

• Study Protocol

Evaluation of the effect of acupuncture on hand pain, functional deficits and health-related quality of life in patients with rheumatoid arthritis— A study protocol for a multicenter, double-blind, randomized clinical trial

Susana Seca^{1,2,3}, Sebastian Kirch^{2,3}, António S. Cabrita¹, Henry J. Greten^{2,3}

1. Faculty of Medicine, University of Coimbra, 3045-137 Coimbra, Portugal

2. Institute of Biomedical Sciences Abel Salazar, University of Porto, 4050-313 Porto, Portugal

3. Heidelberg School of Chinese Medicine, 69126 Heidelberg, Germany

ABSTRACT

BACKGROUND: Rheumatoid arthritis (RA) is a systemic inflammatory disease characterized by functional disability and pain. Although acupuncture is widely used, until now Western acupuncture studies on RA have not shown conclusive positive results. Acupuncture is regarded as a reflex therapy that has effects on the human autonomic nervous system. By establishing a traditional Chinese medicine (TCM) diagnosis first, the practitioner is able to choose acupoints according to the state of each individual patient.

METHODS/DESIGN: We are interested if acupuncture, using a classical diagnostic procedure to allocate acupoints to the patient according to the *Shang Han Lun* theory, can be effective in relieving pain, improving hand function and increasing health-related quality of life in RA. The authors intend to harmonize TCM diagnosis according to clinical and genetic profiles. Patients with the TCM diagnosis of a so-called Turning Point syndrome will be followed up in a randomized, prospective, double-blind, placebo-controlled, multicenter and three-armed parallel-group study with a standardized treatment in order to optimize potential therapeutic effects of acupuncture on pain, strength and muscle function of patients with RA as well as the influence on inflammation and quality of life.

DISCUSSION: The findings of this study will provide important clinical information about the feasibility and efficacy of acupuncture treatment for RA patients. In addition, it will explore the feasibility of further acupuncture research.

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Keywords: acupuncture; rheumatoid arthritis; quality of life; pain; hand strength; study protocol; randomized clinical trial; double-blind method

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Correspondence: Susana Seca, MSc; E-mail: susana.seca@hotmail.com

1 Introduction

Rheumatoid arthritis (RA) is a chronic inflammatory and multisystemic autoimmune disease characterized by symmetrical, persistent inflammatory synovitis and destructive polyarthritis. According to the World Health Organization data, approximately 1% to 2% of all people in the world suffer from RA and its prevalence is about 0.2% to 0.5% in the Portuguese population^[1]. More than 90% of patients with RA have a disorder of the hand joints; RA-related symptoms lead to activity limitations in 30% of the patients^[2].

The social-economic impact is high on the individuals as well as on the health system^[3]. Treatment of RA is dominated by the use of non-steroidal anti-inflammatory drugs, including second-generation cyclooxygenase-2 inhibitors, disease-modifying antirheumatic drugs and analgesics. Recently, the use of biological agents has begun^[3]. However, these medications are associated with many unwanted side effects, have limited efficacy and may lead to toxicity^[4,5]. The biological agents have higher costs and side effects, such as life-threatening infections and increased risk of malignancies, which limit their use^[3].

These and other limitations led between 60% and 90% of unsatisfied arthritis patients to use complementary and alternative medicine (CAM), including acupuncture^[3,5,6]. Acupuncture is one of the most popular and most widely used techniques in traditional Chinese medicine (TCM). It is known that acupuncture stimulates the autonomic nervous system, for example by causing biochemical changes that influence the body's homeostatic mechanisms by releasing neurochemical messenger molecules. It might also positively affect areas of the brain that reduce sensitivity to pain, stress and inflammation by promoting the release of vascular and immunomodulatory factors and by improving biomechanical functions^[7].

Acupuncture in treatment of RA can decrease the levels of pro-inflammatory cytokines, including interleukin-1 (IL-1) and IL-6, increase the levels of inhibitory cytokines (IL-4 and IL-10)^[8], induce vasoactive intestinal peptide expression (an anti-inflammatory neuropeptide)^[9], inhibit the function of synovial mast cells (which are substantially involved in the initiation of inflammatory arthritis), up-regulate plasma adrenocorticotrophic hormone, down-regulate serum cortisol levels and synovial nuclear factor- κ B/p65 immune activity and restore the hypothalamus-pituitary-adrenal axis^[10].

It is also known that acupuncture stimulates the nervous system in a way that leads to the release of endorphins, as well as other neurohumoral factors, and thus to changes in the processing of pain in the brain and spinal cord and to an increase in local microcirculation^[11,12].

The choice of the acupuncture treatment, and consequently the efficacy of TCM therapy, depend on the differentiation of the diagnosis. This process is also called syndrome or pattern (Zheng) differentiation, because the pattern guides the choice of treatment. Pattern differentiation considers the physiological and pathological changes as well as every aspect of a disease phenotype, including the tongue appearance, pulse sensations, and body signs and symptoms^[13].

Although RA is classified as a single disease in Western medicine, it can be the result of different patterns in TCM. In classical TCM, part of the disease is believed to be the result of an invasion of the external pathogens (wind, cold, heat and damp)^[14], reactive heat with yin affection, qi and xue deficiency with stasis and phlegm, as well as the deficiency pattern (liver and kidney yin and yang deficiency)^[15-17].

In the general classification of painful obstructions in TCM, RA is classified as the "Bi" or occlusion syndrome^[18,19]. The "Bi" syndrome is characterized by poor or deficient circulation of qi and xue (stasis) as the result of an invasion of muscles and bones by agents that block the energy flow in the meridians^[20].

The Heidelberg Model of TCM explains basic body regulation using the regulation of temperature in a water bath as a model. In this model, the regulation of a system is mathematically explained by a sinus wave as a projection of regulatory states of the body or uprising and descending energies (up and down) which proceed in circular processes and include antagonistic parts of the movement (compass rose)^[21,22]. Therefore, body regions are predominantly stimulated in a certain internal movement and autonomic activation takes place first in the liver region, then in the center of the thorax and the heart and finally progresses via the hypochondrium region and lungs to the lower abdomen and the kidney region (Figure 1)^[21].

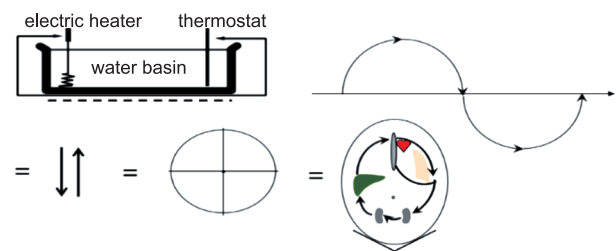


Figure 1 The Heidelberg Model of traditional Chinese medicine concepts

Water basin, sinus wave, upward and downward movements, compass-rose and projection of upward and downward movements in the body region (source: Greten, 2013^[21]).

The Heidelberg Model uses this mathematical representation to explain the six levels of the *Shang Han*

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