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The placebo needle, is it a valid and convincing placebo for use in acupuncture trials? A randomised, single-blind, cross-over pilot trial

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Abstract

The issue of what constitutes an effective and realistic acupuncture placebo control has been a continuing problem for acupuncture research. In order to provide an effective placebo, the control procedure must be convincing, visible and should mimic, in all respects, apart from a physiological effect, the real active treatment. The 'Streitberger' needle might fulfil these criteria and this paper reports on a validation study. This was a single-blind, randomised, cross-over pilot study. Patients were drawn from the orthopaedic hip and knee, joint replacement waiting list. Intervention consisted of either 2 weeks of treatment with real acupuncture followed by 2 weeks on placebo, or vice versa. The prime outcome was a needle sensation questionnaire and there was a range of secondary outcomes. Thirty-seven patients were randomised and completed treatment. Groups were well balanced at baseline. No significant differences between groups or needle types were found for any of the sensations measured. Most patients were unable to discriminate between the needles by penetration; however, nearly 40% were able to detect a difference in treatment type between needles. No major differences in outcome between real and placebo needling could be found. The fact that nearly 40% of subjects did not find that the two interventions were similar, however, raises some concerns with regard to the wholesale adoption of this instrument as a standard acupuncture placebo. Further work on inter-tester reliability and standardisation of technique is highly recommended before we can be confident about using this needle in further studies.

Keywords: Acupuncture; Placebo; Placebo needle

1. Background

Research into the efficacy of acupuncture has raised a number of difficult methodological issues, particularly in relation to the selection of appropriate controls. Separating the specific effects of acupuncture from its non-specific effects is extremely difficult because acupuncture is a physical, invasive, manual procedure involving considerable practitioner time and some ritual. It is however, important to be able to quantify the relative effects of these two factors (Hammerschlag and Morris, 1997; de la Torre, 1993). Other possible confounding factors might be linked to a patient's preconceived ideas of efficacy around a particular treatment regime and this too must be assessed as part of a non-specific effect.

In order to provide an effective and credible placebo (defined as a physiologically inert procedure), the control must be convincing and should mimic, in all respects, apart from a physiological effect, the real active treatment (Ernst and White, 1997; Peck and Coleman, 1991). Various control options have been utilised in the context of clinical research within acupuncture, i.e. insertion of acupuncture needles into non-acupuncture points, several forms of dummy needling and mock TENS, but as yet none have fulfilled all the criterion simultaneously of being either truly inert, easily usable and effective at mimicking real pragmatic acupuncture.

To be truly credible in this context, a placebo should be visible to the patient and it should appear as though the skin is being penetrated, the Streitberger needle might fulfil these criteria (Streitberger and Kleinhenz, 1998). As the needle is pushed against the skin, it causes a pricking sensation but as increased pressure is applied, the shaft of the needle

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disappears into the handle, mimicking a 'stage dagger'. This gives the impression that the needle is actually entering the skin. The needle is held in position by a small adhesive plastic ring, which can also be used with the real needles to aid consistency and credibility. Streitberger evaluated this system on 60 volunteers who were subjected to both real and placebo needling in a cross-over trial. Streitberger reported that 90% of subjects in the acupuncture group and 78% in the placebo group felt needle penetration. No patients had suspected that their skin had not been punctured. It has been pointed out, however, that the needles might not be appropriate for use in certain areas such as the scalp, toes and fingers, also that there may be some limitation in the angle of needle insertion (Kaptchuk, 1998). Despite this the 'placebo' needle (thus named by Streitberger) has been used in a clinical trial (Kleinhenz et al., 1999) and may offer for the first time, a usable and believable non-penetrating acupuncture control.

Before this needle is adopted into general use however, further validation needs to be undertaken. In particular an understanding of inter-tester reliability needs to be examined, i.e. do different practitioners achieve similar results with similar treatments?

2. Method

2.1. Objectives

The primary objective of this study, therefore, was to provide independent validation of the credibility of the Streitberger placebo needle and to compare the needling sensations for the two types of needles. Secondary objectives were to gain an indication of inter-tester reliability when using the placebo needle, and to ascertain if subject's pre-treatment belief in complementary and alternative medicine (CAM) has any influence on outcome.

A cross-over design was used so that each patient would be able to compare both needle types. At the end of each treatment period, patients were asked to complete a questionnaire to assess the sensations felt on needling. Patients were also asked if they felt the needles go into the skin. Designing the trial in this way enabled us to ascertain if patients were readily able to detect a difference between the needles with regard to these parameters. Within-patient comparisons of these assessments were made using non-parametric procedures.

2.2. Patient selection

Subjects were recruited from the orthopaedic hip/knee joint replacement waiting list at Southampton General Hospital. It was felt that this would provide a source of subjects with a chronic yet fairly stable condition who were not undergoing concomitant treatment apart from routine analgesia. Ethical approval was obtained from the Southampton and South West Hants Joint Local Research Ethics Committee. All subjects were contacted by telephone or letter and asked to attend an assessment interview. Inclusion and exclusion criteria were as follows.

Inclusion criteria:

- Aged between 18 and 80 years with chronic/stable pain, predominantly from a single joint (hip or knee) of known mechanical aetiology (i.e. non-systemic).
- Patients should score an average of 3 or more on the visual analogue scale (VAS) in the pre-randomisation phase of the study and not be on any current active treatment (e.g. physiotherapy, homeopathic).
- Literate in English and able to attend clinic twice a week for duration of treatment.

Exclusion criteria:

- Pregnancy, serious comorbidity (including severe back pain), recent (within 6 months for oral and 1 month for injection) or current steroid use and those waiting for hip/knee revision.
- Needle phobia or allergy to sticking plaster.

Patients with previous experience of acupuncture were not excluded for two reasons. Firstly because if a placebo intervention is to have true validity, it must be able to be used with both naïve and experienced patients, and secondly because there is as yet no evidence to suggest that this needle should be confined to acupuncture naïve patients only. This was a single-blind cross-over trial, with subjects randomised to two practitioners and to two treatment sequences, involving real needles and placebo needles. A flow chart of the trial is shown in Fig. 1.

2.3. Intervention

All volunteers were assessed and informed consent was obtained along with a full medical history of the condition. Patients were informed that we were testing two types of needles, a conventional acupuncture needle and a new needle, either of which may be successful in treating their pain. They were also told that half of their treatments would be placebo, but that they would not be told which these were. Whilst subjects were therefore blind to the type of intervention they were receiving, it must be noted that the practitioners were aware of which needle was being used. Patients were then instructed to complete a daily pain diary to record average daily pain on a VAS with a 10 cm line ranging from 'no pain' to 'worst pain imaginable' for seven consecutive days during the baseline period. Subjects were also instructed to carry on taking their normal analgesia and to record this in their diary. One week later (second visit) the pain diary was examined and if the inclusion criteria (which were unknown to the patient) were satisfied, then randomisation to practitioner and treatment sequence occurred and

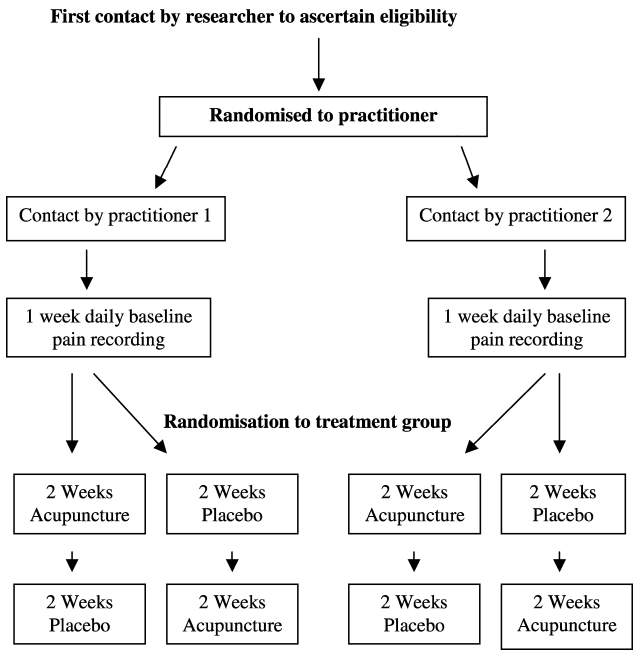

Fig. 1. Trial protocol.

treatment was initiated. Patients were then seen twice a week for the first two weeks of treatment with either real acupuncture needles or with the Streitberger placebo needles. After 2 weeks, subjects were crossed over to the other type of needle and treated for a further 2 weeks. Although the initial pain assessments were used to decide entry to the study, and further assessments of pain were recorded on a daily basis during the 4 weeks of treatment, these efficacy assessments were not used to compare the patients' sensitivity to the different types of needles. As described later, sensitivity to the needles was assessed following each treatment period using a series of questions related to the kind of sensations experienced.

2.4. The needle types: real and placebo acupuncture needles

The needles were single-use, sterile, copper-handle, pre-packed needles without guide tubes. In order to maximise matching of needles, both the real (verum) and placebo needles were manufactured and supplied by Asia-Med and Co., Munich. All needles were 25 mm × 0.25 mm. Point selection was based on individualised 'western' acupuncture techniques using a pre-defined list of points (see Table 1).

Table 1
Acupuncture point selection

	Hip	Knee
Local points	GB 30,31; UB 34; St 31	St 35, 36; Xiyan, GB 34; Sp 9; UB 39, 40
Distal points	GB 34; UB 60	St 41; UB 60

GB, gallbladder; UB, bladder; St, stomach.

The specific points for each individual were decided at each treatment session depending on the distribution of pain and local palpation (i.e. use of tender points). Point prescription was changed if there was failure to improve. Two or three local points and at least one distal point were used. Even though this was not an efficacy study, this regime was used because we felt it was important that the treatment should reflect clinical practice. If the needles are ultimately accepted as a valid control, then it is likely that they will be used in this way. Also, as acupuncture naïve patients were not excluded, the treatment experience should be as realistic and pragmatic as possible. Point location and depth of insertion was as described in traditional texts (Liangyue et al., 1990). Placebo needles were applied using the same point selection as for the real needles. Plastic 'O' rings and adhesive plasters were used for both verum and placebo interventions, as specified by Streitberger and Kleinhenz (1998). Therefore, an average of four points were used on each subject and deqi was obtained on each needle. A timer was set for 20 min, the duration of each treatment. The patient was checked three times (every 6 or 7 min) to ascertain if deqi was present and to manipulate the needles by rotating them about their own longitudinal axis. After 20 min the needles were removed. Subjects were instructed to continue with their normal analgesia if needed and were not given any other specific form of treatment (exercises, stretches, etc.).

2.5. The practitioners

The first therapist (PW) (male) was trained in western acupuncture techniques on an Acupuncture Association of Chartered Physiotherapists (AACP) accredited course and had 7 years' clinical experience in acupuncture. The second therapist (VH) (female) was trained in the UK and China in both Western and Traditional Chinese Techniques and has had 16 years of clinical experience.

2.6. Outcomes

A range of outcomes was used in order to ascertain if there were any major differences between the two interventions.

2.6.1. Primary outcomes

The primary outcome was measured by a series of questions relating to needle sensation. These questions were designed by Park (2000) and are intended to clarify and verify the sensations felt on needling and the similarity between treatments. Four aspects of sensation, namely dull/heavy (pulling, numb), radiating (spreading, pulsing, throbbing), stinging (pricking, tingling) and electric (rather like when you bang your elbow), were each measured using a VAS ranging from 'not at all' to 'extremely severely'. Since the start of this study, the questionnaire has been further amended and used in another trial (Park et al., 2002).

In the current study, the questionnaire was completed at the end of each 2-week period of treatment. Subjects were also asked to record their impression of the similarity of the treatments received by comparing the treatment during the first 2-week period with the last 2-week period using a VAS ranging from 'the same' to 'totally different'.

2.6.2. Secondary outcomes

2.6.2.1. Pain. This was measured in the form of a self-completed pain diary using a VAS and was measured daily for 1 week prior to and throughout treatment. Within-patient mean scores were computed for the final week of treatment with each type of needle.

2.6.2.2. Analgesia. Each patient kept a daily record (in the diary) of his or her analgesia intake. It was required that patients should stay on current medication and simply record tablet intake. Patients were however free to reduce (or increase if appropriate) the dose of analgesia or non-steroidal anti-inflammatory drugs as their pain dictated.

2.6.2.3. Nottingham Health Profile (NHP). This is a quality of life questionnaire and was administered (a) prior to the first treatment, (b) after the first two weeks of treatment and (c) at the end of the trial.

2.6.2.4. The Holistic Health Questionnaire (HHQ). This was administered at baseline only. A similar questionnaire was first developed by Finnigan (1991) and measured attitude to CAM. This was then further developed and validated (Lewith et al., 2000, 2002) and now measures attitudes and health beliefs. The HHQ is a self-completed questionnaire, which produces a single score with higher scores indicating a more positive attitude towards CAM.

2.6.2.5. The credibility rating (Borkovec and Nau, 1972). This was completed prior to and after the first and last treatment of both placebo and real acupuncture groups in order to gain an appreciation of relative credibility of the two interventions.

2.7. Randomisation

A computer program RANDOMLOGUE produced by the University of Southampton, Department of Social Statistics, was used to generate randomisation lists. Three lists were generated, firstly for randomisation to practitioner and then two separate lists (one for each practitioner) to randomise to treatment group, with group A receiving real needles followed by placebo needles and group B receiving placebo needles followed by real needles. Patients were stratified by gender and affected joint (knee or hip) to be treated. These lists were typed onto individual cards by a typist not involved in the trial and were placed in individual sealed, opaque envelopes by the typist for use in the study. At no point did the assessor view either the list or the cards prior to patient randomisation. Envelopes were consecutively numbered within their respective groups and subjects were allocated to treatment group using the next available number.

2.8. Statistical analysis

This study was designed as a cross-over trial with each patient receiving both the real needles and the placebo needles in sequence, each for a period of 2 weeks. At the end of each treatment period, patients were asked to complete the questionnaire (Park, 2000) assessing the sensations felt on needling. The four kinds of sensation were assessed using a VAS ranging from 'not at all' to 'extremely severe'. Within-patient comparisons of these assessments were made using non-parametric ranking procedures. Patients were also asked if they felt the needles go into the skin. McNemar's test was used to compare these responses.

Secondary outcome variables relating to pain and analgesia intake were also compared using ranking methods. The NHP scores were compared using a paired *t*-test.

Responses to the question relating to perceived overall similarity, as measured on the VAS, were summarised using descriptive statistics and compared using a χ^2 test.

3. Results

3.1. Participant flow

Between June 2001 and June 2002, 156 subjects were referred and interviewed over the telephone to assess eligibility for inclusion in the study. Thirty-seven patients met the initial inclusion criteria and were randomised to practitioner. The main reasons for non-inclusion were inability to attend for treatment (transport problems), impending operation, pain in multiple sites, unwilling to be part of a trial, ongoing other treatment, e.g. physiotherapy. There was no drop-out once randomisation occurred and no adverse reactions were noted. A chart of patient flow through the trial is shown in Fig. 2.

3.2. Baseline data

Groups were well balanced at baseline for all measured parameters (Table 2) and there were no statistical differences in the distribution of scores between groups on the credibility rating at any of the time points measured (Fishers exact test). There were four patients in each group who had previous experience of acupuncture. Table 3 shows the division of male and female patients as randomised to the two practitioners.

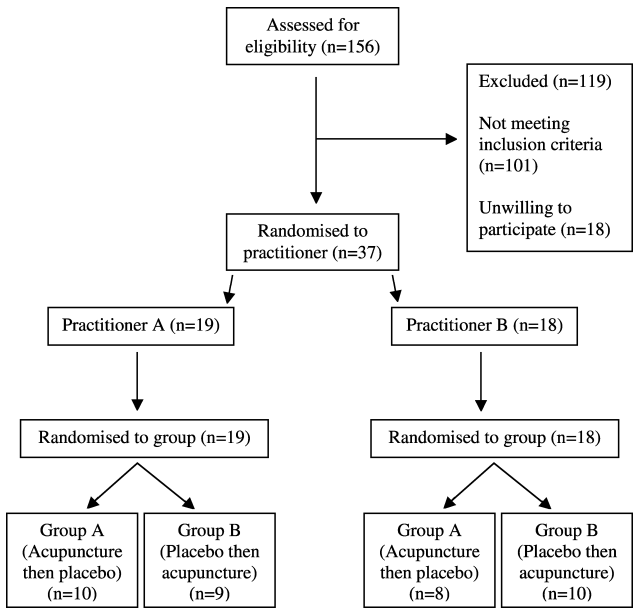

Fig. 2. Consort diagram.

3.3. Outcomes

3.3.1. Needle sensation

The four needle sensation variables were assessed after each treatment using a VAS with low values corresponding to little sensation and high values corresponding to severe sensations. Fig. 3 shows a plot of the scores for the real needles and the placebo needles for each subject, with solid and open circles corresponding to the female and male practitioners, respectively.

It is evident that the scores for dull sensation are very variable, between and within subjects. Although 18 (50%) of the subjects felt a greater dull sensation with the real needles than with the placebo needles, 15 (42%) patients scored the needles the other way for this sensation. The most noticeable feature of Fig. 3a is the relatively lower scores achieved by the female practitioner with either type of needle. Few of the subjects treated by the female practitioner scored more than 10 with either needle for this dull sensation. A comparison of the VAS scores using the sign test and Wilcoxon's signed rank test is shown in Table 4.

Table 3
Results of randomisation

	Group A ($n = 18$, real needles/placebo needles)		Group B ($n = 19$, placebo needles/real needles)	
	Male patients	Female patients	Male patients	Female patients
Male practitioner	5	5	2	7
Female practitioner	3	5	4	6
Total	8	10	6	13

A similar picture emerges for the radiating sensation as shown in Fig. 3b, except that rather more subjects (61%) score higher on the real needles than on the placebo needles (31%). However, this difference is not significant. Again, there is evidence that the scores are generally lower for those patients treated by the female practitioner. Stinging sensations were highly variable for patients treated by either practitioner with many patients scoring quite high values with both types of needles. Finally, electric sensations were hardly evident at all with the female practitioner, but about half the patients treated by the male practitioner recorded relatively high scores for one or both needle types.

3.3.2. Needle penetration

Patients were asked to say whether they felt needle penetration during the treatment with real and placebo needles. Table 5 shows the responses to this question for the 37 patients.

Of the 37 patients, 25 (67.6%) felt the real needles had penetrated, but 22 (59.5%) felt that the placebo needles had penetrated. Previous experience (prior to this trial) of acupuncture did not appear to influence how this question was answered ($P = 0.255$, ANCOVA). Nearly half of the patients, 18 (48.6%) felt penetration with both needles, while 7 (18.9%) felt no penetration with either type of needle. Seven patients correctly distinguished the real needles from the placebo needles, but two felt penetration with the placebo needles but not with the real needles. Most patients, 25 (67.6%), were unable to discriminate between the needles by means of the sensation of needle penetration

Table 2
Comparison of baseline values

	Group A ($n = 18$, real needles/placebo needles)				Group B ($n = 19$, placebo needles/real needles)			
	Mean	Median	SD	Range	Mean	Median	SD	Range
Pain scores	53.3	52.0	22.4	7.9–50.3	50.3	49.9	19.1	6.4–79.3
Analgesia	3.8	2.5	3.4	0–2.8	2.8	2.0	2.7	0–8
Age	65.8	67	8.3	51–64.4	64.4	66	12.7	37–79
HHQ	51.2	53	6.9	34–53.9	53.9	53	5.9	43–65
NHP	0.62	0.58	0.24	0.16–0.57	0.57	0.61	0.20	0.18–0.97

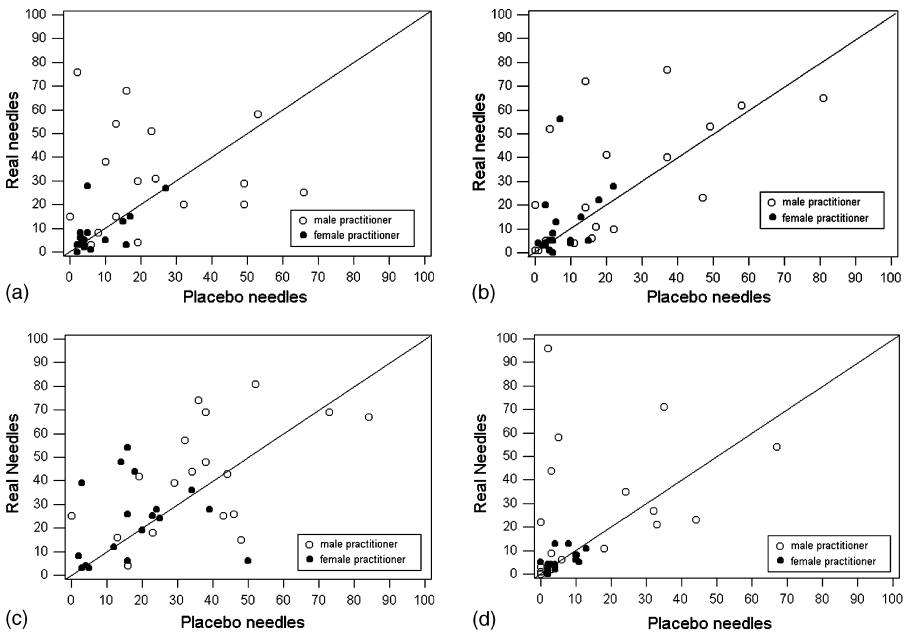

Fig. 3. (a and b) Plots of visual analogue scores for dull sensation and radiating sensation for real and placebo needles. (c and d) Plots of visual analogue scores for stinging sensation and electric sensation for real and placebo needles.

of the skin. McNemar's test gave a χ^2-value of 2.78, which is not significant ($P = 0.095$).

3.4. Similarity of treatments

All but one of the patients (36) responded to the question concerning similarity of treatments. The responses are shown in Table 6. A large proportion of subjects were unable to detect a difference between the two types of needles. Once again, previous experience of acupuncture treatment did not have any significant effect on how subjects responded to this question ($P = 0.292$, ANCOVA). Fourteen subjects (39%) recorded that the needles felt different (probably different and definitely different). Of these, seven were convinced that the needles were definitely different, this was compared to 15 who felt they were definitely the same [there was no significant difference between groups, i.e. order of treatment ($P = 0.821$, χ^2)].

More subjects treated by the female practitioner felt that the two types of needles were similar to each other compared to those treated by the male practitioner. A χ^2 test comparing those who scored less than 50 with those who scored greater than 50 for the two practitioners gave $\chi^2 = 7.48$, which is significant with a P-value of 0.003.

Table 4
Comparison of VAS scores for needle sensations for real and placebo needles using the sign test and Wilcoxon's signed rank test

Sensations	Number of subjects ($n = 36$)			
	Positive difference	Negative difference	P-value for sign test	P-value for Wilcoxon signed rank test
Dull	18 (50.0%)	15 (41.7%)	0.73	0.42
Radiating	22 (61.0%)	11 (30.6%)	0.08	0.27
Stinging	19 (52.8%)	14 (38.9%)	0.49	0.15
Electric	15 (41.7%)	16 (44.4%)	1.00	0.54

Table 5
Responses of patients to penetration question for the two types of needles

Placebo needles	Real needles			
	Yes	No	No response	Total
Yes	18	2	2	22 (59.5%)
No	7	7	–	14 (37.8%)
No response	–	1	–	1
Total	25 (67.6%)	10 (27.0%)	2	37

Table 6
Similarity of the two treatments by practitioner

Perceived similarity on VAS	Male practitioner	Female practitioner	Number of patients	Percentage
Definitely the same 0–25	2	13	15	41.7
Probably the same 26–50	5	2	7	19.4
Probably different 51–75	5	2	7	19.4
Definitely different 76–100	6	1	7	19.4
Total	18	18	36	100

Table 7
Similarity of the two treatments by treatment sequence

Perceived similarity on VAS	Group A	Group B	Number of patients	Percentage
Definitely the same 0–25	6	9	15	41.7
Probably the same 26–50	4	3	7	19.4
Probably different 51–75	4	3	7	19.4
Definitely different 76–100	3	4	7	19.4
Total	17	19	36	100

There is clear evidence that more patients considered that the two needle types were similar with the female practitioner than with the male practitioner. Table 7 shows the same data but for treatment sequence. Group A (real needles followed by placebo) had three fewer patients who felt that the treatments were quite similar than group B (placebo followed by real) but this difference was not significant in the context of this trial, indicating that the order of treatment did not influence the assessment of similarity.

An ordinal log-linear model analysis applied to the similarity codes, treated as an ordered categorical variable with values 1–4, showed that practitioner was the primary predictor of similarity. Treatment group, patient's age and HHQ at baseline were not significant, but there was some evidence that the amount of analgesia taken at baseline had a limited effect. Those patients taking the highest amount of analgesia tended to say that the treatments were dissimilar.

3.5. Improvements in pain, analgesia and NHP

The assessments of pain, analgesia use and NHP were also measured during each treatment period, with the results shown in Figs. 4 and 5.

Fig. 4 shows the within-patient mean VAS scores for the final week of treatment for both the real and placebo needles. It is clear that there is quite a large variation in

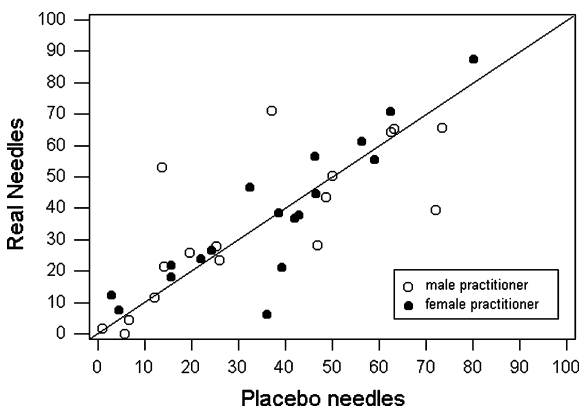

Fig. 4. Plot of mean visual analogue scores for pain for the real and placebo needles.

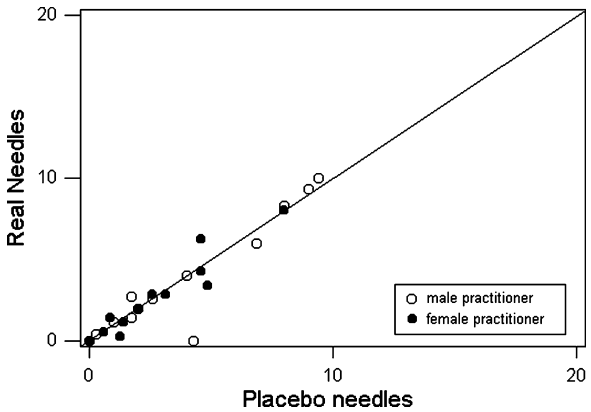

Fig. 5. Plot of mean weekly analgesia use for the real and placebo needles.

these means, but no clear difference between the two needles for either practitioner. The sign test and Wilcoxon signed rank test indicate that there is no difference between these two sets of scores ($P = 0.5$). Similarly analgesia use is compared in Fig. 5 with the same conclusion. The amount of analgesia taken changed very little for patients treated by either practitioner. The average difference between the scores for NHP was −0.1 (95% CI −0.05 to 0.02). This was not significant using a paired t-test ($P = 0.41$).

4. Discussion

The prime aim of this trial was to provide independent validation for the Streitberger placebo needle. The number of subjects recruited, however, was very low and therefore underpowered, which clearly impacts on the generalisability of the results of our study. The results as they are, however, do suggest that sensations normally associated with real acupuncture are similarly felt with the placebo needle and that the order in which these treatments were received does not appear to be a confounding factor. This is an important point for the validity of the Streitberger needle in the context of this trial as clearly it could be argued that patients receiving placebo first would notice a sudden change when the real needle (and therefore real penetration) was used. Similarly, the absence of penetration would be noticed if the real needle had been used first; this was however, not the case in terms of the sensations and penetration noted at the end of each treatment sequence. Indeed, only seven subjects (19%) were able to correctly answer the questions relating to skin penetration. This was partly in line with Streitberger's findings (1998) who questioned his subjects on the presence of 'deqi', pain on needling and whether they felt penetration or not. He found that the majority had felt penetration and similar pain from real and placebo needles. He also found that more subjects had experienced deqi with real acupuncture than with the placebo. Our credibility data also suggest that there was no difference in credibility

between the two interventions thus adding weight to the validity of the Streitberger needle. The question asking 'How similar did you find this needle to the acupuncture needle that you had before?' yielded some interesting results; unfortunately there was no corresponding question in the Streitberger trial. Clearly the largest single group (15 subjects) felt that the two periods of treatment were the same and a further seven subjects were reasonably convinced that this was so. Fourteen subjects, however, felt that there was some doubt and seven of these felt that the treatments were not similar at all. This represents a sizeable proportion of the sample tested in this trial. It must be pointed out that asking if treatments are similar, is not the same as asking if the subject believed the treatment was real or even if it were the same treatment and in hindsight these extra questions would have yielded important information. Our data does imply, however, that there is still some doubt about this issue.

If a prerequisite of a placebo is that it is indistinguishable from the real treatment, then the fact that nearly 40% of subjects did not find that the two interventions were similar, however, raises some concerns with regard to the wholesale adoption of this instrument as a standard acupuncture placebo procedure. Perhaps we should ask ourselves the question, if this were a drug trial, would we be happy if 40% did not find the interventions to be similar, or if 19% were able to correctly distinguish between treatments? This is a very important question to ask in terms of acupuncture research and debate on this issue would be welcomed.

Although the trial by Streitberger (Streitberger and Kleinhenz, 1998) used two practitioners, there was no report on inter-tester reliability. Our trial also involved two practitioners and we found that there was a substantial difference between the two, in terms of how similar subjects felt the interventions to be. Fifteen of the 18 subjects seen by the female practitioner (VH) were at least reasonably sure that the treatments were the same, this was compared with only seven treated by the male practitioner (PW). This discrepancy could occur for several reasons. It may simply be due to the low number of subjects used thus showing random variation. It might also be due to a difference in the way practitioners apply their real treatment. For example if a practitioner tends to have a more aggressive approach to obtaining deqi, this would tend to provide more of a contrast to the placebo needle as compared with a more gentle approach. This might also be reflected in the greater improvement in pain noted by patients treated by one of the practitioners (PW). Similarly, the observed difference between practitioners may be due to a difference in the application of the placebo needle or a difference in their relative persuasive abilities. Whatever the cause, it does raise some interesting points that would need to be clarified before this technique can be adopted as a true acupuncture placebo. It could also be argued that because the Streitberger needle causes a pricking sensation, it might not be completely inactive. Therefore, if this needle is to be used as a placebo in future efficacy studies, more research should be undertaken to ensure that it is indeed truly inert.

We can be confident that pre-existing attitude to CAM was not a confounding factor in the context of this trial as confirmed by others (Lewith et al., 2002; White, 2002). Finally, we must stress that this trial used small numbers of patients from an elderly population, results must therefore be used with caution.

5. Conclusion

No major differences in outcome between real and placebo needling could be found as both groups performed equally well. No patient gender bias was encountered and pre-existing attitudes to CAM had no effect on outcome. This was a very small sample, however, and results should be interpreted with caution. We feel that the Streitberger needle is a convincing control for the majority of people although this may be heavily dependent on how the treatment (both verum and placebo) is delivered.

This needle may, however, represent the best current option for a convincing 'acupuncture like' control but further work on ascertaining its true physiological effect, inter-tester reliability and standardisation of technique is highly recommended before we can be completely confident about using this needle as a placebo in further studies.

References

Borkovec T, Nau S. Credibility of analogue therapy rationales. J Behav Ther Exp Psychiatry 1972;3:257–60.

Ernst E, White AR. A review of problems in clinical acupuncture research. Am J Chin Med 1997;25:3–11.

Finnigan M. Complementary medicine: attitudes and expectations, a scale for evaluation. Comp Med Res 1991;5:79–82.

Hammerschlag R, Morris MM. Clinical trials comparing acupuncture with biomedical standard care: a criteria-based evaluation of research design and reporting (corrected) [published erratum appears in Complement Ther Med 1997 Dec; 5(4):253]. Complement Ther Med 1997;5: 133–40.

Kaptchuk TJ. Placebo needle for acupuncture (letter). Lancet 1998;352: 992.

Kleinhenz J, Streitberger K, Windeler J, Gussbacher A, Mavridis G, Martin E. Randomised clinical trial comparing the effects of acupuncture and a newly designed placebo needle in rotator cuff tendonitis. Pain 1999;83: 235–41.

Lewith G, Watkins A, Hyland M, Shaw S, Broomfield J, Dolan G, Holgate S. A double blind, randomised controlled clinical trial of ultramolecular potencies of dust mite in asthmatic patients; 2000. Unpublished work.

Lewith G, Hyland M, Shaw S. Do attitudes and beliefs about complementary medicine affect treatment outcome? Am J Public Health 2002;92:1604–6.

Liangyue D, Yijun G, Shuhui H, Xiaoping J, Yang L, Rufen W, Wenjing W, Xuetai W, Hengze X, Xiuling X, Juiling Y. Chinese

acupuncture and moxibustion. Beijing: Foreign Languages Press; 1990.
Park J. Acupuncture needle validation. Personal communication; 2000.
Park H, Park J, Lee H, Lee H. Does deqi (needle sensation) exist? Am J Chin Med 2002;30:45–50.
Peck C, Coleman G. Implications of placebo theory for clinical research and practice in pain management. Theor Med 1991;12:247–70.
Streitberger K, Kleinhenz J. Introducing a placebo needle into acupuncture research. Lancet 1998;352:364–5.
de la Torre CS. The choice of control groups in invasive clinical trials such as acupuncture. Front Perspect 1993;3:33–7.
White P. A study for the efficacy of a western acupuncture protocol for the treatment of chronic mechanical neck pain. Thesis/Dissertation, University of Southampton; 2002.