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# Anxiety related to De Qi psychophysical responses as measured by MASS: A sub-study embedded in a multisite randomised clinical trial

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ABSTRACT

Acupuncture has been broadly applied in the management of many diseases and conditions; however, its mechanism of action has been partially elucidated. Additionally, assessment of psychophysical responses in the acupuncture therapy is not common regarding anxiety disorder studies. Taken together, the therapeutic effect of acupuncture appears when De Qi psychophysical response is experienced following stimulation of the afferent sensory nerves.

The present study investigates the level of anxiety perceived at different occasions in acupuncture and mock laser group. Furthermore, it examines the relationship between perceived De Qi psychophysical response and the level of anxiety experienced during administration of each intervention.

The study was embedded in a two-arm parallel design multi-center, randomized clinical trial, the Tennis Elbow Acupuncture-International Study-China, Hong Kong, Australia, Italy. Participants' level of anxiety was measured using a validated instrument, the Massachusetts General Hospital Acupuncture Sensation Mood Scale. Ninety-six participants with Lateral Elbow Pain were randomly allocated into two groups; the acupuncture treatment group (n = 47) and the inactive mock laser control group (n = 49). Data were collected immediately following the interventions at the first and the ninth session within the clinical trial.

Acupuncture with De Qi did not induce higher level of anxiety compared to prior administration of acupuncture. In fact, participants were more relaxed after receiving acupuncture than those who received mock laser. There was also a weak association between participants' perception of anxiety during acupuncture and the MASS De Qi Index in session nine only ($p < 0.01$). Further investigation of the result revealed weak positive correlation between anxiety perceived during administration of acupuncture and the following De Qi characteristics; 'soreness' ($p < 0.01$), 'Deep pressure' ($p < 0.05$), 'Heaviness' ($p < 0.05$), and 'Fullness/distension' ($p < 0.05$).

Acupuncture can be regarded as a potential therapy for preoperative anxiety through its possible regulatory function of emotion. While culture may not alter the expectation of the individual regarding anxiety, symptomology associated with anxiety should be understood within the context of the cultural background.

## 1. Introduction

All physical stimuli has an emotional component as there is also a physiological response to a psychological stimulus,[1] and this response emerges from the interaction of the various sub-systems within the environmental demands.[2] While acupuncture has been used for the

*Abbreviations:* ANS, Autonomic Nervous System; AUS, Australia; CAM, Complementary and Alternative Medicine; CHA, China; CNS, Central Nervous System; CRS, Credibility Rating Scale; CONSORT, CONsolidated Standards of Reporting Trials; DASH, Disabilities of the Arm, Shoulder, and Hand; DMPFC, Dorsomedial Prefrontal Cortex; HK, Hong Kong; IA, Interoceptive Awareness; ITY, Italy; LEP, Lateral Elbow Pain; MASS, Massachusetts General Hospital (MGH) Acupuncture Sensation Scale; MDI, MASS De Qi Index; MMS, MASS Mood Scale; PNS, Parasympathetic Nervous System; SA, state or situational anxiety or pre-operative anxiety; STRICTA, Standards for Reporting Interventions in Clinical Trials of Acupuncture; SNS, Sympathetic Nervous System; TA, Trait Anxiety; TEA IS CHAI, Tennis Elbow Acupuncture-China, Hong Kong, Australia, Italy; TCM, Traditional Chinese Medicine; VAS, Visual Analogue Scale; WHO, World Health Organisation

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management of a wide variety of disorders,[3] its procedures are claimed to provoke autonomic responses such as fear, pain and anticipation of pain,[4] hence potentially evoking mild level of anxiety in some individuals.[5]

Anxiety is considered as a prevalent complaint in any medical environment, specifically in pre-operative and medical settings,[6] and the first stage of the experience of anxiety often involves a shift toward increased sympathetic autonomic activity.[2] In acupuncture research, it is essential to distinguish between the different types of anxiety that may differ with contextual events and conditional situations [State or Situational Anxiety (SA)] or may also be present as a substantially more generalised and steady characteristic [Trait Anxiety (TA)].[5] While the term SA is defined as a '*state of apprehension, discomfort, and anxiety, precipitated by the experience of new or changed situation or event*',[7] there is not always a clear demarcation between TA and SA.[8]

Importantly, there is a growing research on 'Interoceptive Awareness'- (IA), defined as '*the process of receiving, appraising, and responding to internal body sensations*',[9] which may have the potential to integrate many disciplines' views. Interoception has been associated with emotional regulation, a diverse set of cognitive processes,[10] and attention.[11] Somatic awareness,[12] (e.g. proprioception and interoception)[13] by adaptively and internally self-focusing[12,13] (e.g. visual attention)[13] on the in-the-moment bodily changes [12] (e.g. focusing the attention on the acupoints) stands conclusively as a top–down process that is driven by attention, beliefs, expectations, biases, and emotions[12] thus affecting perceptions. Maladaptive forms of IA can however be characterised by hypervigilance and catastrophising over body signals/-sensory responses and are associated with clinical complaints such as anxiety.[14] It has been also postulated that emotions, in particular anxiety, can alter the physiological status of the Autonomic Nervous System (ANS)[5] which is closely linked to the limbic system.[15] The limbic structures are considered to play a central role in the regulation and integration of sensorimotor, autonomic, cognition[16] as well as affect and emotion.[16,17]

In Chinese medical texts such as the *Huang Di Neijing* (The Yellow Emperor's Classic of Internal Medicine) and the *Zhen Jiu Da Cheng* (Great Compendium of Acupuncture and Moxibustion), the patients' psychological state is considered an important factor associated with De Qi [得氣].[18] However in Traditional Chinese Medicine (TCM) there is no such term that corresponds exactly to anxiety, several early Chinese disease entities closely resemble the symptoms related to anxiety such as; '*Jing Kong* (fright and fear)',[19,20] '*Jing Ji* (fear and palpitation)', [19–21] '*Zheng Chong* (panic throbbing)'[19–21] as defined in the *Jing Yue Quan Shu,*[21] '*Zang Zao* (agitation)' in the *Jin Gui Yao Lue,* [21] and '*Li Ji* (Rebellious Qi of the Chong Mai)'.[21] The importance given to De Qi stems often from its purported clinical significance,[22–27] *needling is effective when one obtains De Qi (Ling Shu, chapter3)*,[28] a belief held by practitioners' traditional and conservative viewpoints throughout the many dynasties of ancient China, and which still influence today's clinical practice.[29]

Acupuncture needling often evokes complex somatosensory sensations[30] (literally De Qi), which are often characterised as a conglomerate of unique somatosensory responses.[31–38] The term 'De Qi' is frequently acknowledged as 'obtaining Qi',[22,23,34,39,40] and to be perceived by patients as a unique response[41,42] and/or by the practitioner as needle grasp.[41,42] These complex psychophysical responses are suggested to be particularly important in modulating Central Nervous System (CNS) activity,[43] involving a broad spectrum of afferents nerve fibers[26,29,35,44,45] without reaching the threshold of overt noxious simulation.[26] Neuroimaging studies have also shown that the hypothalamus[46,47] and the limbic system are important networks in mediating acupuncture's diverse effects and the perception of De Qi.[16,17,26,46,48] It is also noteworthy to point out that the therapeutic effects of acupuncture on various psycho-behavioral disorders may also be attributed to the inhibitory effects of acupuncture manipulation with De Qi on Dorsomedial Prefrontal Cortex (DMPFC) activity.[3]

There are different pharmacological and non-pharmacological approaches in the management of anxiety[49] including selective serotonin reuptake inhibitors,[50] administration of benzodiazepine,[49] cognitive behavioral therapy and various self-help measures.[50] The use of Complementary and Alternative Medicine (CAM), as a whole, has been increasing for the management of psychiatric conditions[6] within the western world.[51] Despite this trend, at this point in time there is no evidence to suggest CAM is superior to conventional management.[51] The results of several randomised clinical trials have suggested some beneficial effect of utilising either acupressure or acupuncture in pre-operative anxiety (SA) in different circumstances including hospital transfer,[52] cancer,[49] memory functioning of students,[53] women undergoing in vitro fertilization,[54] gynaecological surgery,[55] and maternal anxiety.[56] Although there is, as yet, insufficient evidence for the treatment of specific anxiety disorder with acupuncture, some reports suggest promising benefits for the management of SA.[50]

Accordingly, it is worthy to investigate participants' level of anxiety reported at different occasions explicitly before and during acupuncture and to examine the role of 'anxiety' in perception of the acupuncture psychophysical responses in two study groups randomised to receive either acupuncture or mock laser. Indeed, exploring such a key component will allow a better understanding of the specific treatment components (e.g. stimuli) and the mechanism underlying acupuncture intervention including the psychological component of acupuncture intervention.

## 2. Material and methods

### 2.1. Trial design

The study was embedded in a stratified randomised, double blinded (outcome assessor, and participant) controlled clinical trial, the Tennis Elbow Acupuncture Study which was administered at four sites – China, Hong Kong, Australia, Italy, to investigate the efficacy of acupuncture for the Lateral Elbow Pain (LEP). The study was designed according to comply with the STRICTA (Standards for Reporting Interventions in Clinical Trials of Acupuncture) and CONSORT (CONsolidated Standards of Reporting Trials) statements.[57,58] The trial was registered with the Australian and New Zealand Clinical Trial Registry on the 11th of October 2013 (Identifier: ACTRN12613001138774) following approval from each of the four institution's ethical committees preceding to the study initiation and adhered to the Declaration of Helsinki.[59] Informed consent obtained for individual participant whom enrolled in the trial and all data were anonymised. For full details regarding participants' recruitment procedure, rational behind chosen interventions, and other procedures please refer to the published protocol.[60]

### 2.2. Inclusion and exclusion criteria

Participants were aged between 18 and 80 with a history of chronic unilateral-LEP for a minimum period of three months. Participants were excluded if they had a history of central or peripheral nervous system disease, inflammatory rheumatic diseases, gout, earlier episodes of LEP that had been treated surgically or with acupuncture within the last three months, or received either acupuncture therapy for any problems or concurrent physiotherapy for LEP within the previous week. Pregnant or needle phobic participants were also excluded.

### 2.3. Randomisation

Ninety-six participants (n = 96) with LEP commonly called tennis elbow (n = 24 per study site) were selected and enrolled in the trial. Participants were randomly assigned to either acupuncture (active treatment group) or mock laser (control group) with a 1: 1 ratio using a computer-generated sequence. Stratification during randomisation was