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## Title page

### **Title:**

**Acupuncture and electro-acupuncture for people diagnosed with subacromial pain syndrome:  
A multicentre randomized trial.**

**Running head:** Acupuncture and exercise for shoulder pain

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The authors declare that they have no competing interests.

### **What does this study add?**

Shoulder pain is common and associated with substantial morbidity. Acupuncture is a popular treatment for shoulder pain. The findings suggest that acupuncture and electro-acupuncture offer no additional benefit over exercise in the treatment of shoulder pain of musculoskeletal origin.

### **Trial and Ethics Registration:**

Trial registration: ID ISRCTN10708719

National Health Service-National Research Ethics Committee (07/Q0401/2).

**Acupuncture and electro-acupuncture for people with subacromial pain syndrome:  
A multicentre randomized trial.**

**Abstract**

**Background:**

Musculoskeletal disorders have been identified globally as the second most common healthcare problem for 'years lived with disability', and of these shoulder conditions are amongst the most common, frequently associated with substantial pain and morbidity. Exercise and acupuncture are often provided as initial treatments for musculoskeletal shoulder conditions but their clinical effectiveness is uncertain. This study compared group exercise with group exercise plus either acupuncture or electro-acupuncture in patients with subacromial pain syndrome.

**Methods:**

227 participants were recruited to a three-arm parallel-group randomized clinical trial. The primary outcome measure was the Oxford Shoulder Score. Follow-up was post treatment, and at 6 and 12 months. Between-group differences (two comparisons: the exercise group versus each of the acupuncture groups) were analysed at 6 months. A similar comparison across all follow-up time points was also conducted. Data were analysed on intention-to-treat principles with imputation of missing values.

**Results:**

Treatment groups were similar at baseline, and all treatment groups demonstrated an improvement over time. Between-group estimates at 6 months were, however, small and non-significant, for both of the comparisons. The analyses across all follow-up time points yielded similar conclusions. There was a high rate of missing values (22% for the Oxford Shoulder Score). A sensitivity analysis using complete data gave similar conclusions to the analysis with missing values imputed.

**Conclusions:**

In the current investigation, neither acupuncture nor electro-acupuncture were found to be more beneficial than exercise alone in the treatment of subacromial pain syndrome. These findings may support clinicians with treatment planning.

**Keywords:**

Shoulder pain, acupuncture, electro-acupuncture, exercise, randomized clinical trial

## Introduction

Musculoskeletal disorders have been identified globally as the second most common condition associated with 'years lived with disability' (Vos *et al.*, 2012). Of these disorders, shoulder conditions are amongst the most common (Charles *et al.*, 2007). Pain is the most common symptom described by people experiencing musculoskeletal shoulder conditions and the most common reason for seeking treatment (van der Windt *et al.*, 1995).

Deriving a definitive diagnosis for most musculoskeletal shoulder conditions is difficult. Orthopaedic tests have been developed to enable clinicians to establish the cause of shoulder symptoms (Magee, 2014). However, narrative and systematic reviews have challenged the usefulness of these tests as a means of assessing isolated individual structures (Lewis, 2009; Hegedus *et al.*, 2012; Lewis *et al.*, 2015).

For those suffering low back pain it is now acceptable to classify symptoms as non-specific, simple or mechanical back pain (Waddell, 2004), without a need to be structurally definitive, and for many clinical presentations, the same may be appropriate for the shoulder region (Lewis, 2009). Conditions such as traumatic shoulder dislocations, frozen shoulder, severe osteoarthritis, avascular necrosis and tumours are ones where diagnoses may be easier to establish than those involving the bursae, the range of rotator cuff pathologies and other tissues under and around the acromion. Accordingly, 'subacromial pain syndrome' may be a more appropriate clinical classification than a specific tissue-based diagnosis or unsubstantiated aetiological mechanism such as subacromial impingement syndrome (Lewis, 2011; 2015; Lewis, 2016). Subacromial pain syndrome embraces: subacromial impingement (Haahr *et al.*, 2005; Haahr & Andersen, 2006; Holmgren *et al.*, 2012), partial-thickness (Kukkonen *et al.*, 2014) and full-thickness (Kuhn *et al.*, 2013) rotator cuff tears, as well as massive irreparable rotator cuff tears (Ainsworth, 2006). The main treatment for subacromial pain syndrome is exercise.

Although exercise is the main treatment for the majority of musculoskeletal shoulder conditions and has been demonstrated to be as effective as surgery (Haahr & Andersen, 2006; Ketola *et al.*, 2013; Kukkonen *et al.*, 2014), both exercise and surgery are frequently not fully curative and are often associated with recurrence and ongoing morbidity and pain (Linsell *et al.*, 2006; Paloneva *et al.*, 2013). Accordingly, many clinicians incorporate other treatments to reduce symptoms. Acupuncture and electro-acupuncture (acupuncture with electrical stimulation of the inserted needles) are other common methods of treating shoulder pain. Despite its popularity (Kleinhenz *et al.*, 1999; Molsberger *et al.*, 2010; Johansson *et al.*, 2011), findings from research investigating acupuncture in the treatment of shoulder pain have proven to be equivocal (Berry *et al.*, 1980; Roach *et al.*, 1991; Kleinhenz *et al.*, 1999;

Guerra de Hoyos *et al.*, 2004; Green *et al.*, 2005; Johansson *et al.*, 2005; Lathia *et al.*, 2009; Molsberger *et al.*, 2010), as well as controversial (e.g. <http://www.dcscience.net/?p=6089>, [Which?http://www.which.co.uk/news/2014/01/five-surprising-facts-about-health-treatments-350088/](http://www.which.co.uk/news/2014/01/five-surprising-facts-about-health-treatments-350088/)).

Current research demonstrates uncertainty regarding the effectiveness of acupuncture in the management of musculoskeletal shoulder pain. Green *et al.* (2005) state that due to the small number of trials to date, and their clinical and methodological diversity, there is little to support or refute the use of acupuncture for shoulder pain. Accordingly, more information is required regarding the effectiveness of acupuncture treatments in the treatment of shoulder conditions.

The aim of this study was to compare the benefits of group exercise, group exercise and acupuncture, and group exercise and electro-acupuncture in the treatment of people with musculoskeletal shoulder pain classified as subacromial pain syndrome.

Standards for Reporting Interventions in Controlled Trials of Acupuncture (STRICTA) were adhered to, and include: 1. Acupuncture rationale, 2. Details of needling, 3. Treatment regimen, 4. Other components of treatment, 5. Practitioner background, and 6. Control or comparator interventions (MacPherson *et al.*, 2010).

## **Methods**

The design of the study was a prospective, multi-centre, randomized clinical trial, with assessor blinding. Between 2007 and 2013, participants with shoulder pain were recruited from four United Kingdom National Health Service (NHS) physiotherapy clinics. Three of these clinics were based in secondary healthcare teaching hospitals and one was based in a primary healthcare community clinic. Participants were referred to the physiotherapy clinics by general practitioners, consultant physicians and surgeons, and other physiotherapists.

Potential participants presenting with shoulder pain were identified prior to commencing treatment and were given both oral and written information about the study. Those interested in learning more about the study were contacted by the principal research physiotherapist at each location. Subject to the study inclusion and exclusion criteria (Table 1), participants who agreed to participate gave written informed consent and then underwent a baseline assessment.

Table 1 near here

At each site, participants were then randomized into one of three groups:

Group I: Shoulder advice and weekly exercise group (six 50-55-minute sessions).

Group II: Shoulder advice and weekly exercise group (six 50-55-minute sessions) together with six treatments of acupuncture.

Group III: Shoulder advice and weekly exercise group (six 50-55-minute sessions) together with six treatments of electro-acupuncture.

Randomization was in a 1:1:1 ratio according to a sequence produced by a random number generator; a separate sequence was generated for each study site. Sequentially numbered opaque envelopes ensured concealment of group allocation.

### *Ethics*

Participants were fully informed of the study, including their right to withdraw from the investigation at any stage without the need to explain their decision, and were told that subsequent care would not be compromised by this decision. Ethical approval was granted by the NHS National Research Ethics Committee (07/Q0401/2).

### *Outcome measures*

The primary outcome measure for this investigation was the Oxford Shoulder Score (OSS) (Dawson *et al.*, 2009). This is a 0–48 health-related quality of life scale on which higher scores are better. Secondary outcome measures were: the Shoulder Pain and Disability Index (SPADI), a 0–100 pain and disability scale on which lower scores are better (Roy *et al.*, 2009); night pain; analgesic use; impact of main functional problem (0–10 scale on which lower scores are better); and shoulder range of movement. Two orthopaedic tests (Neer sign, Hawkin's test) were also included, not as tests to implicate a condition or structure, but as procedures to elicit symptoms associated with subacromial pain syndrome. Outcome measures were obtained prior to randomization, at the end of treatment (6 weeks), at 6 months, and at final follow-up at 12 months. The 6-month data collection was the primary outcome time-point. The data collected and the time-points at which this occurred are detailed in Table 2. Shoulder flexion, abduction, external rotation, and internal rotation ranges of movement were measured as described by Valentine and Lewis (2006).

Table 2 near here

### *Participant, therapist and assessor blinding*

The nature of the interventions did not permit the therapists providing the intervention or the participants receiving the intervention to be unaware of group allocation. However assessors who collected all the outcome data were blind to participants' group allocation at every data collection time-point.

### *Procedures*

A generic shoulder advice and exercise class that might be classified as light to moderate level of exercise, attended by all participants, was conducted once a week for 6 weeks as a circuit program. The class included: (i) warm-up exercises (e.g. static exercise bike), (ii) shoulder range of movement exercises, (iii) resisted internal and external rotation exercises, (iv) generalized shoulder strengthening exercises (e.g. pulling and pushing against resistance), (v) weight-bearing exercises (e.g. pushing Swiss ball against wall, weight through arms on Swiss ball), (vi) lower limb exercises (e.g. step-ups with concomitant upper limb elevation), and (vii) cool-down exercises. Participants who were randomized to receive acupuncture or electro-acupuncture received these additional treatments twice a week for the first 3 weeks of the 6-week shoulder programme. At each site, the shoulder advice and exercise class was conducted by two qualified physiotherapists.

Three acupuncture protocols were used, comprising: (i) an anterolateral shoulder pain protocol, (ii) a posterolateral shoulder pain protocol, and (iii) a general shoulder pain protocol (Table 3). The acupuncture point protocols were designed to correspond to the most common clinical presentations of shoulder pain and to allow some flexibility for the practitioner to modify according to individual patient's complaints; each protocol comprised points with which the practitioners were very familiar. Each participant received the protocol most relevant for his or her pain presentation. The acupuncture treatments (number of points, duration of treatment and frequency of treatment) were based on recommendations for adequate intervention (White *et al.*, 2008). Needles were inserted unilaterally, on the side of symptoms, and up to six local needles were used as well as two distal needles (forearm or

lower leg). Each acupuncture treatment lasted 30 minutes; the timing of each treatment started after the last needle was inserted.

The acupuncture needles used in this investigation were single use Seirin 0.25 x 40mm W/T, Seirin 0.25 x 50mm W/T, Seirin 0.25 x 40mm metal and Seirin 0.25 x 50mm metal (supplied by Scarsboroughs Ltd, Somerset, UK).

In the acupuncture group the needles were stimulated manually and in the electro-acupuncture group the intensity of stimulation was controlled via the stimulator. Typically, the therapists inserted all points intramuscularly (provided there was a muscle under the point) and stimulated all points every 3 to 5 minutes in order to maintain 'Deqi' for the duration of the treatment.

In addition to receiving general information about the research, all participants were made aware of any potential risks and benefits of acupuncture and electro-acupuncture, and were provided with acupuncture information sheets, acupuncture health screening questions, and an acupuncture consent form. All participants went through this process as part of the pre-randomization assessment procedures to ensure that they were aware of the possible interventions and risks and that no participant would be excluded from these treatments on health grounds following randomization. As recommended by the Acupuncture Association of Chartered Physiotherapists (AACP; a special interest group of the UK Chartered Society of Physiotherapy), routine pre- and post-acupuncture treatment advice was provided to all participants.

All physiotherapists providing acupuncture and electro-acupuncture treatments had completed a minimum of 80 hours' training in acupuncture. This period of training is based upon the UK Department of Health recommendation for health professionals (doctors, physiotherapists) wishing to provide acupuncture in the NHS. This is also the requirement of the UK Chartered Society of Physiotherapy and the UK Health and Care Professions Council. These practitioners do not use the protected title 'acupuncturist' unless registered with the British Acupuncture Council. Although having expert musculoskeletal knowledge with respect to anatomy, pathology and physiology, the physiotherapists providing the acupuncture treatment were not required to make a Traditional Chinese Medicine diagnosis or apply specialist techniques such as moxa. All practitioners were very familiar with all the points used in the protocols. As a requirement of the AACP, all physiotherapists who provided the acupuncture treatment participated annually in continuing professional development training.



The acupuncture and electro-acupuncture protocols (Table 3) were developed by a highly experienced acupuncture teacher and researcher (PB).

Table 3 near here

### *Sample size*

In the absence of a defined minimum clinically important difference on the primary outcome measure, the OSS, in this patient group, a difference of 5 points or greater was pragmatically determined to be clinically important. Assuming an associated standard deviation of 10.3 (Ainsworth, 2006), 80% power and a two-sided 5% significance level, data from a minimum 68 participants would be needed in each group, to a total of 204. To allow for 10% loss to follow-up, this figure was inflated to 76 per group, giving a total recruitment target of 228.

### *Data analysis*

Data analysis was performed on intention-to-treat (ITT) principles, with all participants analysed in the group to which they were randomized, and missing data imputed through multiple imputation under a missing at random assumption. A total of 15 multiple imputation datasets were generated. In addition to this ITT analysis with missing values imputed, a sensitivity analysis was performed on complete data only, where appropriate.

Between-group comparisons were conducted between the exercise group and each of the exercise plus (electro-)acupuncture groups. As these two comparisons represented *a priori* contrasts, no adjustment was made to the nominal level of statistical significance (Keppel & Wickens, 2004). Numerical outcome variables were analysed at the primary outcome point (6 months) by analysis of covariance, with group as the intervention factor, and the following covariates, determined *a priori*: centre, age, gender, pain duration, pain type, analgesic use, and baseline values of the relevant outcome variable. Because data on the OSS and the SPADI were negatively and positively skewed, respectively, these variables were log-transformed, after first reflecting the scores on the OSS to convert the negative skew to a positive skew. The logged estimates resulting from these analyses were back-transformed; the between-group estimates thereby become fold-changes, with the exercise only group as the reference group. Estimates on other numeric variables are given as mean differences: exercise plus (electro-)acupuncture minus exercise only.

Analgesic use and the presence of night pain were analysed at 6 months through binary logistic regression, with the same factors and covariates as above, and with the between-

group estimates expressed as odds ratios. For these outcomes, 'no analgesics' and 'no night pain' were the reference category; for the study groups, 'exercise only' was the reference category. The odds ratio therefore expresses how much more (or less) likely analgesic use or night pain is in the relevant (electro-)acupuncture group compared to the exercise only group.

In addition, the same between-group comparisons were performed on numerical outcomes across all three follow-up points simultaneously, using a multilevel model (Hox, 2010). As this analysis can accommodate missing data, no imputations were used in the analysis (Twisk *et al.*, 2013). For analgesic use and night pain, outcomes across follow-up points were compared between groups using generalized estimating equations, but with imputed missing values in order to obtain valid estimates (Birhanu *et al.*, 2011).

Statistical significance was set at  $p \leq .05$  (two-tailed) and 95% confidence intervals (CIs) were calculated for all estimates.

## Results

The CONSORT diagram (Figure 1) details the number of patients randomized, group allocation, data collection time points, and loss to follow-up. In total, 227 participants were recruited, with 43% (n=98) attending NHS community based physiotherapy clinics for treatment and 57% (n=130) attending physiotherapy clinics located in NHS teaching hospitals.

Figure 1 near here

Baseline characteristics were similar across all the groups following randomization, though analgesic use was somewhat lower in the exercise only group (Table 4). At baseline, the median duration of pain in the sample was 6 months and the mean rating of the impact of participants' main functional problem (0–10 scale) was 5.87. The onset of pain had in most cases (68%) been non-traumatic. Activities involving shoulder flexion and abduction were described as the most painful movement by 63% of participants.

Table 4 near here

Values of the outcome measures at the three follow-up times are shown in Table 5. There were higher rates of missing values than were anticipated. At the primary outcome point (6 months) missing values were: OSS,  $n=50$  (22%); SPADI,  $n=75$  (33%); main functional problem,  $n=50$  (22%); shoulder flexion,  $n=50$  (22%); shoulder abduction,  $n=49$  (22%); shoulder lateral rotation,  $n=49$  (22%); analgesic use,  $n=54$  (24%); night pain,  $n= 52$  (23%). There does not seem to be a pattern to the reasons for dropout across the study groups, nor in relation to the study sites (Figure 1).

Table 5 near here

Figures 2 and 3 demonstrate that all groups experienced improvement over the duration of the study, as indicated by higher scores on the OSS and lower scores on the SPADI. Other outcomes show a similar overall improvement within each group, with the exception of lateral rotation of the shoulder joint, in which little change occurred (Table 5). Table 6 shows the estimates of effect at 6 months. In the ITT analysis, for both comparisons, between-group estimates were small and non-significant in respect of all outcomes, and were furthermore not in a consistent direction, with some estimates favouring the acupuncture or electro-acupuncture group and others favouring the exercise only group. The statistical conclusions were similar for the analyses on complete data. The results of the analyses across all follow-up time points are shown in Table 7; again both between-group comparisons yielded small and non-significant effects for all variables.

Figures 2 and 3 near here

Tables 6 and 7 near here

For those randomized to acupuncture or electro-acupuncture treatment, 69.7% received Protocol I (anterolateral), 11.8% received Protocol II (posterolateral), and 18.5% received Protocol (III) (generalized). The median number of treatments given was 6 (interquartile range: 6, 6) in each of the acupuncture groups.

Although participants were requested to complete exercise diaries, the majority of participants either did not complete or return their exercise diaries and compliance data were therefore not analysed.

There were no significant adverse events reported as a result of exercise, or in either of the acupuncture groups. However, the reasons for participants leaving the study were not available for all those dropping out, and the reasons for dropping out may have related to adverse events such as an increase in pain and/or other symptoms.

## Discussion

Although acupuncture is increasingly recommended and used to treat pain associated with musculoskeletal disorders of the shoulder, including subacromial pain syndrome, the evidence to support its use remains equivocal (Green *et al.*, 2005). Accordingly, this study sought to test its effectiveness as an adjunct to exercises in this condition.

In the current investigation, all three groups demonstrated improvement in the outcomes of interest over the period of the study. For nearly all outcomes, between-group differences were small and non-significant, and did not consistently favour any of the study interventions. The observed effect of electro-acupuncture on current analgesic use at six months was clinically meaningful (odds ratio of 0.560; Table 6). However, this was non-significant, as the study was not specifically powered for binary outcomes, and it should be noted that the effect on analgesic use across all follow-up points was smaller (odds ratio of 0.827; Table 7). If analgesic use had been measured, rather than just dichotomized, more informative estimates might have resulted.

These results suggests that acupuncture and electro-acupuncture did not confer any additional benefit over exercise for people diagnosed as having subacromial pain syndrome. This is in contrast to the use of acupuncture in knee pain, where acupuncture treatment has been found to provide significant clinical improvement over standard care and no treatment (White *et al.*, 2007). The role of exercise in the treatment of subacromial pain syndrome is supported by findings in other studies. In investigations comparing exercise and surgery for subacromial impingement syndrome, exercise was found to be as beneficial as subacromial decompression and exercise (Haahr *et al.*, 2005; Haahr & Andersen, 2006; Ketola *et al.*, 2013), and in investigations comparing partial thickness tears of the rotator cuff, exercise was again reported to be as beneficial as surgical repair of the tear and exercise (Kukkonen *et al.*, 2014). As in the current investigation, these other studies did not include a control group and it is therefore not possible to determine if the within-group improvement reported in the current or other published investigations related to natural improvement over time or was due to the exercise therapy received. Although the impact of natural history over time is currently unknown for subacromial pain syndrome, research from investigations that have compared low-level exercise to higher-level and graduated exercise have reported significant clinical benefit in the higher-level exercise groups and a concomitant significant reduction in the need for surgery (Holmgren *et al.*, 2012; Hallgren *et al.*, 2014), findings that suggest a beneficial role for exercise therapy. All participants in this study had similar moderate level exercises; however, the most effective exercise program (type, intensity, duration, frequency, progression) is not currently known. Outcomes may have been enhanced by prescribing and

progressing exercises based on individual assessment, as well as incorporating strength training and additional lower limb exercises.

Despite broad use of acupuncture (with varied success), it has been recognized that treatment protocols vary significantly to allow a robust clinical choice as to the number of points, the intensity of stimulation, the repetition and the duration and total number of treatments (White, 2008). Furthermore, there seems to be controversy as to whether manual acupuncture is comparable in its mechanism of action to that of electro-acupuncture (Langevin *et al.*, 2015). In consideration of these factors, the current acupuncture protocol was designed to reflect a dose of stimulation that can be characterized as adequate, in that it offered a reasonable number of local and distal points, duration of treatment of 30 minutes, and a repetition of the treatment twice weekly for 3 weeks. The protocol also represents acupuncture as typically used within the practice of physiotherapists, and our findings are not necessarily generalizable to the practice of specialist acupuncturists.

The majority of participants randomized to acupuncture or electro-acupuncture received the maximum 6 treatments, and it therefore appears that, whether the reported benefit was due to natural improvement and/or exercise, there was no added benefit from these additional 6 acupuncture treatments. It is possible that greater benefit might have accrued from a longer period of treatment, similar to what is recommended for back pain in NICE guidelines (Savigny *et al.*, 2009). Additionally, it is possible that benefit occurred after the 6-week follow-up at the end of treatment but attenuated prior to the 6-month follow-up, and was therefore undetected. Patient values, beliefs and preference are unquestionably important in determining the appropriate management for any individual seeking treatment for shoulder pain. Communicating the findings of this investigation, together with its limitations, may support both the clinician and patient in the decision making process as to the most appropriate treatment for the individual.

For the primary outcome measure, the OSS, the improvement was most marked at the early follow-up at the end of treatment, which may reflect the fact that the sample was composed of incident cases, who are likely to have consulted when symptoms were at their peak. Again, however, the absence of a no-treatment control group means that we cannot determine to what extent the improvement was due to the treatments that participants received as opposed to spontaneous resolution of symptoms.

Although the final number of participants recruited was just one short of the recruitment target, there were a large number of missing values in this study, which may reflect the nature of long-term clinical trials; participants' commitment to the investigation may change over time, or they may move away from the area where the trial is being conducted or

change their contact information. Although, missing values were replaced through imputation or accommodated within a multilevel model, and a sensitivity analysis on complete data reflected the primary ITT analysis, the rate of missing data leads to some uncertainty in the estimates from the study. It must also be recognized that data were imputed on a missing-at-random assumption, and if data were missing not at random – which cannot be determined from the data at hand (Sterne *et al.*, 2009) – our estimates may be biased.

Additional sources of bias relate to protocol. Greater understanding of the benefit of acupuncture may have been derived by including placebo acupuncture in the exercise only group. This would have introduced an element of participant blinding. However, as no additional benefit was observed in the other two groups the benefit of including placebo acupuncture is uncertain. In addition, this study did not assess participant expectations, which may have had an influence on outcome. We did not, unfortunately, have reliable information on patients who were screened for eligibility but not subsequently recruited, which affects the external validity of our findings. Additionally, the low rate of completion of the exercise diaries does not allow us to determine differential adherence to exercise in the treatment groups.

This study investigated people diagnosed with subacromial pain syndrome and the addition of acupuncture and electro-acupuncture was not found to confer additional benefit to exercise. As acupuncture is a commonly recommended treatment for shoulder pain and research findings are uncertain, other shoulder conditions commonly associated with high levels of constant and protracted pain, such as frozen shoulder and calcific tendinopathy, would benefit from an understanding of the role of acupuncture in their management.

## **Conclusion**

In the current investigation neither acupuncture nor electro-acupuncture were found to be more beneficial than exercise alone in the treatment of subacromial pain syndrome and clinicians should therefore consider carefully the inclusion of (electro-)acupuncture in the management of these patients. Further research is required to understand the natural history of subacromial pain syndrome, and the use of acupuncture and electro-acupuncture in other shoulder pain conditions such as frozen shoulder and calcific tendinopathy.

### **Competing interests**

The authors declare that they have no competing interests

### **Author's Contributions**

JL conceived the idea and secured funding. JL had full access to the data and takes responsibility for the integrity of the data. JL secured ethical approval for the multicentre investigation and generated the randomization tables. JL and PB designed the trial protocol. JL instructed the principal investigators at each site on trial procedure, equipment use, data acquisition and data recording. JS conducted the statistical analysis. JL and JS drafted the manuscript and PB contributed to the manuscript. All authors read and approved the final manuscript.

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