Acupuncture for acute non-specific low back pain: a randomised, controlled, double-blind, placebo trial

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ABSTRACT

Objective To assess the efficacy of Yamamoto's acupuncture method on pain, drug intake, functional capacity and quality of life for the treatment of acute non-specific low back pain (ANLBP).

Methods A prospective, randomised, parallel-group, double-blind, placebo-controlled trial was performed in 80 men and women with ANLBP who were randomly assigned to five acupuncture sessions (intervention group (IG), n=40) and to five non-penetrating acupuncture sessions (sham group (SG), n=40). Patients were evaluated at baseline and at 3, 7, 14, 21 and 28 days. The measurements used were: visual analogue scale (VAS) for cumulative pain (before intervention, VAS1) and immediate pain (after intervention, VAS2); function (Roland–Morris Disability Questionnaire (RM)); quality of life (SF-36); improvement rating; and number of anti-inflammatory tablets taken. The primary endpoint was a decrease of at least 2 cm in VAS1.

Results Pain VAS improved significantly in the IG from day 14 onwards compared with the SG, but the difference did not reach the prespecified clinically relevant value of 2 cm. The IG was significantly superior to the SG in the following outcomes: cumulative pain, function, pain (SF-36) and vitality (SF-36) at days 14, 21 and 28 ($p<0.05$); limitation in physical aspects (SF-36) at all times ($p=0.007$ and $p=0.02$); and functional capacity (SF-36) at days 21 and 28 ($p<0.05$). The IG also took significantly fewer anti-inflammatory tablets than the SG ($p=0.004$) at all evaluation times and the improvement rating was better than the SG ($p<0.001$).

Conclusions Yamamoto's new scalp acupuncture was more effective than sham treatment with regard to decrease in pain and anti-inflammatory intake as well as improving functional status and quality of life for patients with ANLBP.

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INTRODUCTION

Acute non-specific low back pain (ANLBP) is unrelated to any specific disease. According to epidemiological studies, 65–90% of adults suffer an episode of low back pain at some time in their life, with the peak incidence occurring between 35 and 55 years of age. The prevalence is 15–45% and the incidence is 5% among adults per year.[1 2]

ANLBP is self-limiting in 90% of cases, with improvements in pain and incapacity, and participants return to work within 4–6 weeks; only 2–7% will progress to the chronic form.[3] Acute low back pain of non-specific musculoskeletal origin accounts for almost 95% of cases.[4 5] Although the majority of participants improve regardless of medical intervention, a variety of therapeutic interventions are available including acupuncture.[1 3 6 7]

Acupuncture is one of the oldest forms of therapy.[8] Many acupuncture styles have been developed in recent decades.[8 9] Yamamoto's new scalp acupuncture (YNSA) was created by Japanese physician Toshikatsu Yamamoto in 1971. The theory behind YNSA involves seven microsystems, five with therapeutic attributes located in the head (basic, sensory, cerebral, ypsilon points and cranial pairs) and two with diagnostic attributes located in the cervical and abdominal regions. In the treatment of low back pain, basic points said to be specific to conditions of the spine are used.[10 11]

Many studies have analysed the effects of acupuncture on chronic low back pain,[5 12] but rigorous studies have yet to be made to evaluate the efficacy of acupuncture in acute low back pain.[8 9]

The aim of the present study was to assess the efficacy of YNSA on pain, drug

intake, functional capacity and quality of life for the treatment of ANLBP. Our hypothesis is that YNSA can decrease pain and drug intake and improve function and quality of life in patients with ANLBP.

METHODS

A randomised, controlled, double-blind, prospective trial was conducted.[13] Participants were recruited from the emergency room of University Hospital (Federal University of São Paulo—UNIFESP) and assessed by a rheumatologist between August 2006 and September 2007. The inclusion criteria were men or women aged 18–65 years seeking medical assistance for ANLBP, defined as pain and discomfort localised below the costal margin and above the inferior gluteal folds for a period of less than 30 days and unrelated to any specific aetiological factors with a score of 4–8 cm on the pain scale (0–10 cm), who agreed to participate and gave their signed informed consent.

Participants with a secondary diagnosis such as spondyloarthropathy, infection, tumour or fracture, complete sciatalgia, previous surgery on the spinal column, litigation, who had changed physical activity or undergone acupuncture or physical therapy in the previous 3 months, had previously undergone scalp acupuncture or who were pregnant or had a contraindication to anti-inflammatory drugs were excluded.

The participants were randomly assigned using a computer-generated random permuted block method to either an intervention group (IG) who received five acupuncture sessions or a sham group (SG) who received five non-penetrating acupuncture sessions.

Procedures

This study used YNSA because of the experience of the physician acupuncturist in this technique. Only one acupuncturist with 8 years of experience gave treatment. In addition to the shorter duration (20 min) and smaller number of sessions (5 sessions) compared with traditional Chinese acupuncture,[10 11] the technique has the advantage of using low-cost materials and requiring little space.[10 14] The patients are seated and points are located only in the scalp rather than spread throughout the body, making standardisation easier.[10 11]

The treatment was planned for all study participants using the points for treatment of low back pain according to the YNSA technique and was given bilaterally.[10 11 15] The basic points D, H and I and kidney, bladder and liver points of Yamamoto's method were used as standard treatment for ANLBP for both groups (table 1).[10 11] The average number of needles inserted in each participant was 10.

The needle penetrated the skin at an angle of approximately 15° to a depth of 0.3–0.5 cm. Manual palpation of the scalp is the safest method to find the proper location of YNSA points. The patient's facial expression of pain during palpation of the scalp serves to indicate the location of needling. The needles were stimulated manually and retained for 20 min. Sterilised disposable stainless steel needles, 0.20×13 mm, (Suzhou Huanqiu Acupuncture Medical Appliance Co) were used.[10 11 15]

During the session the patients remained seated, wearing a cap with a central orifice exposing the area to receive the needles and a wide brim to blind the patient from the procedure. Five acupuncture sessions were performed, each lasting 30 min. Participants missing more than three acupuncture sessions and evaluations were considered losses.

The IG received five real acupuncture sessions and the SG received five non-penetrating acupuncture sessions in which only the handle came into contact with the skin at the same points as the IG. Manual palpation of the scalp performed by the acupuncturist before the acupuncture session was made in the same way for both groups.

All participants were blinded to which procedure they were receiving. Before randomisation all participants were informed that they could be allocated to

Table 1 Yamamoto's new scalp acupuncture points used

Acupuncture points	Location
Basic point: D	Temporal region, 4 cm from the helix, in front of the ear and 1 cm above the zygomatic arch
Basic points: D1–D6	Another 6 points (D1–D6), like beads forming a vertical line about 2 cm in length, behind the D point, in front of the ear, above the temporomandibular joint
Basic point: H	2 cm to the side of the midline and 0.5 cm above the hairline
Basic point: I	5 cm to the side of the midline and 4 cm above the hairline, at a 45° angle
Y point: Bladder	Below the zygomatic arch
Y point: Kidney	1 cm above the Y point: bladder
Y point: Liver	1 cm above the top of the helix
Diagnostic points of cervical region: Kidney	Posterior border of the sternocleidomastoid muscle or between the strands of the muscle in the insertion above the bladder point
Diagnostic points of cervical region: Bladder	Posterior border of the sternocleidomastoid muscle, behind the clavicle
Diagnostic points of cervical region: Liver	Middle third of the sternocleidomastoid muscle

the needling acupuncture group (IG) or to a group where the needle will touch the surface (SG). The assessor was blinded but the acupuncturist was not.

Both groups were recommended to take 50 mg sodium diclofenac every 8 h for lumbar pain if needed and to record the number of pills on a standardised form. The participants were instructed not to use other medications or therapies for low back pain during the study.

The medical practitioner is a member of the Brazilian Medical Association of Acupuncture and has practised acupuncture for 15 years.

Evaluations

The patients were evaluated six times: at baseline (D0) and after days 3 (D3), 7 (D7), 14 (D14), 21 (D21) and 28 (D28). Outcome measures were recorded by a single assessor who was blinded to group allocation; the assessor was a physiotherapist trained in the instruments used.

The primary clinical outcome evaluated was the visual analogue scale (VAS) for pain, graded in cm from 0 (no pain) to 10 (worst imaginable pain) measured before each acupuncture session (VAS1) to evaluate the cumulative effect and after the session (VAS2) to evaluate the immediate effect of acupuncture.

Secondary outcomes were the Roland–Morris Disability Questionnaire (RM) to assess the functional capacity (score range 0–24 with higher scores denoting poorer functional capacity)[16]; the Short Form 36 Health Survey (SF-36) to assess the quality of life (score range 0–100 with higher scores denoting better quality of life)[17]; improvement rating[7] (based on the patient's and the blinded assessor's answers to the question: "How are you (the patient) feeling today, taking into account how you were at the beginning of treatment?" categorised as 1=much better, 2=slightly better, 3=no change, 4=slightly worse and 5=much worse). Both groups were asked the number of 50 mg sodium diclofenac pills taken per day.

To evaluate sham credibility, the participants were asked at the end of the study (day 28) if they believed they had received acupuncture or sham.[12 14 18]

Before the start of each acupuncture session, participants were asked if they had experienced any adverse reaction to drug intake or needling after the last acupuncture session and this was recorded on the patient's form.

Statistical analysis

To achieve an improvement compared with the SG in VAS pain of 2 cm with a significance of 0.05, a power of 0.80 and a SD of 2 cm in VAS for pain, a minimum of 30 participants per group were necessary. A number of studies have indicated that a change of 1.0–1.3 cm on a VAS scale of 10 cm represents the minimal clinically significant difference[19 20]; based on this, 2 cm was defined as clinically significant in this study. However, 40 participants were randomised as a precaution for a possible 20% loss at follow-up.[21]

The primary endpoint was the difference between the groups in pain VAS. The main analyses were by intention to treat using the last observation carried forward method. A level of significance of $p<0.05$ (two-tailed tests) was accepted for the trial. All tests were performed using SPSS V.15.0 and MINITAB V.14.0. The following analyses were done:

- Repeated measures analysis of variance for normally distributed data and categorical data performed between groups (acupuncture vs non-penetrating acupuncture; between-subject factors) and over time (baseline, 3, 7, 14, 21 and 28 days; within-subject factors).[21]
- Student t test to compare numerical variables with normal distribution at one time.
- χ^2 test or Fisher exact test to determine differences in rates of improvement between the two groups.
- κ index to determine agreement on the improvement rating assessment between patient and assessor.

RESULTS

The flowchart of the study is presented in figure 1. All participants received at least three acupuncture sessions. The two groups were homogeneous with regard to demographic characteristics, duration of pain, education and occupation (table 2).

At baseline the groups were homogeneous for almost all clinical and demographic characteristics (tables 1–3). Differences between groups were found after the first acupuncture session for VAS2 ($p=0.007$) and at baseline for limitation in physical aspects of SF-36 ($p=0.022$).

For pain in VAS1, significant differences were found between the two groups favouring the IG at D14, D21 and D28 ($p=0.024$, 0.003 and 0.005, respectively). The size of the difference was 4.57 cm in the IG and 3.3 in the SG (table 3). For VAS2, significant differences favouring the IG were found at all times ($p=0.007$, table 3). The size of this difference was 2.06 cm in the IG and 1.68 cm in the SG.

With regard to function (RM), the results show an improvement favouring the IG at D14 ($p=0.002$), D21 ($p=0.001$) and D28 ($p=0.002$) (table 3).

There were no significant differences between the groups regarding social aspects, emotional aspects and mental health components of SF-36 ($p>0.05$). However, for functional capacity at D21 ($p=0.022$) and D28 ($p=0.007$), limitation in physical aspects at all evaluation times ($p=0.022$), pain at D14 ($p=0.013$), D21 ($p=0.007$) and D28 (0.044) and vitality at D14 ($p=0.001$), D21 ($p=0.024$) and D28 ($p=0.043$), a more significant improvement was observed in the IG (table 4 and online supplementary table S4).

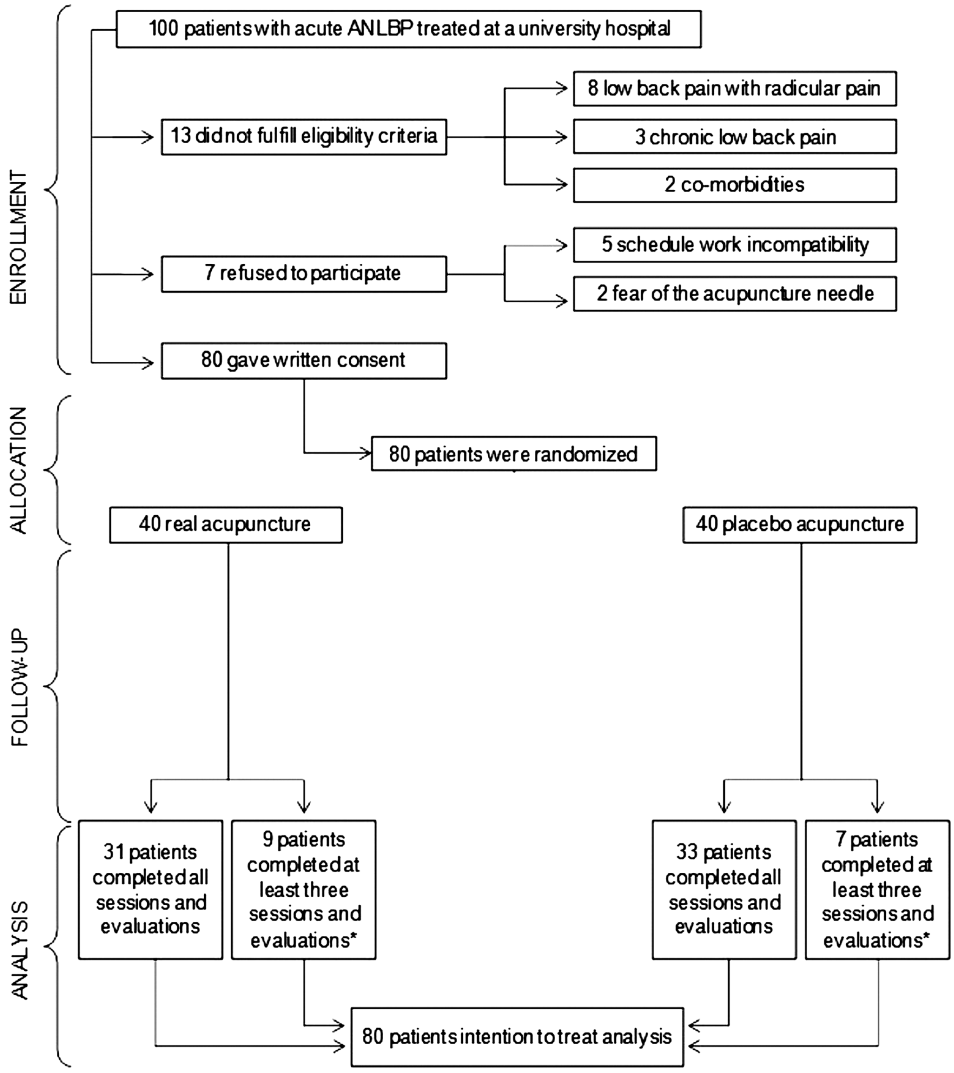

Figure 1 Flowchart of the study. ANLBP, acute non-specific low back pain.

There were significant differences in the recorded anti-inflammatory intake between all evaluations (p=0.004), with the lowest intake in the IG (table 4).

With regard to the improvement rating, the opinion of the participant and the assessor showed significant differences favouring the IG at all times (p<0.001), and the κ index revealed agreement between participants and the assessor regarding this scale (p<0.001).

The sham credibility assessment showed that all participants in the IG believed they were receiving real acupuncture and only four participants in the SG thought they received the sham. Excluding participants who did not believe they received real acupuncture (n=36) in the SG and compared with all participants in the IG (n=40), we found significant differences in VAS1 favouring the IG at D14 (p=0.035), D21 (p=0.002) and D28 (p=0.012).

No side effects were reported with the acupuncture technique used in the study. No patient reported side

Table 2 Clinical and demographic characteristics of participants

	Intervention group (N=40)	Sham group (N=40)	p Value
Mean (±SD) age, years	47.0 (±9.8)	43.9 (±10.9)	0.177
Mean (±SD) years of education	6.6 (±3.6)	5.8 (±3.7)	0.260
Gender			0.816
Men	15 (37.5%)	14 (35.0%)	
Women	25 (62.5%)	26 (65.0%)	
Ethnic background			0.496
Caucasian	25 (62.5%)	22 (55.0%)	
Non-Caucasian	15 (37.5%)	18 (45.0%)	
Mean (±SD) duration of pain in days	15.1 (±11.6)	15.4 (±11.1)	0.961
Occupation			0.239
Heavy worker	35 (87.5%)	31 (77.5%)	
Light worker	5 (12.5%)	9 (22.5%)	

Statistical tests used: χ^2 test and Student t test.

Table 3 Comparison between intervention and placebo groups regarding VAS1, Roland–Morris Disability Questionnaire and number of pills among participants at different evaluation times

	Baseline		Day 3		Day 7		Day 14		Day 21		Day 28	
	IG	SG	IG	SG	IG	SG	IG	SG	IG	SG	IG	SG
VAS1	6.55±1.40	6.68±1.44	4.63±2.23	5.13±2.21	3.83±2.61	4.40±2.09	2.80±2.27	3.95±2.19	2.49±2.40	4.18±2.52	1.98±2.12	3.38±2.26
p Value	0.694		0.317		0.280		0.024*		0.003*		0.005*	
VAS2	3.80±1,88	4.68±2.26	2.90±2.06	4.38±2.44	2.58±2.30	3.30±2.47	1.93±1.83	3.03±2.35	1.74±2.07	3.00±2.41		
p Value	0.007*		0.007*		0.007*		0.007*		0.007*			
Roland–Morris	14.90±4.00	14.60±4.80	10.30±5.40	12.40±4.50	8.10±5.50	10.20±5.30	5.30±4.60	8.90±5.20	4.40±4.40	8.50±6.20	4.10±4.70	8.00±6.10
p Value	0.742		0.062		0.079		0.002*		0.001*		0.002*	
Number of pills			1.5±2.6	2.6±2.8	1.9±3.6	4.2±4.7	1.3±3.1	3.3±6.0	1.2±2.8	3.7±5.2	1.1±2.7	2.3±3.9
p Value			0.004*		0.004*		0.004*		0.004*		0.004*	

Data presented as mean±SD.
*Statistically significant difference (analysis of variance).
IG, intervention group; SG, sham group; VAS1, visual analogue scale of pain before acupuncture sessions; VAS2, visual analogue scale of pain after acupuncture sessions.

Table 4 Comparison between intervention and placebo groups regarding SF-36 domains at baseline and end of the study

	Baseline		Day 28	
	IG	SG	IG	SG
FC	46.40±22.70	55.80±19.20	84.00±19.80	70.90±22.50
p Value	0.050		0.007*	
LPA	18.10±6.50	16.30±26.30	78.80±31.80	55.80±38.30
p Value	0.022*		0.022*	
Pain	27.60±7.90	28.80±19.10	67.80±26.10	56.50±23.40
p Value	0.773		0.044*	
GHS	54.20±5.70	56.50±24.90	69.00±22.90	63.40±22.60
p Value	0.689		0.277	
Vitality	49.40±5.30	47.60±17.30	69.60±23.20	58.80±24.00
p Value	0.719		0.043*	
SA	62.50±34.60	65.90±32.30	89.70±17.40	82.50±25.90
p Value	0.258		0.258	
EA	57.50±41.30	62.50±40.10	81.70±30.10	76.70±36.40
p Value	0.511		0.511	
MH	54.30±22.00	58.50±19.70	66.40±22.50	65.20±22.80
p Value	0.759		0.759	

Data presented as mean±SD.
*Statistically significant difference (analysis of variance).
EA, emotional aspects; FC, functional capacity; GHS, general health state; IG, intervention group; LPA, limitation in physical aspects; MH, mental health; SA, social aspects; SG, sham group.

effects to medication such as stomach ache or nausea and there were no reports of needling reactions or increased pain after acupuncture session.

DISCUSSION

In this study there was a benefit in the IG regarding pain, functional status, some domains of quality of life and reduction in the overall consumption of sodium diclofenac. The difference in pain observed needs to be analysed with caution since, despite an improvement of >2 cm observed for the IG and SG over time, the difference between the groups for immediate pain (1.4 cm) and cumulative pain (1.26 cm) at the end of the study did not reach the prespecified clinically relevant value (2 cm). The overall importance of these findings is that YNSA could be a new tool for use in the treatment of ANLBP, especially for immediate pain relief; thus, the sooner the patient recovers, the sooner he or she can return to their work activities.[1 2 22]

The cumulative effect of YNSA on pain showed a clinically significant improvement during the treatment period (>2 cm), with the IG showing a better result.[21] However, the difference between real and sham YNSA did not reach 2 cm at the end of the study, so this improvement in IG needs to be interpreted with caution. Some or all of the change in the IG could be due to time alone.

For the cumulative effect of acupuncture on pain, both groups improved until D14 with no significant

difference between them but, from this point onwards, the IG exhibited significantly greater improvement with a sustained effect until the end of the study.

Regarding the immediate effect of acupuncture on pain, this study found significant differences between the two groups, favouring the IG at all evaluation times, showing that YNSA led to immediate pain relief from the beginning of treatment.

Until D7, participants in both groups arrived at the sessions with almost the same pain scores, but those in the IG left the sessions with less pain. On D14 and D21, participants in the IG arrived at the sessions with less pain than those in the SG, which could be explained by the cumulative effect of acupuncture. The follow-up period was 28 days, as the literature reports complete resolution of ANLBP within this period in over 90% of cases, justifying why we did not perform the intervention at D28.[1 2 22–24]

The latest Cochrane review included 35 studies (2861 participants) including those published in Chinese and Japanese on the treatment of low back pain, only three of which involved participants with ANLBP. Some studies compared acupuncture with sham or other treatments.[8] Araki *et al*[25] and Sakai *et al*[26] did not find any differences between intervention and sham groups. All these studies had poor methodological quality, leading to inconclusive results.[8]

This study with YNSA differs from previous studies because of its larger sample size and strict control.[8] We took care to include only participants with ANLBP. The mean duration of pain reported at the beginning of this study was 15 days in both groups, compared with other studies that included participants with pain lasting more than 3 months.[26 27]

In view of the acute nature of low back pain, the evaluations in the present study were repeated over short intervals of time. The objective was to obtain a more accurate assessment of the technique for use in the treatment of acute low back pain. Other studies in which the intervals between assessments were very long (over weeks) may not capture the moment of pain improvement.[8 25–29]

Functional assessments were carried out at all evaluation times rather than only at the beginning and end of the study, as in the majority of trials.[29 30] A recent systematic review of acupuncture for the treatment of ANLBP found conflicting results regarding functional capacity.[8 9] No quality of life assessment tools were used in the latest systematic review of acupuncture for the treatment of ANLBP.[8]

There was a significant difference favouring the IG in the patient improvement rating and assessor improvement rating at all evaluation times. Participants in the IG reported feeling 'much better' and 'slightly better' whereas those in the SG reported feeling 'slightly better' and 'no change', indicating significant reproducibility of the method. The clinical implications of these findings are the fast recovery of patients' daily activities, allowing return to work, improvements in their emotional and psychosocial state and improvements in social integration.[8 22]

There was a significantly greater reduction in the overall consumption of sodium diclofenac in the IG than in the SG at all evaluation times. Unlike the present study, studies in the literature do not address the number of anti-inflammatory tablets used throughout the length of the study or at different evaluation times.[8 29] This may be particularly relevant for geriatric populations or those with gastrointestinal and renal comorbidities who should not use high doses of anti-inflammatory drugs.[5]

A major methodological problem in studies of acupuncture is the difficulty in the selection and appropriate use of sham.[14 31 32] The use of sham in acupuncture remains a controversial topic.[31 32] There are several studies in the literature that have sought to find the ideal sham.[5 31 32]

VAS1 results were compared between the participants of the SG who believed they received acupuncture (n=36) and those in the IG (n=40), showing the same significant differences as when the analysis included all the participants of the SG (n=40). This finding is important to the veracity of our results, showing the credibility of the sham technique employed.[32 33]

The limitations of our study were the lack of adjusting for confounders (beyond analgesic intake); sham intervention that might not be as inert as it sounds since the acupuncturist's touch on the scalp could result in pain relief, as shown in some studies,[12 26] although this touch occurred in both groups; and the follow-up duration, since we know that the median recovery time of ANLBP is 58 days[34] and our study duration was 28 days.

Another limitation of our study was the decision to use only one acupuncturist. Although we knew that this could introduce bias, we believe that the use of more than one acupuncturist could introduce other biases. The lack of blinding of the acupuncturist, even though this is difficult to achieve, could also be considered a limitation.

We conclude that YNSA is more effective than sham treatment in ANLBP with regard to decrease in pain and anti-inflammatory intake as well as improving functional status and quality of life, although the differences did not reach clinical significance between the groups at the end of the study. Further larger studies are needed to replicate the findings of this study.

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Contributors TMH: conception and design, data analysis and interpretation. ASB: the assessor of the study; study design, analysis and statistics. MCdS: conception, statistics and analysis of data. AMY: acupuncturist; conception and design, data interpretation. JN: conception and design, drafting the article and revising it critically for important intellectual content and final approval of the version to be published.

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Patient consent Obtained.

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Notes