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Acupuncture for acute non-specific low back pain: A pilot randomised non-penetrating sham controlled trial

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Non-penetrating sham control;
Placebo;
Randomized controlled trial;
Blinding;
Pilot study

Summary
Objective: A pilot study to assess the feasibility of a trial to investigate the efficacy of acupuncture compared to placebo needling for the treatment of acute low back pain (LBP). As part of this, the study was designed to establish the credibility of the placebo control, and to provide data to inform a power analysis to determine numbers for a future trial.
Study design: A pilot patient and assessor blinded randomized controlled trial.
Setting: Primary care health centre facility, South and East Belfast Trust, Northern Ireland.
Patients: Patients from the physiotherapy waiting list ($n = 48$) with LBP of less than 12 weeks duration.
Outcome measures: Roland and Morris Disability Questionnaire (RMDQ), Visual Analogue Scale (VAS), medication use and an exit questionnaire were completed at baseline, end of treatment, and at 3 months follow up.
Results: Ninety-four percent (45/48) of patients completed assigned treatment, 83% (40/48) completed 3 months follow-up. The sham needle used here proved to be credible: 91.7% in the placebo group believed they had received acupuncture, compared to 95.8% in the verum acupuncture group. Differences in baseline characteristics were accounted for using ANCOVA.

There was no significant difference between groups on the RMDQ over time. For pain, the only statistically significant difference was at the 3 months follow up (worst VAS, point estimate, 18.7, 95% CI 1.5—36.0, $p = 0.034$). The majority of patients were taking some form of analgesic medication for LBP at the start of treatment ($n = 44$; 92%), and at the end of treatment the verum acupuncture group were taking significantly fewer tablets of pain control medication (mean (S.D.): 1.0 ± 0.3) than the placebo group (mean (S.D.): 4.2 ± 0.6, $p < 0.05$). Based upon

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these data, power analysis (power = 90%, alpha = 0.05, minimal clinically important difference (MCID) for RMDQ = 2.5 points) indicated that 120 participants (60 per group) would be needed to complete an adequately powered randomized controlled trial.
Conclusions: This study has demonstrated the feasibility of a randomized controlled trial of penetrating needle acupuncture compared to a non-penetrating sham for the treatment of acute LBP in primary care; 120 participants would be required in a fully powered trial. The placebo needle used in this study proved to be a credible form of control.
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Introduction

An unresolved question concerning acupuncture is whether there is a specific effect attributable to the needling procedure itself[1]; to address this issue requires trials using valid sham (placebo) controls.[1,2]

Several non-penetrating needles have been developed (i.e. The Streitberger needle and The Park Sham Device), which have both been shown to be credible and valid controls for acupuncture trials.[3–7] To date, no studies have assessed their potential utility in trials for low back pain (LBP).

Two recent systematic reviews have highlighted the lack of research to support the use of acupuncture in acute LBP, and the need for more well-controlled trials in such an under-researched area.[8,9]

Therefore, the aim of this study was to test the feasibility of a randomized controlled trial to compare the efficacy of verum acupuncture to a non-penetrating sham needling control in acute LBP. Specific objectives were first to provide necessary data upon which to base a power analysis and secondly to assess the credibility of the proposed placebo needle.

Methodology

Study design

This was a pilot (feasibility) study[10,11] for a patient and assessor blind randomised controlled trial. Subjects were randomly allocated into groups using a computer generated randomization table (http://www.randomization.com). To ensure concealment of allocation, an administrative assistant not otherwise involved in the study held the randomization list.

Ethical considerations

Ethical approval was gained from the Queens University Belfast Research Ethics Committee, Northern Ireland. Approval was also gained from South and East Belfast Trust where the trial was completed.

Subjects

Patients currently on the waiting list for physiotherapy through referral by their general practitioner (GP) were contacted by telephone and screened for inclusion in the study.

Inclusion criteria

Adults able to give informed consent, males and females aged 18—70 years. Current episode of non-specific LBP, with or without referred pain, of up to 12 weeks duration. LBP was defined as pain localised below the lowest ribs, and above the inferior gluteal folds, with or without radiation to the lower extremities.[12]

Exclusion criteria

Pain lasting more than 12 weeks. Presentation of red flags as defined by the Clinical Standards Advisory Guidelines[13]; contra-indications to acupuncture or previous acupuncture treatment; conflicting or ongoing treatment.

Clinical interventions

A full conventional clinical assessment was carried out at first attendance by the treating therapist to ensure the patient fulfilled the inclusion criteria. Patients were requested to continue normal activities, and to avoid other forms of treatment for the duration of the study, apart from routine physician management and analgesics. Patients were informed that they may or may not receive acupuncture as part of their treatment; none had previously received acupuncture. Therapists were not permitted to use any treatments other than those in the designated protocol; all treatment records were available in order to verify adherence to the protocol.

Both verum and sham controlled treatments were performed by the same senior experienced physiotherapists ($n = 3$); each had a minimum of 10 years clinical experience, and were members of the Acupuncture Association of Chartered Physiotherapists (AACP).[14] Patients were allocated to the therapists in sequence so that equal numbers of patients were allocated to each therapist.

Verum acupuncture. Acupuncture style was based on a western medical approach: unilateral or bilateral points were chosen to effect analgesia according to the patient's pattern of pain.[15] Each therapist chose points from a set range commonly used in LBP (based on review of textbooks,[16–21] RCTs[22,23]; confirmed by local expert opinion); see Table 1.

Patients were treated in prone lying and received a minimum of three and a maximum of 12 treatments over a 4—6 weeks period. Frequency of treatment was once or twice a week depending on symptom severity, and availability of appointments, and was determined by the treating therapist. Within each treatment the therapist inserted 8—13 needles which were stimulated manually every 5 min until subjective acupuncture specific sensation or *de qi*

Table 1 Acupuncture points

Acupuncture points	Location	Method of insertion
GV3	Below spinous process 4th lumbar vertebra	Perpendicular 0.5—1 in.
GV4	Below spinous process 2nd lumbar vertebra	Perpendicular 0.5—1 in.
BL23	1.5 cun lateral to lower border of spinous process 2nd lumbar vertebra	Perpendicular 1—1.5 in.
BL25	1.5 cun lateral to lower border of spinous process 4th lumbar vertebra, level with iliac crest	Perpendicular 1—1.5 in.
GB29	Midway between ASIS and greater trochanter	Perpendicular 0.5—1 in.
GB30	Junction of middle and lateral third of the distance between great trochanter and sacral hiatus	Perpendicular 2—3 in.
GB31	Midline lat aspect thigh (tip of middle finger)	Perpendicular 0.7—1.2 in.
GB34	In the depression anterior and inferior to fibula head	Perpendicular 1—1.5 in.
BL36	Middle of transverse gluteal fold	Perpendicular 0.7—1.5 in.
BL37	6 cun below BL36	Perpendicular 0.7—1.5 in.
BL40	Middle of transverse crease popliteal fossa	Perpendicular 0.5—1.5 in.
BL56	Centre of belly of gastrocnemius	Perpendicular 0.5—1.5 in.
BL60	Depression between lateral malleolus and TA	Perpendicular 0.5 in.

was achieved, or for 30 s using an even technique. Needle retention time was 30 min per treatment. The Park Sham Device (AcuPrime, UK) with verum acupuncture needles were used (Spring and Scarborough, Wujiang jia chen Acupuncture Devices Co. Ltd.; sterile single use needles with guide tube, size 0.25 mm × 40 mm) to maintain patient blinding.

Control intervention. The same Park Sham Device (AcuPrime, UK) was also used in the control group, so that patients were blinded to treatment[5,7]; however in this group non-penetrating sham needles were used which touched but did not penetrate the skin (sterile single use needles with guide tube, size 0.3 mm × 40 mm, AcuPrime, Dong Bang Acupuncture Inc, Korea). The same acupuncture points and clinical protocol was followed for the control as for the verum acupuncture group to ensure the same therapeutic experience.

Co-interventions. Clinical guidelines recommend advice to remain active and medication as routine care for acute LBP.[13,24] Advice was standardised at the first treatment by giving all participants the Back Book, an evidence-based booklet, developed for use by patients with LBP.[25] Medication intake was not controlled and may have been prescribed by the referring physician or obtained over the counter by the patient. Medication intake was recorded at initial assessment and patients were asked to complete a daily diary to record the type of medication, the dose in mg and the number taken per day.

Blinding. Given the nature of the treatments, it was possible to blind subjects but not therapists with respect to the content of the interventions. The success of patient blinding was assessed at the end of treatment. The primary researcher, who was unaware of patient allocation until the completion of the data analysis, carried out data collection at all time points.

Compliance and drop-outs. Non-compliance was defined as receipt of less than three treatments, but such patients were included in subsequent follow-ups for the purposes of intention-to treat analysis.

Outcome measures and follow-up procedures

A range of outcome measures were used as recommended by Bombardier[26]: these included questionnaires with proven psychometric properties for LBP-specific functional disability[26—28] (Roland and Morris Disability Questionnaire, RMDQ) and pain[29] (Visual Analogue Scale, VAS), and a multidimensional patient-centred questionnaire (work absenteeism, analgesic medication consumption, additional healthcare). These were completed at baseline, discharge, and 3 months (by post). An exit questionnaire which assessed patient satisfaction, success of blinding, and evaluated the credibility of the placebo was also completed by each patient at the end of treatment.

Data analyses

All variables were analysed using the Statistical Package for the Social Sciences (SPSS) version 11. Intention-to-treat analysis was carried out by an investigator who was masked to treatment allocation. Any missing data were replaced by carrying forward the most recent non-missing value. Analysis of covariance (ANCOVA), using pretreatment value as the covariate, was used to determine any differences between the groups at the post-treatment and follow-up visits. Exploratory analysis was carried out using numbers of treatments as an additional covariate, and the numbers of treatments between the groups was compared using the Mann—Whitney test. Analgesic intake between the groups was compared using the Van Elteren test, which is a modification of the Mann—Whitney test that accounts for baseline differences.[30] Because of doubts about the appropriateness of parametric ANCOVA for medication usage, the baseline medication usage was grouped into four categories using quartile cut-points (category 1: 0—25% = 0—2 tablets, category 2: 25—50% = 3—4 tablets, category 3: 50—75% = 5—8 tablets and category 4: 75—100% = 9—15 tablets). The resulting categories were used as baseline scores in a Van Elteren

test to compare post-treatment medication usage between groups.

Data from the exit questionnaire were analysed using Mann–Whitney tests to establish any differences between groups. A power analysis was completed using a between group minimal clinically important difference (MCID) of 2.5 points for the RMDQ,[31] at an alpha of 0.05 and power of 90%.

Results

Forty-eight patients were recruited and randomized into groups: see Fig. 1.[32] Outcome data were obtained from 94% of participants at the end of treatment; at 3 months follow up this had reduced to 83%. Reasons given for not completing treatment were: no benefit gained, no time available, and work commitments.

Outcome measures

Table 2 shows distribution of age, gender, pain distribution, work status, days off work and medication intake, whilst Table 3 shows baseline values for all outcome measures. No significant differences between the two groups were identified; however the placebo group had higher scores on VAS and RMDQ at baseline, thus supporting the use of ANCOVA analysis.

Table 2 Baseline characteristics

	Sham group	Acupuncture group	*p* value
Age			
Mean	44.6	46.5	0.50
S.D.	10.8	11.4	
Sex (%)			
Males	41.7	54.2	0.56
Females	58.3	45.8	
Pain distribution (%)			
Referred pain	46	50	1.00
Simple back pain	54	50	
Work status (%)			
Employed	45.8	54.2	0.20
Sick leave	20.8	29.2	
Unemployed	16.7	4.2	
Homemaker	12.5	8.3	
Retired	4.2	4.2	
Health care usage (%)			
GP	83.3	66.7	0.47
Private physiotherapy	8.3	4.2	
Chiropractor/osteopath	4.2	20.9	
CAM	4.2	8.4	

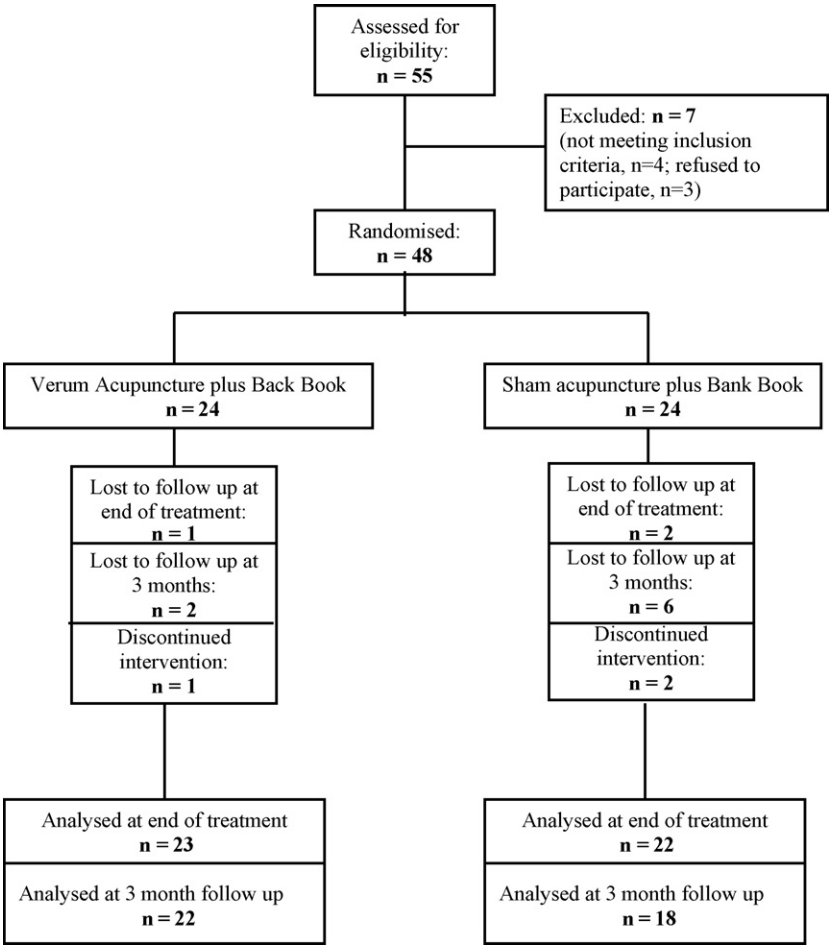

Figure 1 The flow of the trial according to the CONSORT statement.[32]

Table 3 Outcome measure scores expressed as mean ± S.E.M. values

	Verum acupuncture (mean ± S.E.M.)			Sham acupuncture (mean ± S.E.M.)		
	Baseline	End of treatment	3 months follow up	Baseline	End of treatment	3 months follow up
RMDQ	12.7 ± 1.1	6.0 ± 1.0	5.0 ± 1.0	12.8 ± 1.1	7.0 ± 1.3	7.7 ± 1.5
VAS average	56.2 ± 5.7	27.3 ± 4.9	26.5 ± 5.2	62.6 ± 4.0	36.3 ± 6.1	40.7 ± 6.2
VAS worst	76.4 ± 4.7	40.71 ± 6.1	33.3 ± 5.7	73.8 ± 4.1	52.5 ± 6.1	51.7 ± 5.8
Days off work	11.1 ± 4.5	13.9 ± 5.3	–	7.5 ± 2.3	10.9 ± 4.1	–
Medication intake (tablets per day)	4.2 ± 0.6	1.0 ± 0.3	–	5.3 ± 0.8	4.2 ± 0.6	–

The estimated marginal mean differences in all outcome measures at the end of treatment and follow up (adjusted for baseline values) are summarized in Table 4. There was no significant difference between groups on the RMDQ over time.

Pain was measured as average pain and worst pain. There was no significant difference between groups at the end of treatment for average pain or worst pain ($p > 0.05$); however, at follow up there was a trend towards a greater analgesic effect for average pain in the verum acupuncture group (average VAS: estimated marginal mean difference from baseline, 10.6, 95% CI −0.41 to 25.3, $p = 0.152$). In the case of worst pain, such differences were found to be statistically significant at the 3 months follow up (worst VAS: estimated marginal mean difference from baseline, 18.7, 95% CI 1.5–36.0, $p = 0.034$).

Results for medication intake showed that the majority of patients were taking some form of analgesic medication for LBP at the start of treatment ($n = 44$; 92%). At the end of treatment, subjects in the verum acupuncture group were taking significantly fewer doses (tablets per day) of medication (1.0 ± 0.3; mean ± S.E.M.) than the placebo group (4.2 ± 0.6). This difference remained significant after allowance for pretreatment differences in medication usage ($p < 0.05$, Van Elteren test).

Patients received a mean of 5.7 treatments. There was a significant difference between groups in the number of treatments received (Mann–Whitney test, $p = 0.001$). The acupuncture group received more treatments (6.3 ± 1.5; mean ± S.D.): 11 patients in this group received more than six treatments, compared to none in the placebo group (5.2 ± 1.4). In exploring the effect of this on each outcome measure there was only weak evidence ($p = 0.075$) for a positive relationship between RMDQ at the follow-up period and the number of treatments received; however allowance for this by using the number of treatments as a covariate in the analysis did not substantially affect the conclusions.

Power analysis

The current data were used to calculate numbers required to detect significant differences for pain (average VAS) and RMDQ between groups. For average pain, using an estimated

Table 4 This table shows the estimated marginal mean values for verum and placebo acupuncture adjusted for the initial baseline score for each outcome measure, and the between-group difference values plus statistical analyses of these values

	Verum	Placebo	Placebo-verum	Statistical analysis of between group differences (p value)
	Estimated marginal mean	Estimated marginal mean	Estimated marginal mean between-group differences	
RMDQ end of treatment	6.1 ± 1.0 95% CI, 5.0–8.9	7.0 ± 1.0 95% CI, 4.1–8.0	0.9 ± 1.4 95% CI, −1.8–3.7	0.504
3 months	5.1 ± 1.2 95% CI, 2.7–7.4	7.7 ± 1.2 95% CI, 5.3–10.0	2.6 ± 1.6 follow up 95% CI, −0.7–5.9	0.119
VAS average end of treatment	28.8 ± 5.2 95% CI, 18.3–39.2	34.9 ± 5.2 95% CI, 24.4–45.3	6.1 ± 7.4 95% CI, −8.7–20.9	0.12
3 months	28.3 ± 5.1 95% CI, 17.9–38.6	38.9 ± 5.1 95% CI, 28.5–49.2	10.6 ± 7.3 95% CI, −4.1–25.3	0.152
VAS worst end of treatment	40.4 ± 6.1 95% CI, 28.2–52.5	52.8 ± 6.1 95% CI, 40.7–65.0	12.5 ± 8.6 95% CI, −4.8–29.7	0.152
3 months	33.1 ± 6.1 95% CI, 20.8–45.3	51.8 ± 61 95% CI, 39.6–64.0	18.7 ± 8.6 95% CI, 1.5–36.0	**0.034**

Significant differences between groups are in bold for worst VAS, the acupuncture group demonstrated significant hypoalgesia at follow up.

Table 5 Exit questionnaire

	Placebo group (%) (*n*)	Acupuncture group (%) (*n*)	Statistics (*p* value)
Treatment received[a]			
Acupuncture	91.7 (22)	95.8 (23)	1.0
Advice	41.7 (10)	66.7 (16)	
I would have it again			
Strongly disagree			**0.031**
Disagree			
Uncertain	13.6 (3)	17.4 (4)	
Agree	31.8 (7)	82.6 (19)	
Strongly agree	54.5 (12)		
I would recommend it to others			
Strongly disagree			0.068
Disagree			
Uncertain	9.1 (2)	17.4 (4)	
Agree	31.8 (7)	82.6 (19)	
Strongly agree	59.1 (13)		
Overall I was satisfied with my care			
Strongly disagree			0.066
Disagree			
Uncertain	4.5 (1)	13.0 (3)	
Agree	31.8 (7)	87.0 (20)	
Strongly agree	63.6 (14)		
I didn't recover as well as I hoped			
Strongly disagree	27.3 (6)	30.4 (7)	0.747
Disagree	40.9 (9)	39.1 (9)	
Uncertain	9.1 (2)	13.0 (3)	
Agree	18.2 (4)	17.4 (4)	
Strongly agree	4.5 (1)		
Physiotherapy was a complete waste of time			
Strongly disagree	54.5 (12)	82.6 (19)	**0.035**
Disagree	36.4 (8)	17.4 (4)	
Uncertain	9.1% (2)		
Agree			
Strongly agree			
I enjoyed coming for physiotherapy			
Strongly disagree	4.5 (1)		0.244
Disagree		4.3 (1)	
Uncertain	68.2 (15)	8.7 (2)	
Agree	27.3 (6)	34.8 (8)	
Strongly agree		52.2 (12)	
I feel she listened to what I had to say			
Strongly disagree	4.5 (1)		**0.006**
Disagree			
Uncertain	40.9 (9)	8.7 (2)	
Agree	54.5 (12)	91.3 (21)	
Strongly agree			
I was given good advice about my back			
Strongly disagree	4.5 (1)		0.052
Disagree			
Uncertain	27.3 (6)	8.7 (2)	
Agree	68.2 (15)	91.3 (21)	
Strongly agree			
I was given a chance to ask questions			
Strongly disagree	4.5 (1)		**0.012**
Disagree			
Uncertain	36.4 (8)	8.7 (2)	
Agree	59.1 (13)	91.3 (21)	
Strongly agree			

[a] Patients were asked whether they had received acupuncture yes/no; or whether they had received advice yes/no.

within group S.D. of 30 points, an MCID between groups of 20, alpha of 0.05 and power at 90%, a total of 56 subjects (28 in each arm) would need to be recruited. For RMDQ, using the same power and alpha level, an estimated within group S.D. of four points, and an MCID between groups of 2.5, a total of 120 subjects (60 in each arm) would be needed.

Credibility of placebo acupuncture

Results of the exit questionnaire are summarised in Table 5. All patients who offered an opinion (22 placebo group, 23 verum group) believed they had received acupuncture, supporting the credibility of non-penetrating sham acupuncture.

Discussion

Results from this study indicate that a larger trial would require 60 participants in each arm in order to have the power to demonstrate statistically significant changes in both pain and function in acute LBP. Return to function is of primary importance in LBP and should be considered the main outcome in a fully powered trial. To calculate this value we used an RMDQ between group difference value of 2.5 points as recommended by Roland and Fairbanks[31] and an S.D. of four points derived from our pilot data.

This study has also demonstrated the feasibility of a methodologically rigorous, sham-controlled trial in a clinically appropriate setting (a busy hospital outpatient clinic) using a typical group of patients with acute LBP. Acupuncture intervention was carried out as part of the normal workload of treating physiotherapists, and patients accepted completion of a range of validated outcome measures with minimal drop out at the 3 months follow up (placebo 12%; verum 4%). In a main trial we would anticipate recruiting multiple physiotherapy departments across Northern Ireland but would be more prudent and estimate a drop out of 20%.

Finally this study is the first to use the Park Sham Device in acute LBP patients, and thus adds to the validity already demonstrated in healthy adults and those with stroke.[5,7] Furthermore verum acupuncture produced a clinically important (for pain and function[33,34]) and statistically significant (for worst pain) analgesic effect compared to non-penetrating sham acupuncture, at 3 months follow up. Coupled with this effect was a significant reduction in medication intake for the verum group over the course of

treatment. No significant effects were observed for function, although there was a trend for a greater (clinically important) improvement in the verum group at follow up.

Previous studies have been unable to disentangle specific from non-specific placebo effects, as all such trials used penetrating needles[23,35,36] which may produce physiological effects.[37,38] It was interesting the specific effect shown here increased over time to its greatest values at the 3 months follow up, and although difficult to interpret, similar 'delayed' analgesic effects have been observed in other studies[23,39] at a 3 months and at 24 months follow up, respectively.

Treatment dose was not controlled in this trial, as we were interested in any differences in uptake of treatments between groups. Although patients in the verum group received more treatment than those in the sham group, when this was accounted for in the analysis, it did not change results for pain or function. Whilst reasons for such differences are unclear, both therapists and patients could have influenced this; factors explaining these differences should be explored in future trials.

Apart from being underpowered, another limitation of the study was the record of medication intake: patients were asked to record in a daily diary the type of medication, the dose in mg, and the number taken per day. However, compliance was poor and thus data were extracted from the therapists' charts which indicated only the number of tablets per day. In a future trial it would be more useful to record detailed medication intake prior to each treatment, or provide patients with a prompt for a daily entry (e.g. electronically).

In conclusion, this pilot has demonstrated the feasibility of a randomized controlled trial in this area, using RMDQ as a primary outcome, and secondary outcomes of pain and medication intake. Results of such a trial would address the lack of high quality evidence for the specific effect of acupuncture in acute LBP, as highlighted by two recent systematic reviews.[8,9]

Disclosure

Dr Park developed the Park Sham Device and supplied the samples for use in the study.

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