WHAT IS ALREADY KNOWN ON THIS TOPIC

Observational studies have shown a direct association between cardiovascular risk and blood pressure across a broad spectrum of blood pressure levels

Guidelines use different classification schemes for blood pressure levels currently considered as normal (prehypertension versus normal and high normal blood pressure)

Cardiovascular outcomes among people who progress to hypertension are not well defined

WHAT THIS STUDY ADDS

Compared with women with normal blood pressure, those with high normal blood pressure have a substantially higher risk of cardiovascular events and incident hypertension

Maintaining two different blood pressure categories for people with prehypertension seems to be appropriate

Risk of cardiovascular events among women who progress to hypertension is increased shortly after a diagnosis of hypertension has been made

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

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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

Despite growing enthusiasm to provide complementary therapy within the UK National Health Service framework and the positive statement from the National Institutes of Health,[1] the place of acupuncture within mainstream health care remains controversial. We investigated whether acupuncture is a useful adjunct to exercise based physiotherapy for osteoarthritis of the knee in older adults. Practice guidelines from the United Kingdom and Europe emphasise the role of education, exercise, and medicines, and the recommendations for exercise are underpinned by clinical trials.

METHODS

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.

Potential participants were sent information leaflets explaining that they would receive physiotherapy advice and exercise and that they may receive acupuncture, using one of two different acupuncture needles. After a baseline research assessment participants received a physiotherapy assessment of their knee problem. Randomisation took place after the first session of advice and exercise.

Participants were randomised to advice and exercise, advice and exercise plus true acupuncture, or advice and exercise plus non-penetrating acupuncture. Interventions were delivered within 10 working days of randomisation by physiotherapists trained in acupuncture.

Participants allocated to the advice and exercise group received advice supplemented by a leaflet and individualised, progressed exercises. The package consisted of up to six treatment sessions over six weeks. Data on participants' self reported adherence to exercise were collected.

Participants allocated to advice and exercise plus true acupuncture received the acupuncture on traditional Chinese acupuncture points (see bmj.com). Needles were manipulated to achieve the de qi sensation. The package consisted of up to six treatment sessions over three weeks.

Participants randomised to advice and exercise plus non-penetrating acupuncture[2] received acupuncture through a blunt tipped needle with a shaft that collapses into the handle, creating an illusion of insertion. The same protocol was used as for true acupuncture. No attempt was made to elicit de qi but participants were told to report any sensations they felt. The package consisted of up to six treatment sessions over three weeks.

Outcomes

Follow-up was at two and six weeks and six and 12 months 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.[3] Secondary outcomes at six months included the function subscale score of the osteoarthritis index, participants' global assessment of change compared with baseline, treatment response according to the outcome measures in Rheumatology and Osteoarthritis Research Society international initiative (OMERACT-OARSI),[4,5] 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. See the published protocol for full details.[6]

Physiotherapists recorded the number and duration of treatment sessions, exercises prescribed, the location and number of acupuncture points, and adverse reactions. In the acupuncture groups, therapists recorded participants' self reported sensations. Acceptability and credibility of the intervention groups were evaluated by telephone two weeks after treatment started and at six weeks by questionnaire.

Statistical analysis

We assumed a 45% improvement in pain at six months in participants 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.[7] 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).[8] 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 de qi was elicited with

Table 1 | 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.

those with less than 50%, and comparing the effect of treatment in those who had severe knee pain or disability at baseline.

RESULTS

Overall, 352 of 1061 (33.2%) potentially eligible participants (see bmj.com) 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. Baseline characteristics of participants were similar between the groups (see bmj.com).

The median number of treatment sessions was in line with study protocols: six for the advice and exercise group and seven for the groups that also received acupuncture. 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 sessions.

Participants receiving either acupuncture intervention were significantly more confident that treatment could help them than those receiving advice and exercise alone (see bmj.com). Self reported compliance with exercise at two weeks was 63%, 70%, and 64% (see bmj.com). At six months no statistically significant differences were found in change on the Western Ontario and McMaster Universities osteoarthritis index pain subscale from baseline between the groups receiving acupuncture in addition to advice and exercise and the group receiving advice and exercise alone (table 1).

At six weeks the non-penetrating acupuncture group reported small but significantly greater improvements

in pain than did the advice and exercise alone 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 1). At two weeks statistically significant trends were found in favour of better global outcome for the acupuncture groups compared with the advice and exercise alone group (see bmj.com).

No other statistically significant differences were found in the changes in function scores, global assessment, or response status to the OMERACT-OARSI criteria between the three groups at any follow-up points, or in the adjusted analyses (see table 2 and bmj.com).

Statistically significant differences were found between the groups in pain intensity and unpleasantness (see bmj.com). The results at two and six weeks for pain intensity and at six weeks for change in pain unpleasantness favoured the groups receiving advice and exercise plus acupuncture. The results at six and 12 months for both pain intensity and pain unpleasantness favoured the group receiving non-penetrating acupuncture. Satisfaction with care was significantly greater for participants receiving non-penetrating acupuncture than for those receiving advice and exercise alone (see bmj.com).

Exploratory subgroup analyses showed no significant differences in change scores for pain or function between participants in the 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 three treatment groups.

DISCUSSION

Acupuncture delivered by physiotherapists as part of an integrated healthcare package with advice and exercise, for older adults with knee osteoarthritis, provided no additional improvement in pain scores measured at six and 12 months compared with advice and exercise alone. 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.

Previous trials of acupuncture for knee osteoarthritis have compared true acupuncture with sham acupuncture,[9] ongoing stable medication,[10] waiting list controls,[11] or education alone.[12] We decided not to include a no treatment group as guidelines and previous trials recommend advice and exercise for older adults with knee osteoarthritis. The treatment response in our control group of advice and exercise alone was considerably higher than in the control groups of previous trials. We used fewer acupuncture treatment sessions than previous studies.[11-14] 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 six treatments. We included participants with a clinical diagnosis of knee osteoarthritis rather than those with a radiological diagnosis only. We also used the credible acupuncture control of non-penetrating acupuncture at the same points as for true acupuncture rather than minimal depth needling at predefined distant non-acupuncture points. A considerable proportion of participants in this group reported sensations fitting the normal descriptions of de qi and therefore this intervention cannot be considered inert. Only one high quality trial included physiotherapy in an integrated package with acupuncture.[13] In that trial all treatment groups could have up to six sessions with a physiotherapist although these were received by only a minority of participants.

Our trial adds to the debate about acupuncture's mechanisms of action. Participants were not told they may receive a sham intervention, the credibility of the interventions was high, and participants were not asked to guess their treatment. We have shown that

Table 2 | 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.

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

there are no differences when a credible, non-penetrating acupuncture treatment and true acupuncture are added to a course of advice and exercise delivered by physiotherapists. Indeed patient satisfaction, credibility of intervention at six weeks, and reduction in pain intensity and unpleasantness were significantly greater for the non-penetrating acupuncture group than for the advice and exercise group but not for the true acupuncture group. One possibility for this is that non-penetrating acupuncture harnesses some of the benefits of acupuncture without any adverse or unpleasant side effects. Our findings make it difficult to sustain the argument that the observed effects of acupuncture are explained by specific physiological mechanisms of needling and eliciting de qi sensations.[15]

Strengths and weaknesses of the study

In this trial, treatments met the criteria of adequacy for acupuncture and could be adjusted according to individual patients' needs, more participants in the true acupuncture group reported the de qi sensation during treatment, and all adverse reactions were linked to the group receiving true acupuncture.

A potential limitation of this trial is that we used fewer acupuncture treatment sessions than in previous studies of acupuncture. We developed the protocols to fit within current physiotherapy practice in the United Kingdom, however, and they met the minimum criteria for adequacy of acupuncture.

Our trial addressed important questions recommended by the House of Lords report on complementary and alternative medicine.[16] Firstly, true acupuncture did not show any greater therapeutic benefit than a credible control procedure in patients with 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 advice and exercise delivered by physiotherapists. 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.

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Competing interests: None declared.

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