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Understanding rationales for acupuncture treated individuals' beliefs in acupuncture effects, to be able to maximize therapeutic results: A qualitative analysis

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ABSTRACT

Objective: To investigate how individuals expressed rationales for their beliefs regarding efficacy of acupuncture.
Methods: Qualitative data from participants of two different randomized sham-controlled trials, of relaxing (non-cancer volunteers of the general population) or antiemetic (patients with cancer undergoing radiotherapy) effects of acupuncture was analyzed. Participants (n = 441) received genuine (n = 120 and n = 100) or sham (n = 121 and n = 100) (telescopic blunt sham-needle) relaxing or antiemetic acupuncture. The participants (n = 428; 97% response rate) expressed their belief regarding the efficacy of acupuncture, and n = 264 delivered qualitative rationales for their belief, analyzed using qualitative content analysis.
Results: Of the 428 participants, 35 (8%) believed entirely that the acupuncture was effective, 209 (49%) believed much, 136 (32%) believed moderately, 39 (9%) believed a little, and 9 (2%) did not believe that the acupuncture was effective. Five categories and seven subcategories represented the meaning units of the central message of the rationales for the treatment belief. Participants with positive beliefs (believed entirely/much, n = 244) presented rationales related to: "Experienced positive effects", "Knowledge regarding effect-mechanisms of acupuncture", and "General trustworthiness of acupuncture". Participants with more negative beliefs (believed a little or not, n = 48) presented rationales related to: "Lack of feasibility of the acupuncture", "Varying effects", and "The effect is individual, not available for everybody".
Conclusion: In order to strengthen acupuncture treated patients' beliefs in the efficacy of acupuncture during clinical practice or research, acupuncture therapists may consider emphasizing these aspects in the therapeutic situation.

1. Introduction

Despite of the fact that clinicians today are aware of that non-specific effects of the context surrounding the treatment play an important role for the treatment outcomes, clinical research has yet mainly focused on the specific components of treatments.[1,2] Acupuncture is the most commonly practiced Complementary and Alternative Medicine (CAM) method within western oncology care; more than half of 123 European oncology centres practice acupuncture.[3] Three quarters of patients with cancer showed interest in receiving acupuncture during cancer therapy,[4] despite rather weak scientific evidence for effects beside positive non-specific effects.[5–7] Sixty percent of acupuncture treated patients during cancer therapy perceived wellbeing effects, for example relaxing effects, during antiemetic acupuncture.[8] Acupuncture, as well as most or all other CAM or conventional medicine methods, may be divided into a specific treatment component (e.g., the skin-penetration and needle stimulation) and a non-specific component. The non-specific component includes the context surrounding the delivery of treatment, often referred to as the placebo component, for example the interaction between a patient and the therapist, and the treatment expectations.[9,10]

One key component for inducing placebo effects is treatment expectations; the patients' belief in the efficacy of the delivered treatment.[9,10] In general, high expectations to recover or to receive positive treatment effects, predicted greater improvement in a variety of populations and treatment settings,[11–14] so also in patients receiving acupuncture.[15] Previous uncontrolled observational studies[16,17] and a non-randomized study observed relaxing experiences during acupuncture.[18] Positive baseline treatment expectations were related to greater improvement in relaxation in a randomized controlled

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acupuncture study.[19] In another study (n = 277), 81 percent of patients who expected themselves to experience nausea during radiotherapy, despite of the fact that they received antiemetic acupuncture, actually experienced nausea. Only half of patients who expected themselves to be at low risk for nausea experienced nausea.[20] There are studies regarding how the risk for being treated with placebo affected the patients' expectations and experiences during needling in randomized controlled studies of placebo effects.[21] Other studies described what patients expect from acupuncture, in terms of pain relief, improved function and fitness, improved overall well-being (n = 64),[22] and prophylaxis of complications (n = 137).[23] There are also qualitative studies regarding how patients (n = 37) perceive acupuncture[24] and the acupuncture delivering therapist (n = 35).[25] However, researchers and clinicians yet know very little regarding aspects that shape the patients to believe more or less in the efficacy of CAM methods such as acupuncture. Increased knowledge would be helpful in order to maximize the aspects within the acupuncture procedure that tend to shape positive beliefs, and to minimize the aspects that tend to shape negative beliefs. Since strengthening of patients' treatment beliefs seemed to increase positive treatment effects, during acupuncture[15,26] amongst many other therapies,[12] such knowledge may be beneficial for maximizing the effects of acupuncture. The objective of the study was to investigate how individuals expressed rationales for their positive or negative beliefs regarding the efficacy of acupuncture after an acupuncture treatment period.

2. Material and methods

2.1. Design

In this study, we used a qualitative content analysis[27,28] to study how participants expressed rationales for their beliefs regarding acupuncture effects. The participants included in the content analysis participated in two different randomized sham-controlled trials. One trial investigated relaxing effects of acupuncture[19]: the relaxation cohort, non-cancer Swedish "individuals in general". The other trial investigated antiemetic effects of acupuncture[29]: the nausea cohort, patients with cancer undergoing radiotherapy at two Swedish University Hospitals. The trials followed the Swedish Statute (2003:615) concerning the Ethical Review of Research Involving Humans. The relaxation trail was ethically reviewed being part of an academic bachelor thesis. The regional ethics committee (2016/362-31) approved outcome comparisons in a non-acupuncture treated reference group (receiving no acupuncture, just rest for relaxing purpose) being a reference group to the acupuncture groups (receiving genuine and sham acupuncture). However, in the current content analysis we excluded the reference group receiving just rest, since the objective of the study was to investigate how individuals expressed rationales for their positive or negative beliefs regarding the efficacy of *acupuncture*. The antiemetic trial was approved by the regional ethics committee (02-420, M167-04). The trials followed the policy for ethical complementary research[30] and the declaration of Helsinki. All participants gave written informed consent.

2.2. Participants

We consecutively included the two randomized sham-controlled cohorts of participants (n = 458), receiving acupuncture or sham acupuncture to induce relaxing (n = 243) or antiemetic (n = 200) effects, respectively (Fig. 1). Both cohorts received study information in a written letter, and orally during a personal meeting or by phone. The written and oral information said that the trial would randomize the participant to one of two types of acupuncture needles: "You will receive – without being told which – an ordinary acupuncture treatment with needles penetrating the skin or another treatment with needles placed just against the skin". *Relaxation cohort:* Participants not part of any specific patient group, i.e. Swedish "individuals in general", who were interested to receive acupuncture for relaxing effects. They paid attention to the study either by personal communication with the study therapists, or by reading a written flyer. Both the personal initial contact and the flyer contained the same information: "We are conduction a study regarding acupuncture for relaxing effects, would you like to receive further information?". *Nausea cohort:* Participants with cancer entering radiotherapy given with or without concomitant chemotherapy, at two Swedish University Hospitals. Participants in both cohorts were, after informed consent, included according to the inclusion criteria: At least 18 years old, having mental and physical capacity to undergo the study procedure, e.g. capacity to understand Swedish and to give informed consent. Exclusion criterion: Education in acupuncture therapy. For the nausea cohort, the additional inclusion criteria were: radiotherapy to an abdominal or pelvic field of at least 800 cm^3 volume and 25 Gy dose for cancer, no antiemetic treatment or persistent nausea within 24 h prior to the start of radiotherapy, no previous antiemetic acupuncture, and no acupuncture within the past year preceding the study, regardless of indication.

2.3. Acupuncture treatments

Physioherapists (n = 9 in the relaxation cohort, n = 7 in the nausea cohort) administered genuine acupuncture or sham acupuncture, according to a computer generated randomization table. All physiotherapists had formal education in acupuncture (comparable with 15 ECTS points) and experience of practicing acupuncture for two to 20 years. The steel needles were packed sterile, manufactured by Dong Bang Acupuncture(EU)LTDv. The participants could lay down or sit during treatments. In the relaxation cohort, the participants received one single acupuncture session, á 30 min. In the nausea cohort, the therapist performed range 6–19 acupuncture sessions during the entire individual length of the radiotherapy period, median 12 acupuncture sessions. Calibration of the acupuncture procedure between the therapists was made within each cohort, before start and repeatedly during the study period, to secure adherence to the standardized study protocol.

Genuine acupuncture (needle diameter 0.25 × length 40 mm) was in both cohorts delivered bilaterally to the acupuncture point PC6[7] between the tendons of palmaris longus and flexor carpii radialis at two cun (one cun is equivalent with one body-inch, approximately 1.5 cm) proximal to the wrist, at 0.5 cun (body-inch) depth. The therapists manually manipulated the needles three times a treatment by rotating, thrusting and lifting the needles. When the patient reported a sense of numbness or soreness and the therapist noted a minimal muscular contraction around the needle, the therapist registered this as a "needle sensation" ("deqi", according to traditional Chinese medicine).[31]

Sham acupuncture (blunt needles diameter of 0.25 × length 40 mm) was delivered bilaterally to a non-acupuncture point four cun (body-inches) proximal to PC6, with the telescopic non-penetrating Park's sham needle.[32] Park's credible sham needle looks identical to a real needle but glides upward into its handle, giving an illusion of penetration. A marking tube, used during both genuine and sham acupuncture, held the sham needle in place. The therapists manipulated the needles a few seconds three times per session until the needles touched the skin, but no "needle sensation" occurred.

Regarding the communication during the treatments, the physiotherapists communicated according to ordinary routine practice in the nausea cohort (every-day conversations, avoiding the subject nausea). In the relaxation cohort, a randomized protocol standardized the verbal communication during the genuine and sham acupuncture sessions, striving to induce differences between the participants regarding their beliefs in acupuncture effects, similar to a previous study.[26] The therapist expressed at least three of several statements. Positive communication covered e.g., "Many acupuncture studies have shown great results concerning relaxation effects," "Brain imaging