given that guidelines and previous trials recommend advice and exercise for older adults with knee osteoarthritis. Our procedures differed in several important ways from those in previous trials. We used fewer treatment sessions: six acupuncture treatments compared with 10, 12, 15, and 24 in previous studies.²³⁻²⁶ Although it can be argued that this may have rendered the true acupuncture intervention suboptimal, we found no differences between true and non-penetrating acupuncture after

Table 7 | Change in knee pain and function and psychological measures at follow-up. Values are means (standard deviations) unless stated otherwise

End point	Advice and exercise	Advice, exercise, and true acupuncture	Difference (95% CI)*	P value	Advice, exercise, and non-penetrating acupuncture	Difference (95% CI)*	P value
Knee pain and function							
Change in pain intensity†:							
2 weeks	0.27 (2.2)	1.31 (2.2)	1.12 (0.5 to 1.7)	<0.0001	1.51 (2.1)	1.24 (0.7 to 1.8)	<0.0001
6 weeks	0.90 (2.5)	1.81 (2.4)	0.98 (0.3 to 1.6)	0.004	2.18 (2.5)	1.27 (0.6 to 1.9)	<0.0001
6 months	0.95 (2.6)	1.28 (2.4)	0.32 (-0.4 to 1.0)	0.4	1.95 (2.6)	1.01 (0.3 to 1.7)	0.006
12 months	1.21 (2.9)	1.60 (2.6)	0.34 (-0.4 to 1.1)	0.4	2.02 (2.6)	0.84 (0.1 to 1.6)	0.03
Change in pain unpleasantness†:							
6 weeks	1.08 (2.5)	1.91 (2.4)	0.90 (0.2 to 1.6)	0.007	2.23 (2.5)	1.09 (0.4 to 1.8)	0.002
6 months	0.94 (2.6)	1.22 (2.5)	0.30 (-0.4 to 1.0)	0.4	2.07 (2.8)	1.12 (0.4 to 1.9)	0.003
12 months	1.20 (3.0)	1.66 (2.8)	0.43 (-0.4 to 1.2)	0.3	2.15 (2.8)	0.94 (0.2 to 1.7)	0.02
Change in severity of main problem†:							
6 weeks	1.39 (2.6)	1.88 (2.4)	0.58 (-0.1 to 1.3)	0.09	2.13 (2.4)	0.72 (0.1 to 1.4)	0.04
6 months	1.13 (2.7)	1.23 (2.5)	0.12 (-0.6 to 0.8)	0.7	1.76 (2.8)	0.66 (-0.1 to 1.4)	0.08
12 months	1.36 (2.6)	1.60 (2.7)	0.15 (-0.6 to 0.9)	0.7	1.89 (2.7)	0.52 (-0.2 to 1.3)	0.2
Psychological measures							
Change in pain on arthritis self efficacy scale†:							
6 weeks	0.71 (9.5)	-1.46 (9.3)	-2.19 (-4.8 to 0.4)	0.1	-2.54 (10.4)	-2.99 (-5.7 to -0.3)	0.03
6 months	1.64 (11.1)	-0.62 (9.8)	-2.36 (-5.3 to 0.5)	0.1	-1.43 (11.3)	-2.77 (-5.9 to 0.3)	0.08
12 months	0.91 (12.1)	0.33 (12.0)	-0.64 (-4.2 to 2.9)	0.7	0.08 (10.3)	-0.71 (-3.9 to 2.5)	0.7
Change in other symptoms on arthritis self efficacy scale†:							
6 weeks	-0.32 (10.0)	-1.83 (10.1)	-1.42 (-4.2 to 1.3)	0.3	-3.38 (10.4)	-2.74 (-5.5 to 0.02)	0.05
6 months	0.38 (11.2)	-0.68 (11.2)	-1.01 (-4.1 to 2.1)	0.5	-1.88 (12.0)	-2.09 (-5.3 to 1.1)	0.2
12 months	0.55 (11.5)	-0.12 (13.9)	-0.47 (-4.2 to 3.3)	0.8	-1.93 (11.5)	-2.48 (-5.8 to 0.8)	0.1

*Mean difference (advice and exercise plus acupuncture group minus advice and exercise group) adjusted for recruitment age, sex, and duration of pain.

†Change in score from baseline.

six treatments. We included participants with a clinical diagnosis of knee osteoarthritis, who are the patients seen in primary care, rather than those with a confirmed radiological diagnosis only, as used in other trials.²⁴⁻²⁶ We also used the credible acupuncture control of non-penetrating acupuncture at the same points as the true acupuncture rather than minimal depth needling at predefined distant non-acupuncture points. There is much debate within the acupuncture literature about the validity of sham acupuncture, and given that a considerable proportion of participants in our non-penetrating acupuncture group reported sensations fitting the normal descriptions of de qi we cannot consider this intervention as inert. Only one high quality trial included physiotherapy in an integrated package with acupuncture.²⁵ In that trial all treatment groups (true acupuncture, minimal needling acupuncture, and conservative therapy consisting of visits to a general practitioner and drugs) could have up to six sessions with a physiotherapist although these were actually received by only a minority of participants. Although procedural differences make direct comparisons between trials difficult, the treatment response in our control group (a course of advice and exercise) was considerably higher (51% at six weeks, 43% at six months, and 48% at 12 months) than in the control groups of previous trials (29%, 6.5%, and 30% at six months or equivalent).^{23 25 26} Thus it is clear that the course of six sessions of advice plus individualised and supervised exercise in the current trial was considerably more effective than the control

interventions used in previous acupuncture studies. We have shown that acupuncture offers limited additional benefits when delivered alongside an effective package of physiotherapy led advice and exercise.

Secondly, this trial adds to the debate about acupuncture's mechanisms of action. Participants were not told they may receive a sham intervention (rather they were told they may receive one of two forms of acupuncture), the credibility of the interventions was high, and participants were not asked to guess the treatment they had received. We have shown that there are no differences when a credible, non-penetrating acupuncture treatment, delivered under strict participant blinded conditions, and true acupuncture, involving needle penetration, manual stimulation, and elicitation of the de qi sensation are added to a course of advice and exercise. Indeed patient satisfaction, credibility of intervention at six weeks, and reduction in pain intensity and unpleasantness were significantly greater for the advice and exercise plus non-penetrating acupuncture group than for the advice and exercise group but not for the advice and exercise plus true acupuncture group. We cannot explain these findings. One possibility is that non-penetrating acupuncture harnesses some of the benefits of acupuncture, such as acupressure or participants' expectations of benefit, without any adverse or unpleasant side effects, such as minor bleeding, bruising, or pain. Our findings make it difficult to sustain the argument that the observed effects of acupuncture are explained by specific physiological

Table 8 | Change in satisfaction with care at follow-up. Values are numbers (percentages) of participants

Variables	Advice and exercise	Advice, exercise, and true acupuncture	P value* (χ^2 test for trend)	Advice, exercise, and non-penetrating acupuncture	P value † (χ^2 test for trend)
Six weeks:					
Very satisfied	47 (45)	62 (55)		71 (62)	
Quite satisfied	39 (37)	37 (33)		35 (30)	
No opinion	10 (10)	8 (7)	0.07	3 (3)	0.008
Not very satisfied	8 (7)	5 (4)		6 (5)	
Not at all satisfied	1 (1)	0 (0)		0 (0)	
Missing data	1	0		0	
Six months:					
Very satisfied	32 (31)	38 (35)		56 (50)	
Quite satisfied	44 (42)	46 (43)		39 (35)	
No opinion	15 (14)	11 (10)	0.5	6 (5)	0.006
Not very satisfied	10 (10)	11 (10)		9 (8)	
Not at all satisfied	3 (3)	2 (2)		1 (1)	
Missing data	1	1		2	
12 months:					
Very satisfied	28 (29)	33 (33)		47 (44)	
Quite satisfied	37 (38)	45 (45)		40 (38)	
No opinion	20 (20)	12 (12)	0.2	7 (7)	0.009
Not very satisfied	8 (8)	9 (9)		12 (11)	
Not at all satisfied	5 (5)	2 (2)		0 (0)	
Missing data	1	0		0	

*Advice and exercise compared with advice, exercise, and true acupuncture.

†Advice and exercise compared with advice, exercise, and non-penetrating acupuncture.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Guidelines for the management of knee osteoarthritis emphasise patient education and exercise

Acupuncture alongside mainstream healthcare interventions has been advocated

WHAT THIS STUDY ADDS

Acupuncture did not provide greater reduction in pain scores when added to a course of advice and exercise delivered by physiotherapists

Benefits from acupuncture were limited to pain intensity and unpleasantness, were unlikely to be clinically significant, were mostly short lived, and could not be attributed to needling effects

mechanisms of needling and eliciting de qi sensations.⁴² Other possible mechanisms could include placebo effects, effects on the limbic system, light touch stimulating mechanoreceptors thus alleviating pain unpleasantness,⁴³ or patients' expectations of pain relief.^{44,45} We also excluded other possible explanations of acupuncture's effects suggested by previous trials, such as the intensity of provider contact or the physiological effects of needling. One study showed no difference between true acupuncture over minimal shallow needling for knee osteoarthritis.²⁵ Our trial adds to this important finding by showing no difference between true acupuncture and a non-penetrating acupuncture intervention in patients with no experience of true acupuncture who are expecting to receive acupuncture to help their knee problem.

Strengths and weaknesses of the study

Our trial engaged experienced physiotherapists trained to national standards. The treatment protocols were developed from available evidence, using information about traditional Chinese acupuncture points, previous surveys of practice, and consensus workshops. Treatment could be adjusted according to individual patients' needs within boundaries set and agreed within the treatment protocols. We ensured that treatments met the criteria of adequacy for acupuncture, that many more participants in the true acupuncture group reported the de qi sensation during treatment, and that all adverse reactions were linked to the group receiving the true acupuncture intervention. We had successful concealed randomisation, had sufficient power, excellent follow-up rates, and high adherence to the protocol, achieved good credibility and blinding of participants receiving the non-penetrating acupuncture intervention, and successful blinding of the research team.

A potential limitation of this trial is that we used fewer treatment sessions than in previous studies of acupuncture practice, such as those from the United States²³ and Germany.²⁴⁻²⁶ We developed the acupuncture protocols to fit within current physiotherapy practice in the United Kingdom, however, and the protocols met the minimum criteria for adequacy of acupuncture.

Our trial failed to show that acupuncture is a useful adjunct to a course of individualised, exercise based physiotherapy for older adults with knee osteoarthritis. This adds to the existing body of evidence as acupuncture was compared with an effective comparison treatment.

CONCLUSION

Our trial addressed the three important questions recommended by the House of Lords report on complementary and alternative medicine in 2000.⁴⁶ Firstly, true acupuncture did not show any greater therapeutic benefit than a credible control procedure in patients with a clinical diagnosis of knee osteoarthritis. Secondly, acupuncture was safe, with few, minor adverse events. Thirdly, acupuncture provided no additional improvement in pain scores compared with a course of six sessions of physiotherapy led advice and exercise. The small additional benefits from acupuncture were unlikely to be clinically significant, were limited to pain intensity and unpleasantness, were mostly short lived, and could not be attributed to specific acupuncture needling effects. Further research is needed to investigate the possible mechanisms of acupuncture, particularly the role of expectancy effects.

We thank Chan Vohora, Hannah Yates, Rhian Hughes, Jo Bailey, Gail White, Sue Weir, Claire Calverley, Wendy Clow, Peter Croft, and Krysia Dziedzic (Primary Care Musculoskeletal Research Centre); the physiotherapists based at the following NHS trusts: Amber Valley Primary Care Trust, South, Eastern, Heart of, and North Birmingham primary care trusts, East and South Staffordshire primary care trusts, Mid Staffordshire General Hospitals NHS Trust, East Cheshire Primary Care Trust, Mid Cheshire Hospitals NHS Trust, East Cheshire NHS Trust, Derby Hospitals NHS Foundation Trust, Worcestershire Acute Hospitals NHS Trust, Shrewsbury and Telford Hospital NHS Trust, Shropshire Community Primary Care Trust, Burton Hospitals NHS Trust, Robert Jones and Agnes Hunt Orthopaedic Hospital NHS Trust, South Warwickshire Primary Care Trust, South Warwickshire Hospitals NHS Trust, North Stoke, and Staffordshire Moorlands primary care trusts; and Adrian White, Michael Cummings, and Hugh MacPherson for categorising patients on the de qi sensation.

Contributors: All authors participated in the interpretation of the results and drafting of the article. NEF contributed to the design, funding application, advice and exercise intervention, training of the therapists, and management of the trial. ET contributed to the outcomes measured, data management, and analysis. PB contributed to the design, funding application, acupuncture interventions, and training of the therapists. JCH and EM contributed to the management of the trial, data collection, and training of the therapists. JY contributed to the recruitment procedures, data collection, and management. EMH contributed to the design, funding application, and management of the trial. NEF and EMH are guarantors.

Funding: This study was supported by a project grant from the Arthritis Research Campaign, UK (grant H0640) and Support for Science funding secured by the North Staffordshire Primary Care Research Consortium for NHS service support costs. NEF is funded by a primary care career scientist award from the Department of Health and NHS research and development, UK. JCH is funded by a lectureship in physiotherapy from the Arthritis Research Campaign, UK.

Competing interests: None declared.

Ethical approval: This study was approved by the West Midlands multicentre research ethics committee and by 13 local ethics committees.

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Accepted: 8 July 2007