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Designing an Acupuncture Study to Meet Evidence-based Medical Criteria

Methodological Considerations for Logistic Design and Development of Treatment Interventions Arising from the German Randomized Controlled Acupuncture Trial on Chronic Shoulder Pain (GRASP)

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Abstract: The results from studies on potential treatment effects of acupuncture are often limited due to serious difficulties in methodology. Randomized controlled trials on acupuncture should test a widely accepted treatment strategy of verum and sham acupuncture. However, in clinical practice various patterns of acupuncture techniques are employed, and up to now no generally accepted guidelines on how to perform a reliable verum or sham treatment have been established. Another limitation is that in most studies the study populations are too small to obtain reliable data and to detect subtle differences between the unspecific needling of sham acupuncture and specific needling of verum acupuncture with sufficient statistical power. Moreover, only a multicenter trial in an outpatient setting would guarantee a naturalistic environment in which acupuncture is used in clinical practice. In the present report we discuss such methodological aspects in detail and summarize some practical considerations for planning an acupuncture trial that fulfills evidence-based medical criteria. The largest German study on the treatment effects of acupuncture in patients with chronic shoulder pain (recruited patients n = 452), might serve as an example for such a well-designed study. Before we could conduct our study, clear definitions and protocols for the verum and sham acupuncture treatments as well as adequate endpoints had to be developed. For this we used a combination of a comprehensive study of the literature and structured interviews with experienced physicians followed by an expert panel. A total of 41 physicians had to be trained to achieve a homogeneously high quality of acupuncture treatment. The latter represents a prerequisite for reproducibility, constituting a critical component of rigorous efficacy trials in scientific acupuncture research.

Key words: Acupuncture, shoulder, pain treatment, randomized controlled trial, conservative treatment, RCT

Introduction

Since the National Institutes of Health (NIH) issued its consensus statement on acupuncture stating that more high-quality clinical research is needed in this field, studies using randomized controlled trials (RCT) have been published with increasing frequency [33]. Such trials mostly evaluate the effects of verum acupuncture against various control treatments, which have included mere suggestive interventions [23, 30] sham acupuncture with needling of non-acupuncture points, and standard conventional therapy [26, 31]. Much effort has been put into designing trials of high methodological quality oriented toward the methodology used in pharmacological trials, but less attention has been paid to the rationale for and quality of the acupuncture procedure itself [28]. Time and effort has been spent on trials investigating exotic or seldom-used acupuncture procedures, without taking into account the environment in which the procedure is performed [21, 37]. Other studies tried to establish a rigid set of fixed acupuncture points, even though individualized point selection (based on patients' individual energetic properties) is still one of the most important paradigms of acupuncture treatment [26]. The situation is further complicated by a lack of accepted guidelines or recommendations concerning the number and frequency of treatment sessions for a given disorder and by the fact that RCTs which evaluate acupuncture against non-inert control interventions like sham acupuncture or standard therapies need large sample sizes to detect small differences in efficacy with sufficient power [45]. This paper discusses the design of the trial and the methods we used to develop a widely accepted acupuncture procedure for locomotive disorders with high degree of internal and external validity, and to create a methodology facilitating a large randomized multicenter trial in a naturalistic environment. We selected shoulder pain as the appropri-

ate condition because the incidence and prevalence is high and the conventional treatment not satisfactory [8, 17, 32]. It also describes in detail the verum acupuncture, sham acupuncture and standard therapy that were administered for chronic shoulder pain in our trial. Although a large number of physicians (n = 41) was trained to perform the acupuncture procedure, the organization of this study aimed at ensuring that a previously well-defined and reliable acupuncture technique was applied. Our positive experience with the GRASP trial substantially contributed to the design of the later German acupuncture (GERAC) trial, which, to the best of our knowledge, is the largest RCT worldwide on treatment response to acupuncture and which is currently being evaluated [11, 29].

Methods

Selection of the Appropriate Disorder and Number of Trial Centers

We decided to test verum acupuncture of the Traditional Chinese Medicine (TCM) style against unspecific needling (sham acupuncture) and against conventional therapy, and to do so in a naturalistic environment. In order to identify the most appropriate disorder and develop specific intervention protocols that were supported by a broad consensus, we conducted an extensive literature search as well as interviews with experienced practitioners, followed by consultation with organized expert panels.

36 orthopaedic specialists who were also experienced acupuncture practitioners were interviewed to determine which condition, in their view, would be most suited to a large RCT. Key questions were:

- What disorders can be treated very effectively with acupuncture, using a treatment strategy that is not too complex or too individualized to be standardizable in major aspects?
- What disorders are frequent among outpatients, of high economic relevance, but for which an effective conventional therapy without severe adverse effects has not yet been developed?

The majority of the practitioners interviewed identified chronic shoulder pain (cSP) as a suitable disorder for a large RCT for the following reasons: (i) Many ambulatory patients suffer from chronic shoulder pain. (ii) The reported incidence of shoulder pain has increased 100% over the last ten years, mainly because of changing work habits and sports activities, but also because of more sensitive diagnostic procedures. (iii) While in the 70's orthopaedic interest focused on the hip joint, emphasis shifted to the knee in the 80s and then to the shoulder in the 90's [14, 35].

Funding for the trial was approved by an expert committee of the BMBF (German Ministry of Research), and the design was also approved by the responsible ethics committee as meeting the criteria of the Helsinki declaration. The trial protocol was finalized in 1996. The clinical phase began in January1997 and continued until April 1999. During that time 452 patients with no previous experience of acupuncture were recruited for the trial and, after testing for the inclusion/exclusion criteria, were allocated randomly to one of the three treatment groups. Patients were blinded to verum acupuncture versus sham acupuncture, but not to standard therapy.

Logistics of a Multicenter Acupuncture Trial in an Outpatient Environment

Based on the results of practitioner interviews and expert panel recommendations, we decided to test acupuncture in its naturalistic environment, that is to say in an outpatient setting. We trained 41 orthopaedic physicians working out of private practices as trial centers, in order to be able to recruit the sufficiently large number of patients needed to test the expected subtle differences between the verum, sham and standard interventions. To ensure a homogeneous quality of acupuncture in all trial centers, all of the orthopaedists had to have passed nationally recognized examinations of the German Acupuncture Research Group with a minimum of 140 hours of acupuncture training, and all were accustomed to the specific requirements of treating locomotive disorders, especially cSP, with acupuncture.

Additionally, prior to the start of the trial all of the participating orthopaedists had attended a one-day seminar on the specific modalities of the trial therapy. In this seminar the examination of the shoulder-pain patient and the documentation of the trial data were presented. Emphasis was on the specific trial interventions. The specific location and needle techniques for all verum and sham acupuncture points to be used in the trial were presented and practiced. The point selection rules developed for this trial were discussed and it was ensured that they were uniformly applied by all physicians involved. The various standard therapy options were also presented and practiced. All physicians were advised how to interact with the patient in such a way that the patient could not detect from the physician's behavior whether he was receiving verum or sham acupuncture. All physicians agreed to be visited by trial monitors.

Development of the Treatment Protocols

Verum acupuncture

A therapeutic procedure on which most of the books agreed was extracted from widely accepted Western and Chinese (in English translation) acupuncture textbooks [1, 6, 15, 20, 24, 27, 33, 41, 42, 47-49]. An expert panel, consisting of five opinion leaders, authors of leading German acupuncture textbooks and renowned teachers of acupuncture, was invited to discuss the result. They also gave suggestions on how the acupuncture therapy distilled from the literature could be improved. Since it is a paradigm of acupuncture treatment to use an individual set of points for each patient, which also has to be adjusted over the course of treatment to the changing energetic condition of the patient, we had to develop a procedure describing defined acupuncture points as well as defined point selection rules, along with the type and intensity of needle stimulation, and the number and frequency of the treatment sessions.

Ultimately the following consensus for a verum acupuncture protocol was formulated. Patients would receive 15 acupuncture treatments, up to three per week, each lasting for 20 minutes. Points were subdivided into "obligatory points", to be needled in all cases, and "individual points". These individual points were adjacent and distal points according to well-established channel selection rules. One to three Ahshi points (locus dolendi points) were to be identified and needled with appropriate depth; the aim at the Ahshi points was to induce the typical individual feeling of shoulder pain by manual needle manipulation and then to withdraw the needle 1-2 mm. Distal points on the homolateral leg were to be selected from stomach 38 and gallbladder 34. While needling these points a short movement of the shoulder was allowed. Depending on the site and quality of the reported pain, 5 to 10 needles (average 8) needles (AsiaMed 0.3 mm) would be inserted unilaterally to a depth of 1 – 3 cm. Needle manipulation was mild to strong, so that a numb, warm feeling around the acupuncture point (Deqi) was achieved. Point selection according to TCM syndromes was not allowed. No further treatment was administered (see Table 1).

Sham acupuncture

A search of the literature, interviews and expert panel opinions were used to develop the sham acupuncture protocol [5, 40, 45]. Sham acupuncture had to be of minimal effectiveness but at the same time had to be as similar as possible to the verum acupuncture, so that acupuncture-naïve patients would not be able to distinguish sham from verum acupuncture. Therefore sham acupuncture had to meet the following criteria: insertion of needles into the skin at non-acupuncture points; same number of needles and same needle material; same duration of treatment session, same number and frequency of treatments; interaction with the patient as similar as possible to verum acupuncture. Therefore in our study patients received up to 15 treatments of sham acupuncture, 1 to 3 treatments per week, lasting for 20 minutes each. Sham acupuncture was carried out by the same physicians and was standardized to 8 needles at defined non-acupuncture points, 4 needles above the medial part of the tibia bilaterally, depth of needle insertion less than 5 mm. Other than the application of sham acupuncture, information and handling of these patients was identical to those in the verum group (see Table 1).

Standard therapy

In the absence of generally accepted guidelines of conservative standard therapy for shoulder pain conditions, we undertook a literature review and conducted interviews with selected orthopaedic experts to develop a consensually agreed standard therapy [16, 34, 36, 43]We decided that all patients of the standard group would receive 50 mg diclofenac on a daily basis. Additionally, 15 sessions of conventional conservative orthopaedic treatments were selected on an individual

Table 1.

Verum acupuncture	**Sham acupuncture**	**Standard therapy**
General Information: Average number of needles: 8 15 treatment sessions over 5 to 9 weeks Treatment time: 20 minutes Needle material: AsiaMed 0.3 Depth of needling: 1-3 cm	**General Information:** Average number of needles: 8 15 treatment sessions over 5 to 9 weeks Treatment time: 20 minutes Needle material: AsiaMed 0.3 Depth of needling: 0.5 cm	**General Information:** 15 treatment sessions over 5 to 9 weeks. Treatment time: 20 minutes
Obligatory points: depending on location of the pain: 1-3 Ahshi points (locus dolendi). GB 34, St 38	**Obligatory points:** 8 points, 4 points on the front of the tibia on each leg on non acupuncture points	**Obligatory treatment** 50 mg diclofenac daily
Individual points depending on location of the pain and channel: Lung: Lu1, 2, Jianneiling, Lu 7, 5 Large Intestine: LI 15, 14, 11, 4 Sanjiao: SJ 14, 13, 5 Small Intestine: SI 10, 9, 3 Points for the neck: SI 11, 12,13, Gb 21, SI 3, Lu 7	No individual points	**Individual treatment:** Physiotherapy, physical exercise, heat or cold therapy, ultrasound treatment, TENS.
Stimulation technique: Chronic pain: strong stimulation and Deqi at adjacent and Ahshi points, weaker stimulation and Deqi at distal points. Activated pain: strong stimulation and Deqi at distal points, weaker stimulation and Deqi at adjacent and Ahshi points.	**Stimulation technique:** superficial needling, no manual stimulation, no Deqi.	**Stimulation technique:** according to selected treatment. **Not allowed:** Injections or cortisone of any kind

GB = Gallbladder; St 0 Stomach; Lu = Lung; LI =Large Intestine; SJ = Sanjiou / Triple Warmer; SI = Small Intestine

basis from: physiotherapy, physical exercise, heat or cold therapy, ultrasound treatment and transcutaneous electric nerve stimulation (TENS). Care was taken to exclude standard therapy procedures that could interfere with acupuncture needling, especially injections that might coincidentally be placed in acupuncture points. For this reason injections or cortisone applications of any kind were not allowed. Other than that, management of these patients was identical to that of the other two groups (see Table 1).

Assessment of Data

The data assessment procedures and endpoints were selected as being suitable to an ambulatory environment. It was mandatory that data collection be precise, non- bureaucratic and not vulnerable to error. All trial centers were supported and data collection was reviewed and verified by trial monitors.

Assessment Prior to Treatment

The personal data and details of the patient's medical history and present condition that were collected included: localization and duration of cSP; history of trauma; influence of particular postures on pain; patient being compromised by (i) work or sports activity or (ii) activities up to thigh, thorax, neck, top of head, or above head; pain worse at night; number of physicians consulted for cSP; previous treatments; surgical recommendations, and medical drug intake for last 14 days.

Pain intensity was scored on 100 mm VA scales, with 0 representing "no pain at all" and 100 mm representing "most intense pain imaginable" and on a four-point box scale (no, light, moderate and severe pain). Additionally, patients kept a pain diary by documenting their daily pain score on a VA scale.

The physical record of the shoulder included x-rays to detect omarthrosis or other bone pathology, testing for diminished strength or atrophy of the muscle, tenderness on palpation, range of passive motion (abduction, adduction, elevation, retroversion, ARO, IRO with arm downwards or 90° abduction). Diagnostic tests were Jobe, Yergason, sulcus, apprehension, horizontal arc, hand on/behind the head and elbow ventral/dorsal. Data required for correct acupuncture treatment were taken: precise pain location and its relation to an acupuncture channel, pain quality (deep or superficial, fixed or moving, influenced by cold or heat).

Assessment after Treatment and after 3 Months

Directly after the end of the six-week treatment protocol and again three months later, physical data were recorded again. Additionally the following data were assessed: degree of pain relief on a VA scale (average pain level during the last seven days); overall rating of the treatment and the success of the treatment on a four-point scale (excellent, good, satisfactory, failed). In case of treatment protocol failures the reasons for failure were documented (e.g. requirement for surgery, worsening of the disease).

Randomization

Patients admitted to the study were randomly assigned to one of the three groups (verum acupuncture, sham acupuncture, standard therapy) according to a computer-generated randomization list. Central telephone randomization was provided by the Department of Statistics in Medicine, Heinrich Heine University, Düsseldorf. Randomization was stratified into two balanced strata according to the age of the patient: (stratum 1) ≥ 25 and ≤ 45; (stratum 2) $\geq$ and ≤ 65

Endpoints

From pilot data, clinical experience and previous acupuncture trials, we observed that treatment outcome tended to be better three months after the end of treatment compared to the outcome directly after the end of treatment. Therefore the primary endpoint was defined as a reduction of at least 50% of the baseline VAS score three months after the end of the treatment protocol (the VAS score referring to average pain level during the last 7 days before measurement).

Secondary endpoints were a VAS change of at least 50% from baseline directly after the end of the treatment protocol and an "excellent or good" rating of treatment effect on the four-point scale at the end of the treatment protocol as well as three months later.

Hypothesis to be tested

In the treatment of chronic shoulder pain, the effect of verum acupuncture exceeds that of sham acupuncture or that of conservative orthopaedic treatment alone.

Sample size

On the basis of pilot studies and reviews of published acupuncture trials our trial was planned to detect an effect of verum over standard therapy of at least 20%. Under the least favorable assumption of 30% protocol failures, to reach a test power of 90% with a global level of significance of a=0.05 (as well as adjustments for multiple testing and three interim analyses) the calculated sample size was 420 valuable patients.

Discussion

Rationale of the Design and Multicenter Logistics

The multicenter trial design meant that we were able to test acupuncture in its naturalistic setting. During the clinical phase of the trial it turned out that only 26 out of the 41 (63%) trained physicians were able to recruit and treat patients for the trial; therefore15 trial centers not contributing to the trial had to be closed. Notices had to be placed in the media to assist in recruiting the required number of patients. These experiences regarding cooperation of ambulatory trial centers and the need for support by public media might serve the development of future ambulatory trials.

Nevertheless the multicenter design allowed us to recruit 452 patients, 32 more than the required number calculated. Since all physicians in the trial had passed nationally recognized examinations with a minimum of 140 hours of training in acupuncture and ad-

ditionally had attended a one-day seminar on the specific modalities of the trial therapy, we were able to test a homogenous style and quality of acupuncture. This is a prerequisite for reproducibility and generalizability, which are critical components of rigorous efficacy trials [18].

For some researchers the highest priority in acupuncture research is the test of efficacy; for others it is the evaluation of its clinical relevance [11, 37]. For the former the question is: "Is verum acupuncture more effective than the unspecific needling of sham acupuncture?" For the latter it is: "Is verum acupuncture just as effective as or more effective than an established standard therapy?" We decided to address both questions simultaneously by designing a three-armed trial, testing verum acupuncture against both unspecific needling (for efficacy) and against established standard therapy (for clinical relevance).

TCM acupuncture treatment is based on theoretical concepts and clinical experience. Many acupuncture textbooks exist in China, the USA, Germany and elsewhere; however, well established guidelines are lacking worldwide. Also there is considerable variability among practitioners with respect to TCM diagnosis, selection of points and recommended number of treatments [18]. The teachings of different acupuncture schools, the background of the practitioner – medical doctor or non-medical doctor of Oriental medicine – as well as socioeconomic factors, all influence acupuncture practice. Therefore we chose to develop the verum treatment protocol by conducting a literature review, supplemented by interviews with experienced practitioners and the recommendations of an expert panel. This procedure recently has been recommended by other authors as well: the use of practitioner surveys can enhance the systematic development of acupuncture treatment protocols and should therefore be part of this process in future clinical trials of common conditions [38]. Limitations associated with this process are that clinicians will favor locally accepted acupuncture styles, and that is why we began with the international literature review. Future studies also should consider international expert recommendations.

We selected shoulder pain as the appropriate condition because it meets important criteria for a large acupuncture RCT. The incidence is high enough to facilitate successful recruitment of patients [14, 35], the conventional treatment is not always satisfactory [8, 17, 32]and the propagated success rate of acupuncture allows one to expect significant results with the planned 420 patients. Furthermore, acupuncture treatment of shoulder pain can be clearly described. In shoulder pain only tendons, muscles, nerves and the fibrotic structures of the capsula are affected. Therefore the majority of textbooks recommend point selection based on Ahshi, local and distal points according to the affected channels; this has been confirmed 1999 by Lehmann [25]. For these point selection rules Sherman has shown a high agreement among practitioners regarding the use of local and distal points, the use of points on the meridians traversing the affected area, the use of points determined by palpation, and the importance of eliciting De Qi [38]. If in contrast the disorder were of multilocal character (e.g. fibromyalgia), also affected the bone structures (low back pain), or were complicated by possible psychosomatic attributes (e.g. headache), the selection of points would have to become more sophisticated. In these cases point selection would be determined not only by the affected meridians but also by the so-called syndromes of TCM. Here the definitions are not as clear-cut; the TCM diagnosis of the syndrome and the corresponding acupuncture points vary from one acupuncture school to another, so that they ultimately might depend more on the practitioner than on the patient's disease [18].

Treatment Interventions

Acupuncture textbooks provided no guidance on how many treatments are appropriate for chronic shoulder pain. Ezzo et al. found that RCTs with more than six treatments show better results than those with fewer than six [12]. Acupuncturists in Washington, DC believe that nine treatments are sufficient for a locomotive disorder such as low back pain [38]. On the other hand a trial with eight treatments for shoulder pain showed improvement directly after treatment but not after three months [23]. Other studies we reviewed on locomotive disorders showed better results after 12 and 15 [2, 31] treatments than after 5 and 9 [7, 19]. We felt that economic rather than clinical reasons have led to trials with too few treatments in the past. In accordance with the recommendation of the clinicians we interviewed and of the expert panel, as well as our own unpublished retrospective data, we settled on 15 treatments.

Since an individual point prescription is mandatory according to most textbooks, but since on the other hand it is still unclear whether an individual approach is better than a fixed prescription, we decided to use a combination of both, i.e. obligatory and individual points [18]. For shoulder pain we could show that it was possible to reach a consensus on the usefulness of acupuncture treatment consisting of the obligatory points as well as individual ones. We were able to describe point selection for an individualized therapy in terms of an algorithm and to train physicians to follow the treatment protocol successfully.

For sham acupuncture, we followed other authors in rejecting sophisticated techniques like the Streitberger needle because they would have required substantial deviations from the usual practices of acupuncturists [11, 37, 40]. We used 8 needles superficially inserted in non-acupuncture points on the tibia. This method is open to discussion. Birch states that superficial needling might have effects similar to the Japanese style of acupuncture, and that non- acupuncture points might be regarded as effective in other acupuncture systems [5]. Points on the leg might not be as convincing as on the arm, or might be to close to highly effective acupuncture points like Stomach 38 and therefore would elicit a specific effect [40]. Nevertheless, our sham procedure was based on several considerations. In Germany a wide variety of acupuncture styles are known, among them some avoid needling any points on an affected joint – e.g. hand, scalp or ear

acupuncture only selecting points in those respective regions [13]; Sherman demonstrated that even pricking an acupuncture point with a toothpick is a convincing sham method [39]; and we only included acupuncture-naïve patients. Putting together these aspects we decided on this protocol to test verum needling against unspecific needling and did not find any data in our trial that would have indicated an insufficiently convincing sham intervention.

The origin of shoulder pain is manifold and not always clear. Generally accepted guidelines for the conventional treatment of shoulder pain conditions do not exist [17] [8, 32]. Care was taken to exclude standard therapy procedures of unproven efficacy, such as injections of any kind, that could interfere with acupuncture needling, especially when coincidentally placed in acupuncture points [3, 4, 22, 44, 46].In the absence of accepted guidelines, the standard therapy protocol was developed by consulting textbooks on orthopaedic treatment of shoulder pain, experienced clinicians and an expert panel. The standard therapy protocol therefore reflects the usual clinical treatment of shoulder pain in Germany, with the exception that neither injections of any kind nor cortisone therapy were allowed.

Due to the setting of the trial in ambulatory treatment centers (primary care centers) the trial is patient blinded but not observer blinded All investigators were advised and trained to give equal information, time and care to all patients, regardless of whether the patients belonged to the verum, sham or standard group.

In view to the ambulatory setting of the trial we chose endpoints that are generally accepted for shoulder pain and that are not too difficult to assess. Since acupuncture is primarily regarded as a pain treatment, the VAS was selected as the primary outcome criteria. The CONSTANT score was not used, because only 15% of it refers to pain and the remaining 85% to shoulder function [10]. We also obtained an overall rating of the treatment on the four-point scale (excellent, good, satisfactory, failed). Collins et al (2001) showed in a meta-analysis that the overall rating of excellent or very good correlates highly with very complex tools of pain or functional measurements, and that, according to Collins, it is an even more appropriate endpoint than pain intensity alone [9].

Conclusion

We showed that it is possible to develop a large RCT on the use of acupuncture for the treatment of shoulder pain in a naturalistic environment, namely in the offices of orthopaedic physicians. Using a multicenter design 452 patients were recruited for the trial. Even though 26 different acupuncturists took part as active test centers, homogeneous quality of acupuncture treatment was applied. By means of an extensive literature review, along with interviews with experienced practitioners and expert panel recommendations, we were able to design an acupuncture treatment protocol that was the object of a broad consensus. By subdividing the treatment into obligatory points and individual points, a clear treatment algorithm could be formulated, and the treatment could be individualized by using specified point selection algorithms. Thus the trial is open to replication and the results are highly generalizable. Our positive experience with the GRASP trial substantially contributed to the design of the later German acupuncture (GERAC) trial on acupuncture for chronic low back pain, tension type headache, migraine and osteoarthrosis of the knee [11, 29].

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