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Pilot / Double Mask / Randomized Controlled Trials

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Abstract

Currently, the needle most commonly used for acupuncture treatment in most clinical settings is a filiform needle (毫鍼), which is inserted into the skin.

The purpose of this clinical study was to assess the usefulness of a spoon needle (鍉鍼), which is not inserted into the skin. We decided to conduct this trial because we thought that the study of non-insertion acupuncture would be an important way for practitioners of acupuncture and moxibustion to extend the sphere of acupuncture techniques.

First of all, we tested the credibility of a sham spoon needle (偽鍉鍼), which we modeled on a Kozato style spoon needle (小里式鍉鍼). The result of the credibility test showed that the sham spoon needle was not understood to be a sham. Secondly, an exploratory randomized controlled trial was designed for a sham spoon needle. An effect size was calculated, rather than using the p-value, because of the small size samples.

The result showed the effect size was .33, and could be considered medium-level. This showed that a group of sham spoon needles was moderately more effective than a group of actual spoon needles. A confirmatory randomized trial needs to be conducted in the future that includes increasing the frequency of treatment for identical health problems and improving the method of masking. The effect size may be changed by improving the sensitivity of testing. Therefore, confirmatory randomized controlled trials need to be designed.

1. Objective

Currently, the needle most commonly used for acupuncture treatment in most clinical settings is a filiform needle (毫鍼), which is inserted into the skin.

According to the volume of “Nine Classical Needles and Twelve Sources” on “The Yellow Emperor’s Inner Classic, Spiritual Pivot”, needles were classified in nine categories. These nine categories were called “Nine Classical Needles”, and also classified in three types, which were “a puncturing needle (破る鍼)”, ”an insertion needle (刺す鍼)” and ”a non-insertion needle (刺さない鍼)”. “A puncturing needle (破る鍼)” is a technique which draws out pus by cutting the skin. It is outside the sphere of acupuncture techniques because it corresponds

to a present-day surgical operation. There is a question as to why "a non-insertion needle (刺さない鍼)" is not often used currently, although nine kinds of needles were introduced in "The Yellow Emperor's Inner Classic". If the "a non-insertion needle (刺さない鍼)" technique is developed it can be used without causing anxiety for patients who are needle phobic or don't like stimulation by needles. A non-insertion needle could also be used in the field of beauty acupuncture and moxibustion because it has no risk of internal bleeding.

In surveys of attitudes about acupuncture treatment in 2000 and 2005 more than 50% of respondents answered that it "looks painful" or "is scary".[1), 2)] The utilization rate of acupuncture treatment was also low, at 6.5%.[3)] The low utilization could be thought to be due to those impressions of acupuncture treatment. We found it necessary to develop studies of not only insertion needles but also non-insertion needles and to inform the general public of the effectiveness of treatment by non-insertion needles so that more patients become comfortable with receiving acupuncture treatment in the future.

Spoon needles and round-pointed needles are presented as non-insertion needles in textbooks on acupuncture and moxibustion theory. We chose a Kozato style spoon needle, which can be purchased at a low price, to examine the treatment effect of non-insertion needles in this study. For an insertion needle such as a filiform needle, a sham needle with some degree of usefulness is already available and can be used in clinical studies to evaluate the effect of acupuncture.[4)] However, a randomized controlled trial to examine the treatment effect of a spoon needle has itself not been done in the past. Nor has there been any research into sham spoon needles. These mean that a sham spoon needle does not exist. First of all, we created a sham spoon needle modeled on a Kozato style spoon needle and tested the credibility of it before going on to a clinical study. If we could succeed in masking with the sham spoon needle we created, we would perform a clinical trial.

< The Kozato style spoon needle >

A needle tip shaped like a grain of millet is introduced in the "Nine Classical Needles and Twelve Sources" volume on "The Yellow Emperor's Inner Classic, Spiritual Pivot".

The Kozato style spoon needle was created by the late Katsuyuki Kozato, who was the first vice-president of the "Toyo Hari Medical Association". There are two types of Kozato style needles. One type, seen in "The Yellow Emperor's Inner Classic, Spiritual Pivot", is a spoon needle with a round tip. Another type, in "The Illustrated Supplement to the Classic of Categories" [5)], is a spoon needle without a round tip. These spoon needles are made by the Maeda Toyokichi Shoten, which was established in the Edo period. The material used may be gold, silver, copper or titanium. For this study, we have chosen one that is a gold-plate on brass model with a length of 5.2 cm (see fig 1).

Fig 1 --- Kozato style spoon needle for this study

2. Pre-test of credibility

1) Date of Implementation

September 20th, 2011

2) Participants

13 students who belong to the Teacher-Training Course for Oriental Medicine Program

3) Methods

13 participants were randomly allocated to a true spoon needle group or a sham spoon needle group by the coin-toss method.

The Kozato style spoon needle made by the Maeda Toyokichi Shoten was used as a true spoon needle, and a toothpick with a tip cut to give it a sensation similar to a Kozato style spoon needle was used as a sham spoon needle (see fig 2). The same type of plastic tube, made by Seirin, was used for both groups.

Five acupuncture points were examined for each subject. The points were GB-21 and SI-14 on both the right and left side, and GV-21. The examiner put a spoon needle set in a tube on each point. The examiner tapped 30 times on the top of the needle's handle as if using the gentle tapping insertion technique. Immediately after the examination of each point, the subject answered by intuition as to whether they had felt a true or a sham spoon needle.

Fig 2 --- Sham spoon needle (using the cut-off tip of a toothpick)

4) Results

Table 1

	A true spoon needle	A sham spoon needle
Answering a true spoon needle	4	4
Answering a sham spoon needle	4	1

Results of analysis: χ^2 test, Yates correction; p=.514, κ=-.300, NND=-3.500, φ=-.395

In Japan, the χ^2 test is often used for determining credibility. However, the χ^2 test is not a scale to show strength of association itself because significance is affected by sample size. The χ^2 test presents just significance of association. Even if the result of the test was "no significant difference" between a true and a sham needle, it does not mean that the effect of a true needle equals the effect of a sham needle. In other words, the result of "no significant difference" does not mean a sham needle is useful. The correct interpretation of "no significant difference" in a null hypothesis is "not able to determine whether the two groups are equivalent". We decided to use the test just for a reference, looking at the substantial difference seen in the degree of agreement and association.[6)]

According to Shichido[6)], when Kappa coefficient is used for determining the degree of agreement for qualitative data between a sham and a true spoon needle, $\kappa \leqq .6$ is not considered in agreement. The measurement of association of the Phi(ϕ) coefficient is considered to show association if $\phi \geqq .7$. A Phi coefficient of less than .35 can be taken to mean that the sham spoon needle is not understood to be a sham.

The Number Needed to Diagnose (NND) is the number of people needed to diagnose a patient. In other words, NND in this study represents the number of subjects needed to understand a sham spoon needle is a sham. When NND is more than three, masking is a success, because it means that the sham needle is not understood to be a sham.

From these results, a toothpick with its tip cut to give it a sensation similar to a Kozato style spoon needle had a high probability of utility as a sham spoon needle in clinical trials. We decided to conduct a clinical trial of a spoon needle by increasing the number of samples.

3. Credibility Test

1) Date of Implementation

September 20th, 2011 through November 10th, 2011

2) Participants

141 subjects were students of the daytime and nighttime sections of the Osaka College of Medical Technology Department of Acupuncture & Moxibustion's Acupuncture & Moxibustion Therapist Program, Health & Beauty Therapist Program, and their Teacher-Training Course for Oriental Medicine Program, along with instructors in the department of Acupuncture & Moxibustion.

3) Methods

Each subject was randomly allocated to either a true spoon needle group or a sham spoon needle group by the coin-toss method.

Five acupuncture points were examined for each subject. The points, which were the same as for the pre-test, were GB-21 and SI-14 on both the right and left side, and GV-21. The examiner put a spoon needle set in a tube on each examination point. The examiner tapped 30 times on the top of the needle's handle as if using the gentle tapping insertion technique. Immediately after

the examination of a point, the subject answered by intuition whether the subject had felt a true or a sham spoon needle.

4) Results

Table 2: 121 subjects, excluding subjects in the pre-test

	A true spoon needle	A sham spoon needle
Answering a true spoon needle	26	27
Answering a sham spoon needle	30	45

Results of analysis: χ^2 test, Yates correction; p=.403, κ=-.090, NND=11.200, φ=.090

The pooled data including the pre-test were used for analysis because results of both the pre-test and the credibility test showed the same directionality.

Table 3: 141 subjects including the subjects in the pre-test

	A true spoon needle	A sham spoon needle
Answering a true spoon needle	26	29
Answering a sham spoon needle	36	50

Results of analysis: χ^2 test, Yates correction; p=.647, κ=.053, NND=19.133, φ=.053

As with the pre-test, the degrees of agreement and association indicated a substantial difference.

The degree of agreement seen in κ can be declared to be "non-existent" between a sham and a true spoon needle when $\kappa \leqq .2$. κ=.053 in this study was not considered to constitute a degree of agreement.

If the Phi coefficient indicating the measurement of association is $\varphi \leqq .35$, it can be said the sham spoon needle is not understood to be a sham. The φ=.053 value in this study means it can be said the sham spoon needle is not understood to be a sham.

If NND$\geqq$3, then it can be said the sham spoon needle is not understood to be a sham.[6] In this study NND=19.133, so it can be said that masking was successful.

The results of this study indicated that a toothpick with its tip cut to give it a sensation similar to a Kozato style spoon needle can be used as a sham spoon needle in clinical trials. With these results, we decided to conduct a clinical trial of the spoon needle.

4. Pilot Randomized Controlled Trial

The research question addressed in this study was: Whether a spoon needle was more effective than a modified toothpick. The null hypothesis was that both a spoon needle and a toothpick had equal effects. However, statistical hypothesis testing was not done because the sample size was small. Cohen's d was calculated as the effect size.[13]

1) Treatment Period

Clinical trial implementation period: October 3rd, 2011, through November 30th,

2011.

Treatment for each patient was once a week on average and took three to four weeks.

2) Participants

23 subjects were students of the daytime and nighttime sections of the Osaka College of Medical Technology Department of Acupuncture & Moxibustion's Acupuncture & Moxibustion Therapist Program, Health & Beauty Therapist Program, and their Teacher-Training Course for Oriental Medicine. The subjects were healthy people. Even though healthy people do not have specific serious symptoms, they do exhibit various health problems every day. For those health problems, the treatment effect of a spoon needle was examined in an exploratory fashion.

3) Pre-designed sample size and analysis method

100 samples in each group were needed to calculate the two-group independent sample t-test with a 5% significant level and 80% power. However, this was not feasible because there was no way to recruit 100 people for each group. Therefore, since statistical hypothesis testing was out of the question, we decided to determine the effect size instead.

4) Method of Randomized Allocation

The subjects were randomly allocated between a true spoon needle group (experimental group) and a sham spoon needle group (control group) by the coin-toss method. The coin-toss method is a method of randomly allocating people to either group based on whether a coin tossed by someone other than a member of the research team comes down heads or tails when caught in the palm of the hand.

5) Treatment Methods

The STRICTA checklist was referred to regarding the standards for the spoon needles used.

CONSORT was referred to regarding RCT procedures.[9)]

Randomized allocation between the true spoon needle group and the sham spoon needle group was conducted at the first treatment. Each patient was treated by the same type of spoon needle once a week on average for three to four weeks. The examiner put the pointy end of the spoon needle between the index finger and the thumb, and used the thumb to control the pressure against the patient's skin. As treatment for the whole body, the examiner tapped rhythmically on the top of the spoon needle along the right and left side of the meridian passage of the stomach, the gall bladder, the large intestine, the triple energizers and the small intestine, with the subject lying supine.

The subject was then in a prone position. Both sides of the meridian passage of the medial (first) branch and the lateral (second) branch of the bladder on the patients' back, and then the meridians of the bladder and the gall bladder on the legs were examined in the same way, in a supine position.

Next, specific areas were treated. Patients were asked to list any specific ailments on VAS (Visual Analogue Scale), and these were treated with the same gentle tapping technique used with the credibility test. The treatment took 10 to 15 minutes for each patient.

6) Measuring Outcomes

VAS was used to record the pain intensity of the patients' problems both before and immediately after treatment. Patients also wrote down their health problems, such as stiff shoulders or lower back pain, on VAS at that time.

VAS is a 100mm horizontal line with the right end (100mm) representing "the maximum amount of pain imaginable" and the left end (0mm) representing "no pain at all". Patients were asked to draw a perpendicular line along this scale to record their pain intensity before and immediately after each treatment. The length from the left end (0mm) to the perpendicular line was measured. Each VAS entry was done on a separate sheet of paper so that patients could not check their previous entries when recording their pain intensity.[12)]

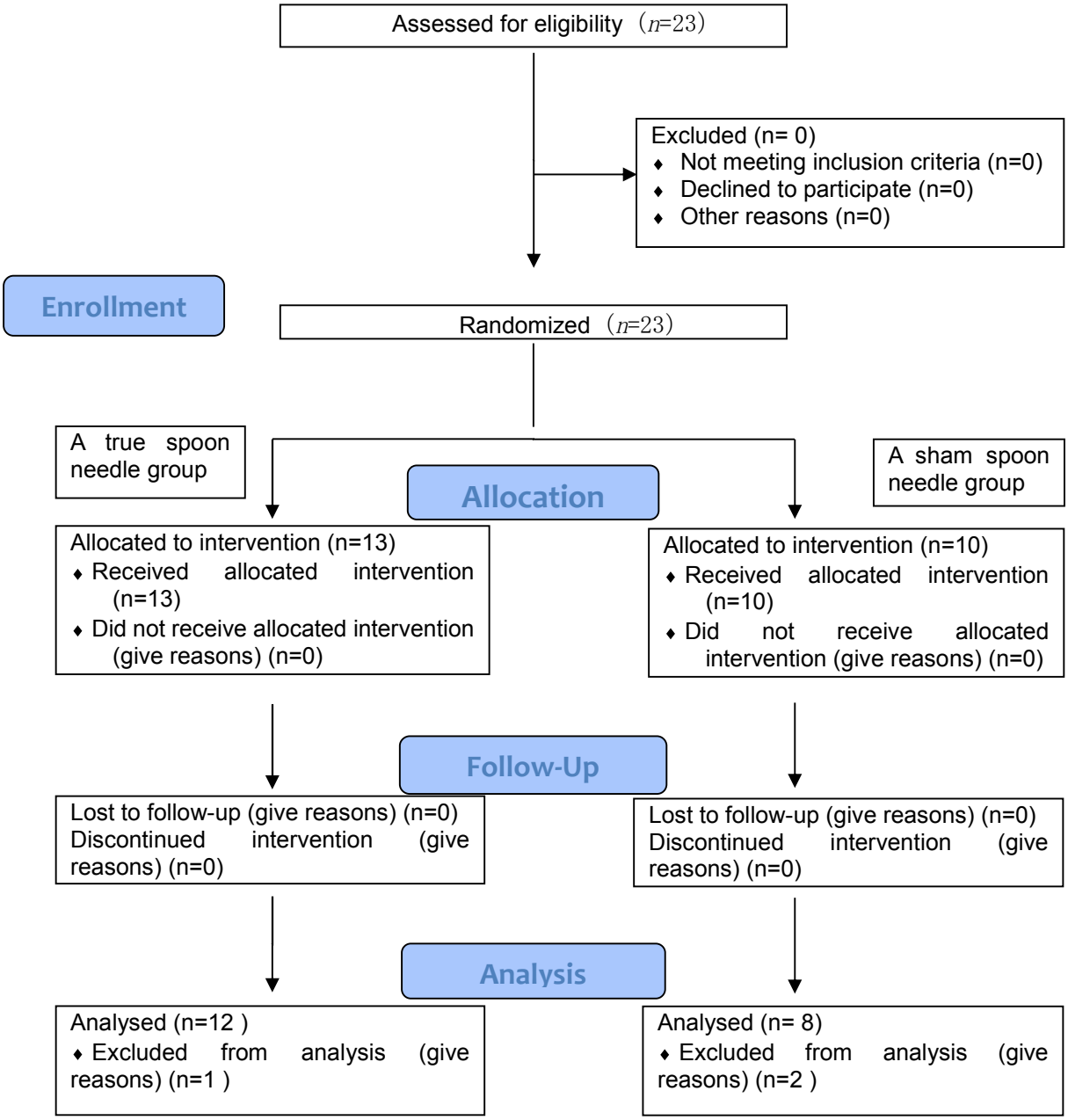

Chart 1: CONSORT 2010 Flow Diagram

7) Subject Backgrounds and Baseline Analysis

The subject backgrounds are in Table 4.

We would like to examine their comparability here. The results of the chi-square test of independence for gender differences were a p-value of .026, and a phi coefficient of .56. Those results show that gender difference is significantly associated with two interventions.

In addition, age was also associated with these gender differences (see Table 4). For age, it was determined that there would probably be generational differences as shown in Chart 3 apparent in the difference between the median and the dispersion of both groups in Chart 2.

Based on these finding, logistic regression models were calculated by classification into generations. Males in their twenties were significant (Wald's test; p=.026). Three male subjects in their twenties, one male in the true spoon needle group and two males in the sham spoon needle group, were eliminated, and logistic regression models were calculated again. Comparability was assured, with p=.899 by the Walt's test.

Based on those results, the effect size was calculated without the three male subjects in their twenties. Calculation was done using SPSS Ver.11.0

Table 4: Subject Backgrounds

	A true spoon needle group	A sham spoon needle group
The number of cases	13	10
Gender	Male(2), Female(11)	Male(7), Female(3)
Twenties	Male(1), Female(8)	Male(2), Female(2)
Thirties	Male(1), Female(1)	Male(1), Female(0)
Forties	Male(0), Female(1)	Male(2), Female(1)
Fifties	Male(0), Female(1)	Male(1), Female(0)
The average of ages	29.34±21.66	35±10
Health problems	Stiff shoulders(5), Fatigue(3), Stiff neck(1), Tiredness(2), Swelling of the foot(1), Low back pain(1)	Stiff shoulders(7), Headache(1), Stiff neck(1), Pain on the Scapulas(1)
Experience of spoon needle treatment	Experienced(9), No experience(4)	Experienced(5), No experience(5)
The initial value of VAS	58.9±29.1	56.9±32.9

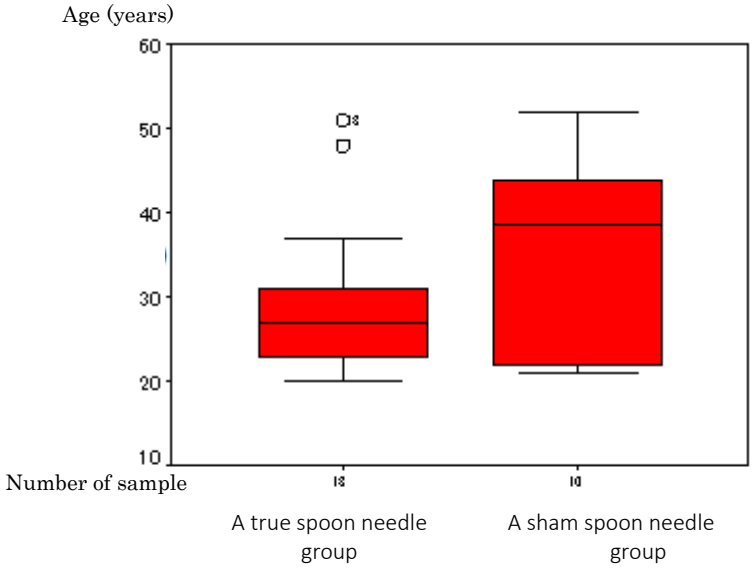

Chart 2: Background factor (Ages)

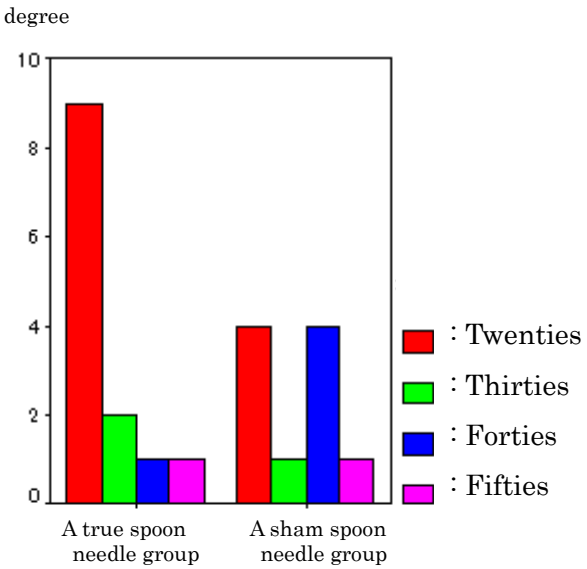

Chart 3: Background factor (Generation)

8) Results

The mean VAS of pain relief reported by 10 subjects in the sham spoon needle group was 23.19mm.

The mean VAS of pain relief reported by 10 subjects in the true spoon needle group was 17.45mm.

The effect size between two groups was .33, with the sham spoon needle proving more effective.

9) Discussion

Finding that a toothpick had the same effect as an acupuncture needle and was more effective than the usual care for chronic Lower Back Pain, the randomized controlled trial conducted by Cherkin, et al., was sensational for acupuncturists. The results also became the basis for an answer to the question of whether acupuncture treatment might simply produce a placebo effect. This article[7] also presented the opportunity for us to conduct this trial with the sham needle created.

First of all, a large enough number of samples was recruited for the credibility test, and we succeeded in creating a sham spoon needle which was not understood to be a sham. This confirmed that the sham spoon needle works as a placebo needle with no physiologic activity, and that it is possible to mask it from both subjects and examiners in clinical trials.

In the randomized controlled trial, conducted as the pilot trial with the sham spoon needle, the sham spoon needle group rated effectiveness more highly than the true spoon needle group. Comparisons within each group show effectiveness, and the improvement trends in each indicate that trials without control groups may produce mistaken conclusions. This drove home the point that establishing randomized control groups is quite important. Based on the hypothesis gained from this exploratory trial, confirmatory trials should be conducted using a large enough sample size, such as that produced by collaboration among many facilities. Issues going into confirmatory trials are considered below:

The reasons why the placebo spoon needle was more effective than the true spoon needle may have been due to the following: (1) The subjects' problems examined were not identical; (2) The subjects were healthy people rather than actual patients.

Also, it is possible that there was a problem with the method of allocation concealment. The examiners and the person who tossed the coin for randomized allocation were different. However, the examiners were conducting treatment while knowing which group they were working with (the true or the sham needle). It is said that results could be exaggerated by as much as 41% (compared to odds rations by multiple logistic regression models) due to inadequate concealment.[8] Even if there was no problem with the masked sham spoon needle used as a placebo needle, this study forces consideration of there perhaps being a peculiarity in acupuncture RCT wherein allocation concealment might fail. It cannot be denied that the psychological effect from examiners knowing the allocation outcomes might have influenced the results.

The assumption that a metal spoon needle is more effective is also only a hypothesis. The possibility that an acupuncture needle made of wood is more effective than one of metal has not necessarily been rejected.

Moreover, susceptibility to treatment by a spoon needle, the examiner's skill as an acupuncturist, and the acupuncture points for each patient's physiology and symptoms may have influenced the results. Those factors have to be considered in future studies.

Next we would like to use the assessment method to consider the placebo effect. Even though there is a question as to how many millimeters difference VAS must show in order to be considered clinically effective, researchers in Japan tend to ignore this and assess it as effective even if only a few millimeters. 13 mm or more on VAS are considered effective for acute pain. Less than 13 mm on VAS is improvement but cannot be said to show effectiveness.[10),11)] If shoulder pain is considered to equal acute pain, this study only showed 6 mm difference between the two groups, which does not have any meaning clinically. The 6 mm difference may put it in the range where the true spoon needle can be said to have the same placebo effect as the sham spoon needle.

To solve this problem, because stiff shoulders were given as the primary example, research needs to be done right away here in Japan[12)], where stiff shoulders are a characteristic trait, to determine how many millimeters on VAS are necessary for treatment to be considered effective.

10) Conclusions

The result of the credibility test for conducting a clinical trial of non-insertion needles (spoon needles) showed that the sham spoon needle was credible as a placebo. Based on this result, the preliminary, double masked, randomized controlled trial was conducted. This showed the sham spoon needle, with a poor effect size, to be effective. The sensitivity of this study should be increased and work should proceed on verification studies.

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