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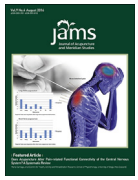

RESEARCH ARTICLE

Acupuncture for Symptom Relief in Palliative Care—Study Protocol and Semistandardized Treatment Schemes

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Abstract
The use of complementary and alternative medicine methods such as acupuncture in palliative care has increased over the past years. Well-planned trials are warranted to show its effectiveness in relieving distressing symptoms. The development of treatment schemes to be used in the trial for both acupuncture and medical symptom control is challenging, as both acupuncture and palliative care are highly individualized. Thus, standardized care plans of a randomized controlled trial will have difficulties in producing treatment results that compare to the clinical practice. As an alternative, treatment protocols for both acupuncture and medical symptom control of dyspnea, pruritus, hypersalivation, depression, anxiety, and xerostomia were designed with the input of experts. They are designed to provide sufficient symptom control and comparability for a three-arm, randomized controlled trial. Medical symptom control will be provided to all groups. The two control groups will be medical treatment and sham-laser acupuncture.

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1. Introduction

Palliative care aims at the improvement of the quality of life for patients with progressive incurable diseases [1]. According to the World Health Organization, the control of distressing symptoms within these patients is a high priority [2]. Usually, this goal is achieved by a highly individualized care plan combining medical, social, and spiritual care. Complementary and alternative medicine (CAM) plays an increasing role in the treatment of these patients [3,4]. Acupuncture is one of the most popular CAM methods [5]. It is a relatively safe procedure, assuming that rules are followed [6]. During recent years, an extensive amount of research regarding the effectiveness of acupuncture in treatment of cancer symptoms has been performed [7]. To date, there is some evidence for the treatment of chemotherapy-induced nausea and vomiting [8,9], pain [10], hot flashes [11,12], insomnia [13], myelosuppression [14,15], and fatigue [16] by acupuncture. For other important symptoms like e.g. dyspnea, depression and anxiety, there is still a lack of enough high-quality research to gather scientific evidence. To keep track of the principles of evidence-based medicine, more well-planned trials are necessary.

The design of clinical trials has been an important topic in acupuncture research for some years now [17—19]. Quality criteria have been published [20,21], and there is an ongoing discussion regarding the choice of the control (sham) treatment [22,23]. Therefore, any acupuncture trial has to consider the design of treatment schemes as well as the control device.

The choice of the control treatment in palliative care is equally challenging: In the daily palliative practice, an effective treatment often consists of a combination of the various different available medications. In the context of a randomized controlled trial, an individualized pharmacological combination is difficult to combine with the required comparability. Considering the variety and different intensity of the symptoms, a practitioner experienced in palliative care is usually required for optimum symptom control [24]. Therefore, we decided to involve several experts in the field of palliative care into the configuration of the pharmacological control for this trial.

Taking all these objectives into consideration, for the design of this trial evaluating the effectiveness of acupuncture for symptom control of highly relevant and distressing symptoms such as dyspnea, itching, hypersalivation, depression, anxiety, and xerostomia in palliative care (the AcuPall Study), it was required to develop:

1. Acupuncture treatment schemes with semistandardized choice of acupuncture points.
2. Pharmacological treatment schemes for an optimum of symptom control in every group.

2. Materials and methods

2.1. Design

The AcuPall study is a three-arm, partially blinded, randomized controlled trial. It investigates the efficacy of (a) pharmacological symptom control without additional treatment versus (b) add-on acupuncture versus (c) add-on sham laser acupuncture in a palliative care setting. The six different investigated symptoms are dyspnea, pruritus, hypersalivation, xerostomia, depression, and anxiety. Pharmacological treatment follows specially designed protocols. Treatment will be provided to all patients, ensuring that a sufficient symptom control is guaranteed. First, there will be the pilot study as an exploratory part of the trial. It aims to recruit 60 patients per symptom. A sample size calculation will be performed for the confirmatory part of the trial, according to the size of observed effects. Apart from the sample size calculation, the design will be similar in both parts: After randomization, patients in both acupuncture groups receive three treatment sessions per week over a minimum period of 2 weeks (maximum 4 weeks). Psychological, social, and spiritual care will be provided to all patients. The total follow-up study period per patient is 6 weeks. The study protocol is in accordance to the declaration of Helsinki and the "ICH E6 Guideline for Good Clinical Practice." Written informed consent is obtained from all patients. Ethical approval has been given by the Ethics Committee of the University of Munich, Munich, Germany (number 146-09).

2.2. Randomization and blinding

For each symptom separately, patients will be randomized, using a series of sealed, sequentially numbered envelopes containing the treatment assignments. The envelopes will be prepared by an external person. When a patient fulfils the inclusion criteria, the acupuncturist will open the lowest numbered envelope to reveal the patient's group allocation. Neither the physician prescribing pharmacological treatment according to the treatment protocols nor the patient will know if they receive sham or verum treatment. Patients will be told that they will receive acupuncture, laser acupuncture, or standard medical treatment. They are further told that one treatment of the two types of acupuncture will be a placebo treatment. It will be left open if needle or laser acupuncture will be the sham treatment.

2.3. Patients

Patients will be recruited from the ward of the Interdisciplinary Palliative Care Centre, University of Munich and three other palliative care wards at community hospitals in Munich connected to the university and at the university hospital of the Paracelsus Medical University in Salzburg. Exclusion criteria are as follows: patients younger than 18 years, severe impairment of blood coagulation, noncompliance, pregnancy or lactation, acupuncture or transdermal electric neurostimulation treatment within the past 4 weeks, contraindications against one of the substances included in the treatment protocol (as listed in the summary of product characteristics), and the inability to sign written informed consent.

2.4. Participating physicians/acupuncturists

Participating trial physicians are from the above-mentioned institutions. All are experienced in palliative symptom

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