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# ''I assumed that one was a placebo'': Exploring the consent process in a sham controlled acupressure trial

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**KEYWORDS**
Acupressure;
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Placebo;
Consent process;
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**Summary**
*Objectives:* In clinical trials where participants are likely to be able to distinguish between true and sham interventions, informing participants that they may receive a sham intervention increases the likelihood of participants 'breaking the blind' and invalidating trial findings. The present study explored participants' perceptions of the consent process in a sham controlled acupressure trial which did not explicitly indicate participants may receive a sham intervention.
*Design:* Nested qualitative study within a randomised sham controlled trial of acupressure wristbands for chemotherapy-related nausea. Convenience sample of 26 patients participated in semi-structured interviews. Interviews were audio-recorded and transcribed verbatim. Transcripts analysed thematically using framework analysis.
*Setting:* Study conducted within three geographical sites in the UK: Manchester, Liverpool, and Plymouth.
*Results:* All participants indicated that they believed they were fully informed when providing written consent to participate in the trial. Participants' perceived it was acceptable to employ a sham intervention within the trial of acupressure wristbands without informing potential participants that they may receive a sham treatment. Despite the fact that participants were not informed that one of the treatment arms was a sham intervention the majority indicated they assumed one of the treatment arms would be placebo.

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*Conclusions:* Many trials of acupuncture and acupressure do not inform participants they may receive a sham intervention. The current study indicates patients' perceive this approach to the consent process as acceptable. However, the fact participants assume one treatment may be placebo threatens the methodological basis for utilising this approach to the consent process.


## Introduction

Full informed consent is an enshrined tenet of health care research globally. Typically this involves informing potential participants if there is a possibility they could be randomly assigned to receive a placebo (or sham) intervention.[1] However, there are exceptions to this general principle. One such instance are clinical trials in which the sham intervention could be easily distinguishable from the active intervention, and were revealing to participants that they may receive a sham intervention could therefore threaten the validity of findings through participants 'breaking the blind'.

Sham interventions in acupuncture, and associated techniques such as acupressure, are notoriously difficult to design to be both physiologically inert and indistinguishable from the active intervention.[2] Despite objections that it could deviate from the requirements of full informed consent,[3] this has led to many acupuncture trials not explicitly informing potential participants that they may receive a sham intervention. Linde and Dincer conducted a review of how published sham controlled trials of acupuncture reported on the information given to potential participants about the interventions under investigation. Of 47 published trials included in the review, 37 (79%) did not report how patients were informed about the interventions under investigation. Of the 10 trials which did provide details none had used the words 'placebo' or 'sham', with most appearing to have implied to participants that two different types of acupuncture were being compared.[4]

A number of sham controlled acupuncture trials published since the Linde and Dincer review have continued to imply to prospective participants that their trial would compare two (or more) different types of acupuncture. In a trial of acupuncture for osteoarthritis of the knee, Witt et al. employed minimal acupuncture as a sham intervention and informed participants that 'in this study, different types of acupuncture will be compared. One type is similar to the acupuncture treatment used in China. The other does not follow these principles, but has also been associated with positive outcomes in clinical studies.'[5] While in a four-armed trial of acupuncture for fibromyalgia which contained three different sham interventions, Assefi et al. informed participants that 'they had an equal chance of being assigned to 1 of 4 acupuncture interventions, none of which has been proven but 1 of which was believed to have the most potential to improve the symptoms of fibromyalgia.'[6] Many other trials of acupuncture and acupressure have employed a similar approach and not explicitly indicated that there was a possibility of receiving a sham or placebo intervention when informing potential participants of the trial interventions.[7–9]

Despite the fact that a number of acupuncture/acupressure trials do not inform potential participants that they may receive a sham or placebo intervention, no previous research has been conducted to explore participants' views on presenting trial information in this manner.

## Methodology

The present study is a nested qualitative study within a trial of acupressure wristbands for chemotherapy-related nausea.[10] The aim of the nested qualitative study was to explore participants' experiences of using the wristbands and taking part in the trial, including their perceptions of the presentation of interventions in the consent procedure for the trial. The study was conducted within three geographical sites in the UK: Manchester, Liverpool, Plymouth and the surrounding regions. Ethical approval for both the acupressure wristband trial and the nested qualitative study were obtained from Central Manchester Research Ethics Committee [REC reference number: 08/H1008/2].

## The trial

A randomised, single-blind, sham-controlled, clinical trial was conducted to evaluate the effectiveness of acupressure wristbands for chemotherapy-related nausea.[10] 500 patients with heterogeneous cancer diagnoses receiving high, moderate and low emetogenic chemotherapy participated in the trial. Trial arms consisted of standardised antiemetics plus either acupressure wristbands, sham acupressure wristbands or antiemetics alone. The true acupressure group was provided with a pair of elastic wristbands with a 1 cm protruding round plastic button, which presses on the P6 acu-point. The sham wristband group received identically appearing wristbands, with a flat button in place of the protruding button, thus exerting no pressure on the P6 acu-point.

Patients were informed about the study by their hospital consultants at participating sites. Members of the research team provided interested patients with a patient information sheet and detailed verbal information regarding the study. Details of the treatment arms and the randomisation process were included in the verbal and written information. Due to methodological concerns that participants might distinguish the sham acupressure wristbands from the true acupressure wristbands (as these are available in the market commercially and patients could have access to them easily), the trial did not explicitly indicate that participants may receive a sham treatment. Potential participants were informed that they could be randomised to receive wristbands A or B, and that it was thought that one of those may be more effective than the other but that we were not sure yet. This approach was agreed following discussion with the patient advisors to the trial and the Ethics committee,