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Contribution of Vision, Touch, and Hearing to the Use of Sham Devices in Acupuncture-Related Studies

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This study investigates whether visual deprivation influences participants' accuracy in differentiating between real and sham acupuncture needles. It also evaluates the relative contributions of tactile, visual, and auditory cues that participants use in their decision-making processes. In addition, a simple sensory decision-making model for research using acupuncture sham devices as comparative controls is proposed. Forty healthy individuals underwent two conditions (blindfolded and sighted) in random sequence. Four sham and four real needles were randomly applied to the participants' lower limb acupoints (ST32 to ST39). Participants responded which needle type was applied. Participants then verbally answered a questionnaire on which sensory cues influenced their decision-making. The proportion of correct judgments, P(C), was calculated to indicate the participants' accuracy in distinguishing between the needle types. Visual deprivation did not significantly influence the participants' discrimination accuracy. Tactile cues were the dominant sensory modality used in decision-making, followed by visual and auditory cues. Sharp and blunt sensations were associated with the real and sham needles, respectively, for both conditions. This study confirmed that tactile cues were the main sensory modalities used in participant decision-making during acupuncture administration. Also, short-term blindfolding of participants during procedures will unlikely influence blinding effectiveness.

Clinical trial registration number: Not applicable. This study does not fall under the definition of a clinical trial under the ICMJE guidelines.

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1. Introduction

Credible sham acupuncture devices are used as a type of research control strategy for investigating acupuncture treatment effects by mimicking the real acupuncture intervention [1]. Credibility studies have generally found the participant blinding effectiveness of these sham devices to be fair or good [2,3]. Given the likely continued adoption of sham devices for acupuncture clinical studies, it is important that research effort is invested in elucidating the factors that facilitate and hinder the credibility of sham devices. This paper will focus on the sensory factors that influence research participants' perception of the credibility of nonpenetrative sham devices.

In studies assessing the credibility of nonpenetrative sham acupuncture devices, both participants and researchers reported that the real needles stimulated a sharper and more painful skin sensation, whereas the sham needles caused a relatively blunter or absence of skin sensation [4-6]. These tactile differences may reveal a crucial cue to participants for determining in their own minds, correctly or erroneously, if a real or sham acupuncture application was presented. Fortunately, the overall blinding effect of sham devices is generally maintained.

Although it is recognized that real and nonpenetrative sham needles generate different tactile sensations, the extent to which research participants make their decisions about the needle types (real or sham) based on other sensory inputs is, however, unknown. Two other likely sensory stimuli that research participants encounter during a clinical trial setting are visual (e.g., viewing the needle application) and auditory (e.g., clinician's voice) inputs. In order to remove visual cues, some researchers have blindfolded their research participants as a strategy to minimize this possible bias [7-9].

Blindfolding is a logical step toward minimizing visual cues. Nevertheless, this may have implications in terms of participants using their other senses for compensating for the loss of visual input. It has been shown that when one sensory modality is deprived, the person may adapt by compensating with another sensory modality [10]. This is demonstrated in sensory cross-modality compensation studies that showed tactile perception [11,12] and even auditory perception [13,14] improve when the visual system underwent short periods of deprivation. Neurologically, this is reflected in the enhanced excitability of the visual and motor cortices during short-term visual deprivation for periods as short as between 30 and 180 minutes [15,16]. This compensatory process may be indicative of an adaptive strategy for improving recognition of the environment by enhancing the remaining senses. The aforementioned findings of possible improvements in tactile perception during visual deprivation have obvious implications for the researcher considering blindfolding as a research procedure. A literature search did not reveal any acupuncture-related research investigating the absence of participants' auditory input as part of the research design procedures.

For studies using sham acupuncture devices, it is unknown whether deprivation of visual information from

participants will lead to the use of other senses to compensate for decision-making, thereby influencing the overall decision accuracy. It is also crucial to establish the extent to which tactile and other sensations contribute to the decision-making strategies adopted by participants.

The research aim of this study is to investigate the contribution of tactile, visual, and auditory sensation to the acupuncture research participants' decision-making in discriminating between real and sham needles. This study also aims to investigate whether removal of visual cues will bias the participant to compensate with the other senses, in particular the tactile sensation. Based on the results of our study, a simple sensory model is proposed for decision-making in real-sham acupuncture discrimination using nonpenetrative sham devices.

2. Methods

2.1. Design

This study used a within-subject, randomized controlled experimental design. The two conditions were blindfolded versus sighted. Participants also verbally reported which sensory input influenced their decision for choice of needle type.

2.2. Participants

The inclusion criteria for this study were: (a) age of 18 years or more and (b) able to provide informed consent. The exclusion criteria were: (a) the presence of medical conditions that caused anesthesia to the dominant lower limb, (b) any wounds or injury to the lower limb, (c) needle phobia, (d) consumption of potentially analgesic medications 24 hours before the study procedures, and (e) pregnancy. This study has gained ethical approval from the University Research Ethics Committee. Students and staff of the University were recruited as participants using convenience sampling. All participants provided written, informed consent for this study. Participants were allowed to withdraw from the study at any juncture of the study without providing reasons for doing so.

2.3. Background of researcher and assistant

One author, in the role of the assistant, recruited and inducted participants to the study, prepared the equipment, and assisted the researcher during the procedure. Another author took on the role of the researcher and administered the needles to all participants. The researcher is a podiatrist with 10 years of medical acupuncture clinical experience.

2.4. Acupuncture needles and points

The Park sham acupuncture device was used for administering the sham and real needles [17]. The device consists of a ring-base unit and a special oversized tube (Park tube). The ring base of the device is kept in place on

the participant's skin using double-sided tape. The internal circumference of the ring base fits tightly around the Park tube. A guide tube that is included with the device makes a sliding fit into the Park tube. Both types of needles were of the same dimensions (0.25 mm × 40 mm) and manufactured by Dong Bang Acupuncture, Inc. However, the real needle had a shorter steel handle (20 mm) compared to the sham needle (25 mm). This issue was resolved by trimming the handles of the sham needles to the same length as the real needles.

Eight stomach acupoints were chosen for this study: ST32, ST33, ST34, ST35, ST36, ST37, ST38, and ST39. The depths of needle penetration were approximately 20 mm.

2.5. Sensory cues questionnaire

A question set was designed based on unpublished participants' feedback of factors that influenced their decision-making from previous studies (Fig. 1) [18,19]. Three sensory modalities were previously identified: visual, auditory, and tactile stimuli. The assistant verbally administered the questions and participants verbally responded to the questions.

2.6. Randomization

The sequences for the blindfolded versus sighted conditions were randomized and balanced. The needle types for each participant were randomized and balanced (i.e., four sham needles and four real needles per condition). The randomization sequences were produced using an online randomization generator (<http://www.randomization.com>) at the beginning of the study.

2.7. Procedures

During recruitment, potential participants were given information on the study procedures, the Park sham device, and both acupuncture needle types (real and sham) used during the study. Shortly before the actual conduct of the study session, participants were also shown a Park sham device and specimens of the real and sham needles to familiarize them with the equipment. Participants were not informed of the prior probabilities of the needle types throughout the study to avoid introducing possible bias in their decision-making, thus potentially altering their response patterns.

Before the participant entered the laboratory, all the real and sham needles were placed on a sterile tray by the assistant. Upon arrival, the participant was asked to rest on a plinth in a half-lying position. In this position, the participant's back was supported by the plinth angled at approximately 60°. The participant's lower limbs were placed in a relaxed position, with the hip slightly flexed and the knee slightly flexed with a small pillow supporting the popliteal region. The ankles were in a comfortable neutral position. This position allowed the participant to have full visual view of the thighs, knees, and ankles in the non-blinded condition. The researcher then attached the sham devices over the eight chosen acupoints. For the

blindfolded condition, the participant was blindfolded so that he/she was not able to view the procedure.

At the start of the needle insertion procedure, the assistant handed the appropriate needle (real or sham) to the researcher for administration. The needle was placed inside the sham device. The real needle insertion into the skin occurred in two stages. In the first stage, the researcher slid the guide tube downward to approximately halfway down the acupoint penetration depth (10 mm). The researcher then held the interface between the guide tube and the Park tube firmly and slightly depressed the device down onto the skin. This procedure simulated the clinical practice of stretching the skin using the needle guide tube before needle insertion. A quick gentle tap was applied to the proximal end of the needle handle for needle penetration into the skin. In the second stage, the guide tube was moved down an additional 10 mm. The researcher then gripped the needle handle and slid the needle to the appropriate tissue depth without twirling the needle. The procedure for administration of the sham needle is similar to that of the real needle. However, the sham needle did not penetrate the skin but retracted into the handle, thus providing the illusion of insertion.

Immediately after the needle insertion, the assistant then asked the participants: "Do you think that was the real or the sham acupuncture needle?". The participants responded either "real" or "sham." The research assistant recorded the participant's judgment on a score sheet. The assistant then verbally asked the participant what sensory information influenced their judgment of the needle type based on the sensory cues questionnaire (Fig. 1). Participants are allowed to choose more than one sensory cue that contributed to their decision-making. Once the participant completed the questionnaire, this signaled the end of one administration. Each participant received a total of 16 administrations for the two conditions. The entire procedure lasted approximately 30 minutes.

2.8. Analysis

Similar to our previous studies, we have operationalized blinding effectiveness as the (in)ability of participants to differentiate between the real and sham needles administered in an experimental or clinical study, measured in terms of proportion of correct identification between needle types administered [19]. In other words, the participants' discrimination accuracy between the needle types is used as the outcome measure for blinding effectiveness. Blinding effectiveness is seen as a continuous variable because it is stated in terms of proportions, percentages, and probability. That is, we do not view blinding effectiveness as an all or none phenomenon. We have used proportions as the units of measurement for blinding effectiveness in this study. This is also a commonly used definition for one aspect of the credibility of sham devices in other studies [18,20,21].

For the accuracy of participant's judgment of needle type administered, P(C) (proportion of correct judgments) was computed for all conditions per participant. P(C) is calculated as the (total number of correct judgments)/(total needles administered). See our previous paper for a

Sensory Cues Questionnaire

Participant number _____

Acupoint name/nomenclature								
Needle type administered								
Real	<input type="checkbox"/>							
Sham	<input type="checkbox"/>							
1. Did you receive the real needle?								
YES	<input type="checkbox"/>							
NO	<input type="checkbox"/>							
2. What made you think this?								
Visual factors (i.e. what you saw)	<input type="checkbox"/>							
Auditory factors (i.e. what you heard)	<input type="checkbox"/>							
Tactile factors (i.e. what you felt on your skin)	<input type="checkbox"/>							
3. If visual, what was it relating to?								
View of needle application	<input type="checkbox"/>							
Body language of acupuncturist	<input type="checkbox"/>							
Body language of assistant	<input type="checkbox"/>							
Other _____	<input type="checkbox"/>							
4. If auditory, what was it relating to?								
Sounds from procedures	<input type="checkbox"/>							
Acupuncturist's voice/commands	<input type="checkbox"/>							
Assistant's voice/commands	<input type="checkbox"/>							
Other _____	<input type="checkbox"/>							
5. If tactile, what was it relating to?								
Pressure of acupuncturist's hand	<input type="checkbox"/>							
Sharp/Stabbing/Pricking sensation	<input type="checkbox"/>							
Numb/Aching sensation	<input type="checkbox"/>							
Blunt /Not sharp enough/No sensation	<input type="checkbox"/>							
Other _____	<input type="checkbox"/>							

Fig. 1 Sensory cues questionnaire. Firstly, the participant is asked to state their decision on whether s/he thinks the real or sham needle was administered. Then the following questions delve more specifically to the sensory modalities and their components that the participant used to make that decision.

calculated example of P(C) [19]. The outcome measure is a representation of the participant's accuracy in differentiating between the real and sham needles. Participants with a P(C) of 0.50 implies complete inability to differentiate between the real and sham needles, and a P(C) of 1.0 implies perfect accuracy. A Wilcoxon signed rank test was performed to compare if the participants' accuracy is statistically significant between the conditions. For the sensory cues questionnaire, descriptive statistics of all responses were tallied and presented for each condition. The percentage differences between the real and sham needles within each condition were compared using the χ^2 test.

2.9. Sample size

For a priori determined power = 0.8 and $\alpha = 0.05$ (two-tailed), the sample size required for this study was 36 participants. This sample size calculation was based on a P(C) difference of 0.125 between conditions and standard deviation of 0.26, a reasonable decision error allowance for participants. The standard deviation estimate was based on the results from a previous study [19]. Forty participants were recruited in the event of participant dropout or occurrence of unusable data.

3. Results

3.1. Participants

Forty healthy volunteers (27 women and 13 men) took part in the experiment with no participant dropouts. The participants' median age was 23 years (range: 21–40 years).

3.2. Participants' accuracy

Participant's responses were pooled and categorized to provide an overview of their ability to differentiate between the needle types for both conditions. Table 1 shows the needle type–response matrix of all judgments and the matrices of all participants' judgments for the two conditions (blindfolded versus sighted).

Each participant's P(C) was also computed. For the blindfolded condition, the median P(C) of participants for all acupoints was 0.75 (min to max = 0.38 to 1.00). For the sighted condition, the median P(C) of participants for all acupoints was 0.63 (min to max = 0.13 to 1.00). The

participants' P(C) were not statistically significant between the conditions ($W = 316.5, p = 0.793$).

3.3. Sensory cues used for decision-making

The participants' choices of sensory cues used for decision-making during the study were categorized based on the needle types. Table 2 shows the percentage of participants who used each type of sensory cues. For the blindfolded condition, the participants used mainly tactile sensations, with some auditory input, to differentiate between the real and sham needles. The sensory cues that yielded a statistically significant difference in usage between real and sham needles are: a) sounds from the procedures, b) sharp/stabbing/pricking sensations, and c) blunt/not sharp enough/no sensation. For the nonblinded condition, the participants also used mostly tactile sensations to differentiate between the needle types. There was some visual and auditory input during decision-making. The sensory cues that yielded a statistically significant difference in usage between real and sham needles are: a) sharp/stabbing/pricking and b) blunt/not sharp/no sensation.

It is interesting to note that the noxious tactile sensation of "sharp/stabbing/pricking" was used frequently to indicate the presence of real needles (Table 2), whereas the tactile sensation of "blunt/not sharp enough/no sensation" was used to signpost the presence of the sham needle. There was some use of auditory cues for both conditions, especially for the blindfolded–sham needle condition. In our discussion, we have provided a possible explanation for this unique use of auditory cues.

4. Discussion

4.1. Summary of study

This study found that the participants' accuracy of needle types administered was not significantly different between the blindfolded and sighted conditions. Participants differentiated between needle types based largely on tactile cues. Visual cues were the next most often used sensory modality, followed by auditory cues.

4.2. Participants' accuracy

Although there was no statistically significant difference, the median P(C) for the blindfolded condition was higher than that for the sighted condition. It is unlikely that this P(C) difference will have a practical impact given that it is only 12% higher. This is less than the predefined decision error allowance of 12.5%. This means that any variability between the groups was mainly due to natural fluctuation of decision error. Practically, incorporating blindfolding as a visual deprivation procedure will unlikely influence participants' accuracy compared to sighted procedures. In a similar study, Park et al [22] also found no difference in participant accuracy between their blindfolded and sighted groups.

Despite previous research indicating that visual deprivation may increase tactile accuracy, our results did not

Table 1 Summary of participants' responses for both the blindfolded and sighted conditions.

	Participants' responses (proportions)			
	Blindfolded		Sighted	
Needle type	Real	Sham	Real	Sham
Real	0.69	0.24	0.66	0.25
Sham	0.31	0.76	0.34	0.75

Table 2 Percentage of participants using sensory cues for each needle type.

Sensory Cues [†]	Blindfolded*			Sighted		
	Real (%)	Sham (%)	<i>p</i> _‡	Real (%)	Sham (%)	<i>p</i> _‡
Visual						
View of needle application	—	—	—	12.6	13.7	0.771
Body language of acupuncturist	—	—	—	0.0	0.6	0.327
Body language of assistant	—	—	—	0.0	0.0	—
Auditory						
Sounds from procedures	2.5	8.1	0.025	2.5	3.7	0.536
Acupuncturist's voice	0.0	0.0	—	0.0	0.0	—
Assistant's voice	0.0	0.0	—	0.0	0.0	—
Tactile						
Pressure from acupuncturist's hands	3.8	3.1	0.732	3.1	3.1	1.000
Sharp/Stabbing/pricking	74.4	32.5	<0.001	65.0	27.3	<0.001
Numb/aching	3.8	6.9	0.218	1.9	4.3	0.216
Blunt/not sharp enough/no sensation	10.0	35.6	<0.001	11.9	37.9	<0.001

[‡]*p* values of χ^2 test.

* For the blindfolded condition, there are no percentages for the vision category due to the removal of this cue.

[†] The percentages do not sum to 100% because each participant may use multiple categories to describe the sensations felt for each needle.

demonstrate this [11,12]. The most likely explanation for our finding is that cross-modality adaptation to increase tactile sensitivity has not occurred. The absence of this adaptation is probably due to the relatively shorter time duration of our procedures. In cross-modality studies, it is usual to blindfold the participants for 30 minutes before commencement of the experimental tasks [16,23]. In our study, the visual deprivation was conducted in tandem with the experimental procedures that lasted only 30 minutes. Therefore, it is unlikely that tactile adaptation influenced the participants' accuracy. This cross-modality adaptation may also be absent in past studies investigating sham device credibility and mechanisms [7,24,25].

4.3. Sensory cues used for decision-making

Our study participants reported that real needles elicited sharper tactile sensations compared to non-penetrating sham needles. These tactile descriptions are similar to other sham device credibility studies [4,22,26,27]. Furthermore, our study probed further by explicitly asking participants if the sensations influenced their decision-making. From the profile of sensory modalities (Table 2), it is clear that participants predominantly used the sharp tactile sensation for determining the presence of real needles. This decision-making behavior may have been influenced by the participants' beliefs of what constitutes a needle penetration sensation [28].

It is worthwhile to note that for the blindfolded condition, there was a statistically significant threefold increase in using "sounds from the procedures" as an auditory cue for decision-making with the sham needle administrations. This suggests that some audible aspects of the sham needle procedures may have provided some clues to its use. We reenacted the sham needle application on ourselves to explicate the probable cause of this auditory cue. We observed that during the sham needles' mimicry of needle

penetration, the sliding of the needle shaft within the handle produced a terse vibration and zipping sound. Although this sound production was fairly soft, it was sufficiently noticeable for more attentive participants. It is important to note that no other researchers have noted this phenomenon, and it may be unique to our study.

Our study also found that there was a high proportion of correct guesses ($p = 0.75$) for the sham needles, which partly contributed to the high P(C) value. By contrast, another study [19] with a similar protocol on the lower limb found the proportion of correct guesses to be only $p = 0.38$. One possible explanation for this high proportion of correct guesses for the sham needles could be linked to the extraneous sound from the sham needle administration procedure as previously described. Another possible explanation is that sham devices may not provide adequate blinding procedurally, as noted in a systematic review on acupuncture sham devices [29].

4.4. Sensory cues questionnaire

During the analysis of the participants' responses to the sensory cues questionnaire, we discerned that there may be some interpretational ambiguity for the tactile subcategory of "numb/aching" sensations. The original inclusion of this subcategory was to account for any possible needling deqi sensations. Previous studies have described deqi sensations to be throbbing, aching, tingling, sore, and numbing [30-32]. Given studies have shown that participants have a higher relative risk of perceiving deqi with real needles compared with nonpenetrating ones, our prediction was that more participants would use this category as a sensory cue to indicate the presence of real needles [20,26]. Contrarily, participants were two times more likely to associate this sensory descriptor with the sham needles. However, this increased association was statistically nonsignificant. Due to our wording imprecision for this

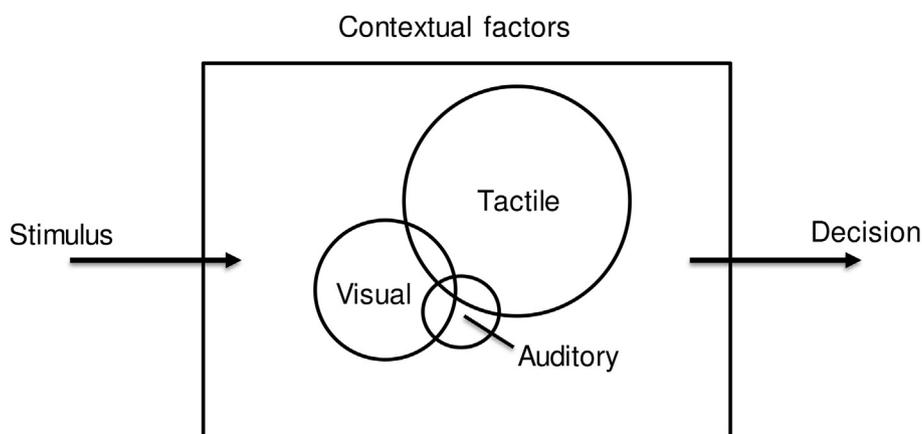


Fig. 2 The sensory decision-making model in acupuncture research using sham devices as control procedures. When the researcher/clinician provides the multimodal stimuli (visual, tactile, and auditory) to the participant, s/he receives it and makes a decision based within the context of the local environment. S/he follows this by responding appropriately based on this decision. Due to the contextual factors in different environments (e.g., laboratory or clinic), the relative proportions of the sensory modalities contributing to the participant's decision-making are localized.

subcategory and the semantic difficulties in allocating a descriptor for the construct of *deqi*, we recommend removing this subcategory descriptor of “numb/aching” or refining the wording to avoid interpretational ambiguity.

4.5. A simple sensation model of decision-making

This study proposes a simple sensation model of decision-making for acupuncture trials that uses sham devices based on the preliminary results from this study (Fig. 2). We propose that tactile, visual, and auditory sensory cues contribute to the research participant's decision-making. The tactile cue has a larger influence (hence surface area on the model) relative to the visual and auditory cues. Auditory cues are used less frequently in decision-making thereby given the least emphasis. The three sensory modalities intersect to represent the cross-modality strategies that participants may adopt for optimizing decision-making due to the deprivation of any sensory modality. Although our study provided some observational evidence for this intersectional aspect of the model, nevertheless it requires further experimental confirmation.

The sensory-based decision-making is enfolded within the contextual factors of the research setting. Research participants will likely make their decisions within the context of the clinical/research environment and the specific interactions with the clinicians/researchers. The contribution of contextual factors on research participants' decision-making about placebos and how they respond to it is well researched. The oft-mentioned contextual factors in the placebo effects and response literature are [33]: a) open administration of interventions, b) inclusion of suggestions of intervention effectiveness, c) previous experience of the intervention, d) expectations of intervention effectiveness, e) therapeutic relationship between clinician and participant, and f) the physical environment. Therefore, contextual factors need to be considered within the realm of acupuncture research designs.

We propose that this model may be a useful framework to consider when research studies incorporate an

acupuncture sham procedure or device within the design. We are suggesting that researchers take into account their local contextual conditions within this model. One practical execution of this recommendation is using the sensory cues questionnaire, in conjunction with the model, as a tool to determine the proportional contribution of sensory cues toward the participants' decision-making process. This can be performed within a feasibility or pilot study. If a particular sensory cue is deemed to unacceptably bias the participants' decision-making process, then remedial steps can be taken to modify or lessen its impact: for example, blindfolding the participant. Any remedial action will of course have to consider the trade-off of potentially decreasing a study's ecological validity [34].

5. Conclusion

This study confirmed the results of past studies that tactile cues were the primary sensory cues used by research participants in their decision-making processes. The introduction of visual deprivation, in the form of blindfolding participants in our study, did not bias participants' accuracy in differentiating between the real and sham needles. This is despite the slight increase in reliance of tactile cue for decision-making in the blindfolded condition. We proposed a sensory decision-making model, based on this study data, to reflect the relative contributions of the three investigated senses in participant decision-making. We recommend that the sensory decision-making model may help researchers understand the relative contributions of sensory cues in their own research. This can lead to better understanding and resolution of any sensory influences that may challenge the internal validity of study.

Ethical approval

This study was approved by the Queen Margaret University Research Ethics Committee.

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Declaration of competing interest

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