MARIA FERNANDA MONTANS ARANHA JORGE FERREIRA

EVALUATION OF ACUPUNCTURE, ELECTROACUPUNCTURE AND SHAM ACUPUNCTURE ON THE TREATMENT OF MYOFASCIAL PAIN AT THE UPPER TRAPEZIUS MUSCLE

AVALIAÇÃO DA ACUPUNTURA, DA ELETROACUPUNTURA E DA ACUPUNTURA SHAM NO TRATAMENTO DA DOR MIOFASCIAL NA PARTE SUPERIOR DO MÚSCULO TRAPÉZIO

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ABSTRACT

Myofascial pain (MP), caused by myofascial trigger points (MTrP), is the main cause of headache and neck pain. It is associated with muscular stiffness, stress and can influence the quality of life of symptomatic patients. Aiming to evaluate the effect of acupuncture and electroacupuncture on the treatment of MP at the upper trapezius muscle, sixty women aged between 18 and 40 years (27,33±4,95 years), presenting at least one active MTrP at the upper trapezius and local or referred pain for more than six months were randomized in to and three groups: electroacupuncture (EA), acupuncture (AC) and SHAM-acupuncture (SHAM). Both examiner (CEEM) and volunteers were blinded to the treatments. The selected acupoints were VB20, VB21, F3 and IG4, besides a maximum of 2 "ashi points" in each upper trapezius. The effectiveness of treatment (eight sessions), as well as it maintenance till one month follow up, were evaluated concerning the intensity of pain (Visual analog scale: VAS), range of motion (fleximetry), quality of life (SF-36), stress (area under the curve: AUC_G; cortisol awaking response: CAR) and ultrasound (US) image (MTrP area). Influencing factors and the menstrual cycle phases were monitored. According to its distribution, data were analyzed by pared *t-test, Wilcoxon signed rank,* ANOVA repeated measures, Friedman test, ANOVA or Kruskal Wallis. Pearson's correlation was applied. The level of significance was set in $\alpha = 0.05$. It was observed reduction on general pain on treated groups after all sessions (EA: $P<0.001$; AC: $P<0.001$). After treatment, intensity of pain on the right trapezius (RTPz) decreased in the EA ($P<0.001$) and AC ($P=0.025$) groups, but on the left trapezius (LTPz) it was only observed in the EA group ($P<0.001$). There was interaction of factor "time of evaluation" with factor "group" for general pain in the AC and EA groups; and for pain at the RTPz and LTPz only in the EA group. There was increase on rotation to the left in the EA group ($P=0.049$) and on inclination and rotation to the right on group AC ($P=0.005$; $P=0.032$). There was increase on AUC_G ($P=0.006$) and CAR ($P<0.001$) in the AC group. While SHAM presented significant increase only on bodily pain ($P=0.005$), EA and AC showed increase at the same following domains, with respectively *P* values: physical function (P=0.011; P=0.016), role physical

(P=0.027; P=0.13), bodily pain (P=0.010; P=0.003), general health (P=0.017; P=0.011), vitality (P=0.010; P=0.011), mental health (P=0.018; P=0.014) and physical components (P=0.019; 0.002). It was observed a decrease on MTrP area (US) in the groups EA (TPzD: P<0.001; TPzE: P=0.001) and AC (RTPz e LTPz P<0.001), and in the SHAM group (LTPz: P=0.036). The EA group has shown to be more effective on pain relief when compared to other groups. Both AC and EA were effectiveness improving tissue morphology and quality of life. AC seems to be more indicated to the decrease stress and increase cervical range of motion than EA in women with myofascial pain at the upper trapezius.

Key words: Musculoskeletal Pain. Myalgia. Pain, Referred. Acupuncture. Electroacupuncture. range of motion, Articular. Stress. Psychological. Quality of Life. Ultrasonography.

RESUMO

A dor miofascial (DM), proveniente de um ponto gatilho miofascial (Pg), é a principal causa de dor de cabeça e pescoço. Sua presença é associada à rigidez muscular e estresse e pode influenciar a qualidade de vida de pacientes sintomáticos. Com o objetivo de avaliar o efeito da acupuntura e da eletroacupuntura no tratamento da DM da parte superior do músculo trapézio, sessenta voluntárias com idade entre 18 e 40 anos (27.33±4.95 anos), com pelo menos um Pg ativo na parte superior do músculo trapézio, dor local ou referida por mais de seis meses foram randomizadas em três grupos: eletroacupuntura (EA), acupuntura (AC) e acupuntura SHAM (SHAM). O avaliador e as voluntárias eram cegos aos tratamentos. Os pontos de acupuntura utilizados foram: VB20, VB21, F3 e IG4, além de no máximo, 2 pontos ashi em cada lado do trapézio superior. A efetividade do tratamento (oito sessões), assim como a manutenção dos resultados até um mês após o final do tratamento foram avaliadas pela intensidade de dor (escala visual analógica: EVA), amplitude de movimento cervical (fleximetria), qualidade de vida (SF-36), estresse (área abaixo da curva: AUC_G; resposta do cortisol ao acordar: CAR), imagem de ultrassom (US). De acordo com sua distribuição os dados foram analisados pelos testes: *teste-t pareado, Wilcoxon signed rank*, *ANOVA* para medidas repetidas ou teste de *Friedman*, *ANOVA* ou *Kruskal Wallis*. Foi aplicado o teste de correlação de Pearson. O nível de significância foi de α= 0,05. Foi observada redução na dor geral nos grupos EA (P<0.001) e AC (P<0.001) após todas as sessões. Na reavaliação, a dor no trapézio direito (TPzD) diminuiu nos grupos EA (P<0.001) e AC (P=0.025), já no trapézio esquerdo (TPzE), diminuiu no grupo EA (P<0.001). Em relação à dor geral correu interação dos fatores “fase de avaliação” e “grupo” para AC e EA, e para dor no TPzD e E apenas para o grupo EA. Após o tratamento houve aumento da rotação para a esquerda no grupo EA (P=0.049), e aumento da inclinação e rotação para a direita no grupo AC (P=0.005; P=0.032). Houve aumento da AUC_G (P=0.006) e CAR (P<0.001) no grupo AC. Em relação aos dados obtidos pelo SF-36, o grupo SHAM apresentou aumento significativo da dor (P=0.005); os grupos EA e AC mostraram aumento nos mesmos domínios, com valores respectivos de P:

capacidade funcional (P=0.011; P=0.016), aspectos físicos (P=0.027; P=0.13), dor (P=0.010; P=0.003), estado geral da saúde (P=0.017; P=0.011), vitalidade (P=0.010; P=0.011), saúde mental (P=0.018; P=0.014) e componente físicos (P=0.019; 0.002). Ocorreu diminuição na área do Pg (US) nos grupos EA (TPzD: P<0.001; TPzE: P=0.001) e AC (TPzD e TPzE P<0.001), e no grupo SHAM (TPzE: P=0.036). A EA se mostrou mais eficaz no alívio da dor quando comparada aos outros grupos. Tanto AC quanto EA foram eficazes na melhora da morfologia do tecido muscular (US) e da qualidade de vida. A AC parece ser mais indicada na diminuição do estresse e na melhora da amplitude de movimento cervical em mulheres com dor miofascial no trapézio superior.

Palavras Chave: Dor Musculoesquelética. Dor Referida. Acupuntura. Eletroacupuntura. Amplitude de Movimento Articular. Estresse psicológico. Qualidade de Vida. Ultrassonografia.

SUMÁRIO

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INTRODUÇÃO

A dor miofascial (DM) se origina de um ponto gatilho miofascial (Pg), comumente associado a disfunções sensoriais, motoras e autonômicas (Sun et al., 2010). O Pg localiza-se em uma banda tensa palpável em um músculo esquelético, é sensível à palpação e pode causar apenas disfunções motoras como rigidez e limitação na amplitude de movimento, identificando um Pg latente; ou pode também, além destas disfunções motoras, deflagrar dor espontânea no local da anormalidade muscular ou presença de dor referida, identificando então, um Pg ativo (Simons et al., 1999; Gerber et al., 2013). A dor referida é a dor percebida distante do Pg, podendo ser exacerbada à compressão e reconhecida como familiar, constituindo um dos critérios diagnósticos disponíveis mais importantes quando achados palpáveis também estão presentes (Gerwin, 1997).

Estudos epidemiológicos indicam que a dor miofascial é uma importante disfunção musculoesquelética (Fricton et al., 1985; Gerwin, 1999), sendo a principal causa de cefaléia e de dor cervical (Grosshandler et al., 1985). Há grande prevalência de Pgs na parte superior do músculo trapézio, tendo sido identificados em 70% de indivíduos com cefaleia tensional (Fernández-de-las-Peñas et al., 2007) e em 58% de sujeitos com dor nos ombros (Bron et al., 2011).

A acupuntura advém da Medicina Tradicional Chinesa. Esta técnica tem sido amplamente utilizada na China por mais de 4000 anos (Chon and Lee, 2013), e é reconhecida atualmente em outras partes do mundo. É definida como a inserção e manipulação de agulhas em pontos específicos do corpo, com o objetivo de atingir efeitos terapêuticos (Itoh et al., 2007; Sun et al., 2010; Chon and Lee, 2013). Apesar da reconhecida eficácia da acupuntura pela Organização Mundial de Saúde para o tratamento de diversas condições não apenas dolorosas, como insônia, ansiedade, infertilidade, estresse, constipação entre outros (World Health Organization, 2003), a grande maioria dos estudos relacionados à acupuntura aborda, predominantemente, o seu aspecto analgésico.

Nesse sentido, especial atenção tem sido dada à eletroacupuntura (EA), uma forma de acupuntura que inclui a passagem de uma corrente elétrica pelas agulhas (Koski et al., 2009). Pacientes com dor crônica, tratados com EA, mostraram significativa redução da administração de opióides (Zheng et al. 2008) e diminuição do limiar de dor à pressão (He et a., 2004). Ainda em relação à EA, foi descrito que a estimulação aplicada a 2Hz promove a liberação de encefalina, beta-endorfina e endorfina; enquanto o estímulo a 100Hz promove a liberação de dinorfina e, a combinação alternada destas duas frequências produz simultaneamente a liberação do conjunto destes peptídeos, resultando em máximo efeito terapêutico (Han, 2004).

Por outro lado, há evidências de que a acupuntura manual (AC) também promova analgesia. O estudo experimental de Bing et al. (1999) relatou a liberação de encefalinas após inserção e manipulação da agulha em ratos. Da mesma forma, foi descrito aumento significativo do limiar de dor em sujeitos com dor crônica (Grant et al., 1999) e do limiar de dor ao calor e à pressão em indivíduos saudáveis (Lang et al., 2010) submetidos à acupuntura .

Para comprovar os efeitos dos tratamentos no alívio da dor, a escala visual analógica (EVA) apresenta efetividade quando comparada a outros instrumentos para mensuração da dor (Jensen et al., 1999). Este instrumento tem sido amplamente utilizado para identificar intensidade de dor em pacientes com dor crônica (He et al., 2004; Xue et al., 2004; Nohama e Silvério-Lopes, 2009; Aranha et al., 2011; Gerber et al., 2013).

Além da dor, alterações relacionadas à rigidez característica do músculo com Pg devem ser mensuradas (Gerber et al.,2013). O flexímetro é um instrumento utilizado para a mensuração da amplitude de movimento articular que apresentou moderada a excelente confiabilidade intra e inter-examinador (Florencio et al., 2010).

É comum o paciente com dor crônica apresentar traços de ansiedade e tensão, desesperança ou depressão, inclusive alterações na qualidade de vida (Simons et al., 1999; Sun et al., 2010), tornando-se de importância a avaliação da possível influência dos

tratamentos em tais condições. Neste contexto, o Inventário de qualidade de vida SF-36 é um instrumento indicado, pois abrange vários domínios referentes à capacidade funcional, aspectos físicos, aspectos emocionais, intensidade da dor, estado geral da dor, vitalidade, aspectos sociais e saúde mental. Este instrumento foi traduzido para o português e as suas propriedades psicométricas já foram testadas e validadas (Ciconelli et al., 1999).

Ainda nesse sentido, estudos tem mostrado alteração na atividade do eixo hipotálamo-hipófise-suprarrenal na regulação de cortisol em indivíduos com dor crônica (Gaab et al. 2005; Riva et al., 2010). Uma vez que pode haver influência do estado emocional dos indivíduos com Pgs na condição dolorosa dos mesmos, a análise do cortisol possibilita o monitoramento dos níveis de estresse de indivíduos submetidos a tratamento de forma objetiva, auxiliando a análise dos resultados. A quantificação de cortisol na saliva tem se mostrado um método bastante eficaz para medir o estresse por ser simples, de fácil coleta e independente do fluxo salivar; diferentemente do método de quantificação do cortisol sanguíneo, que requer profissionais especializados e punção venosa, gerando maior estresse ao indivíduo e interferindo nos resultados. A concentração de cortisol na saliva serve de parâmetro para a concentração plasmática, sendo assim, sua investigação na saliva é conveniente para o monitoramento do sistema de resposta hipotálamo-hipófise-adrenal frente a estímulos estressores (Groschl, 2008).

Além da implicação da dor nos aspectos fisiológicos, emocionais e sociais, a avaliação das características morfológicas dos músculos possibilita a complementação do diagnóstico. Neste contexto, a ultrassonografia (US) é uma forma de diagnóstico objetiva, não invasiva e em tempo real, amplamente utilizada para visualização de músculos, tendões, fáscias, entre outros tecidos e órgãos. A US tem o potencial de caracterizar as propriedades viscoelásticas do tecido miofascial (Sikdar et al. 2009), quantificar as mudanças hemodinâmicas resultantes da compressão de vasos sanguíneos, fornecer medidas dinâmicas da performance muscular, como por exemplo durante a contração, e

demonstrar correlação entre estrutura e função (Chi-Fishman et al., 2004). Além disto, constitui um método de baixo risco para obtenção da informação descritiva do tecido, como a presença de gordura, fibras e fluídos, além das propriedades mecânicas (Shamdasani et al., 2008). A US foi recentemente testada quanto à complementação do diagnóstico clínico do Pg por Skidar et al. (2009). Estes autores concluíram que a técnica constitui um instrumento para identificação do tecido muscular normal e do tecido com Pgs, sendo este caracterizado por múltiplos focos de lesão muscular e presença de hetereogenicidade referente à variação da escala de cinza nas imagens obtidas e também quanto à consistência. Desta forma, os resultados subjetivos obtidos ao final de um tratamento de um Pg podem ser confirmados pelo uso do ultrassom.

Estudos relativos ao tratamento da dor miofascial têm mostrado a efetividade da acupuntura (Grant et al., 1999; Ceccherelli et al., 2005; Sun et al., 2010) e da eletroacupuntura (Aranha et al., 2011). No entanto, a literatura é escassa em pesquisas clínicas randomizadas e controladas comparando os efeitos das respectivas formas de aplicação.

Assim, este trabalho teve como objetivo comparar o efeito da acupuntura e da eletroacupuntura no tratamento da dor miofascial quanto à intensidade de dor, amplitude de movimento, qualidade de vida, estresse e imagem ultrassonográfica da parte superior do músculo trapézio superior.

CAPÍTULOS

Esta dissertação está baseada na Resolução CCPG UNICAMP/002/06 que regulamenta o formato alternativo para teses de Mestrado e Doutorado e permite a inserção de artigos científicos de autoria ou coautoria do candidato. Por se tratar de pesquisa envolvendo seres humanos, o projeto de pesquisa deste trabalho foi submetido à apreciação do Comitê de ética em Pesquisa da Faculdade de Odontologia de Piracicaba, tendo sido aprovado com o protocolo número 003/2011 (Anexo 1). Sendo assim, esta dissertação é composta de 3 capítulos, conforme descrito abaixo:

CAPÍTULO 1

Pain and range of motion in women with myofascial syndrome treated with acupuncture–and electroacupuncture: a double-blinded, randomized clinical tria.l Aranha MFM, Müller CEE, Gavião MBD

CAPÍTULO 2

Evaluation of acupuncture and electroacupuncture on pain, stress and quality of life in women myofascial pain syndrome: a double blinded, randomized clinical trial. Aranha MFM, Müller CEE, Gavião MBD

CAPÍTULO 3

Influence of acupuncture and electroacupuncture on trigger point ultrasound images after treatment of myofascial pain: A randomized controlled pilot study. . Aranha MFM, Müller CEE, Gavião MBD

CAPÍTULO 1

Pain and range of motion in women with myofascial syndrome treated with acupuncture and electroacupuncture: a double-blinded, randomized clinical trial

Short title: Pain and range of motion after treatment of myofascial syndrome pain

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Background: Myofascial pain treatment should promote the decrease of pain, the unstringing of contracted fibers and an increased range of motion. **Objective:** The aim was to evaluate the effect of electroacupuncture (EA) and acupuncture (AC) for myofascial pain of the upper trapezius and cervical range of motion (ROM), using SHAM acupuncture as control. **Method:** Sixty women presenting at least one trigger point at the upper trapezius and local or referred pain for more than six months were randomized into EA, AC and SHAM groups. Eight sessions were scheduled, and their effectiveness was evaluated in terms of pain and ROM: flexion (F), extension (E), inclination to the right (IR) and to the left (RL), rotation to the right (RR) and to the left (RL). Data were analyzed using paired t or Wilcoxon's tests, Friedman's test or an ANOVA with repeated measures, ANOVA or Kruskal-Wallis's and Pearson's correlations (α= 0.05). **Results:** There was reduction in general pain in the EA and AC groups after eight sessions (P<0.001). A significant decrease in pain intensity was observed for the right trapezius (RTPz) in all groups; for the left trapezius (LTPz), only the EA and AC groups showed reductions in pain intensity. Intergroup comparisons showed significant improvement in general pain in the EA and AC groups, and in the pain intensity for RTPz and LTPz in the EA group (P<0.05). Post-treatment, the EA group showed an increase in RL (P=0.049), while the AC group showed increases in IR (P=0.005) and RR (P=0.032). The AC group's results for IR were sustained until follow-up (P>0.05). **Conclusion**: EA and AC were effective for reducing the intensity of pain compared with SHAM acupuncture. AC also improved the cervical ROM.

Key words: Myofascial pain syndromes; acupuncture therapy; trapezius muscle

Introduction

Myofascial pain (MP) is characterized by the presence of tender, firm nodules called myofascial trigger points (MTgP). Within each trigger point is a hyperirritable spot, the "taut-band", which is composed of hyper contracted muscle fibers[1,2]. Clinically, the muscle with MTrP presents with stiffness and is associated with diminished strength and restricted range of motion[1,3] (ROM). Palpation of this spot within the trigger point provokes radiating, aching-type pain into localized referred zones consisting in an important musculoskeletal dysfunction[4,5] and one of main causes of headache and neck pain[6].

The treatment of MP requires that MTrP and muscles be identified as primary or ancillary pain generators[2]. Acupuncture has been used as an alternative to more traditional treatments for musculoskeletal pain, because it neurophysiologically or physically denervates the neural loop of the trigger point, reducing pain and to solve muscular over contraction. Acupuncture manually or electrically stimulates points on the body, via the insertion of needles to prevent or modify the perception of pain or to alter physiologic functions[7]. Electroacupuncture (EA) includes the passage of an electrical current through the needle[8].

Although acupuncture (AC)[7,9] and EA[10,11,12] have been shown effectively decrease the intensity of chronic pain, it is still unknown whether one of these treatments is more effective than the other for treating myofascial pain.

Clinically, myofascial pain treatment should increase the functioning of the evaluated muscle[3], promoting the decrease of pain and the unstringing of the contracted fibers. Subsequent to this, a reduction in muscle stiffness and an increased ROM would be expected.

Fiber contraction in the upper trapezius muscle, which presents a high prevalence of MTrP[13,14,15], promotes the extension and inclination of the head to the same side and

rotation to the opposite side[16]. Therefore, to evaluate this muscle's functioning, cervical ROM should be evaluated.

To this purpose, non-invasive methods are available, although most have poor reliability data. The *Cervical Range of Motion* device (CROM) developed by Performance Attainment Associates (Roseville, MN, USA)[17] and the fleximeter (under patent by the Institute Code de Pesquisa)[18] have presented moderate to excellent reliability for both intra- and interexaminer measurements. Although both methods are effective, fleximetry, offers lower costs and easier handling and can be used to evaluate other body segments, while CROM was designed specifically for the cervical segment.

Thus, the aim of this study was to evaluate the effectiveness of electroacupuncture and acupuncture on pain intensity and cervical ROM in women with myofascial pain in the upper trapezius, using SHAM acupuncture as a control.

Materials and Methods

This research was conducted at the laboratory of the Clinical Research of Department of Pediatric Dentistry, Piracicaba Dental School, University of Campinas, Piracicaba, SP, Brazil. The recruitments and the follow-up of the participants occurred from June 2012 to August 2013 when the sample size was achieved, according to Aranha[12]. The Research Ethical Committee of Piracicaba Dental School approved the project (protocol 003/2011). The volunteers were asked to read and sign the consent form. They were informed about the procedures, discomfort or risks, the benefits of the research and the needs to attend all sessions. Participants were blinded to group allocation, as well as the researcher who did the assessments (CEEM). The Brazilian Clinical Trials Registry number is RBR-42kz9z (available at: http:// www.ensaiosclinicos.gov.br/rg/RBR-42kz9z/).

Women suffering from head and neck pain were included in the study. The participants were submitted to careful anamneses to obtain information about general health pertaining to the inclusion and exclusion criteria, which were as follows: (1) Inclusion criteria: age range from 18 to 40 years, regular menstrual cycle (regardless of oral contraception use), body max index between 18 and 29.9 km/m^2 and at least one MTrP in the upper trapezius muscle with local or referred persistent pain for at least six months. (2) Exclusion criteria: accentuated postural abnormalities, verified by the physiotherapist (CEEM), fibromyalgia syndrome, cervical radiculopathy, systemic disease or physical therapy interventions for myofascial pain within one month before the study, pregnancy, chronic pacemaker or electronic implant use (as reported by the subject). The continuous use of medications to treat headache and muscular pain was also an exclusion criterion. Moreover, if the examiner (CEEM) observed evident cognitive impairment or communication difficulties at the first meeting, the subject was not included.

Initially, 82 volunteers were eligible. Ten were not included; of those ten, five did not present the inclusion criteria (two were above the body mass index (BMI) limit, one did not present with active MTrPs, one had had pain for less than six months, and one did not have a regular menstrual cycle) and five presented an exclusion criterion (one was pregnant, one had a cervical hernia, one had trigeminal neuralgia and two had fibromyalgia). Thus, 72 volunteers were included. Of these, seven dropped out before the first session and five started but did not complete the eight treatment sessions (Figure 1).

In accordance with members of the Sex, Gender and Pain Special Interest Group of the International Association for the Study of Pain[19], if the menstrual cycle itself is not a factor to be evaluated, the researcher should plan to evaluate women in the same phase of their cycle because both absolute and relative hormone levels could influence pain. Thus, measurements (pre-, post-treatment and follow-up) were fixed between the second and the fifth day of menstruation period, with 28 days between each measurement. Between evaluation and reevaluation, eight sessions were scheduled, two per week.

Reevaluation was scheduled three to six days after the last session, coinciding with the second to the fifth day of volunteer's menstrual phase.

All volunteers were diagnosed as having active MTrPs bilaterally. Each side was analyzed separately. The volunteers were distributed among three treatment groups: EA, AC and SHAM. First, the volunteers were coded, by the blinded examiner, according to their use of oral contraceptives, as follows: paused oral contraception (POC), continuous oral contraception (COC) and without oral contraception (WOC). After that, they were randomly allocated to each treatment group using Excel. Therefore, all volunteers had the same chance of being allocated to any group, avoiding the predominance of one oral contraceptive condition in any treatment group.

Instrumentation

The equipment used for the EA was the EL608 NKL (ANVISA 80191680002). The needles were stainless steel, individually wrapped, sterile, and disposable, with a diameter of 0.25 mm and a length of 30 mm (Dong-Bang, Korea).

The Visual Analog Scale (VAS) assessed the intensity of general pain and pain in the right (RTPz) and left upper trapezius (LTPz). The scale consists of an unanchored horizontal line 10 centimeters in length, the extremes corresponding to zero ("no pain") and 10 ("maximum pain").

The fleximeter, developed and manufactured in Brazil and patented at the Code Institute of Research, consisted of a gravity-dependent inclinometer with scale of one grade, attached to the head with Velcro tape (Figure 2).

To monitor intercurrences between sessions, an additional data form (ADF) consisting of open questions about traumas, headaches, neck and shoulder pain, medications (such as analgesics, non-steroidal anti-inflammatories, and spasmolytic drugs) and the doses used, was applied at the beginning of the sessions. Additionally, emotional

stress conditions that could occur between sessions were considered because muscle tension can be an expression of anxiety and emotional tension[1]. Such conditions were considered influencing factors, i.e., they could interfere with the treatment effects.

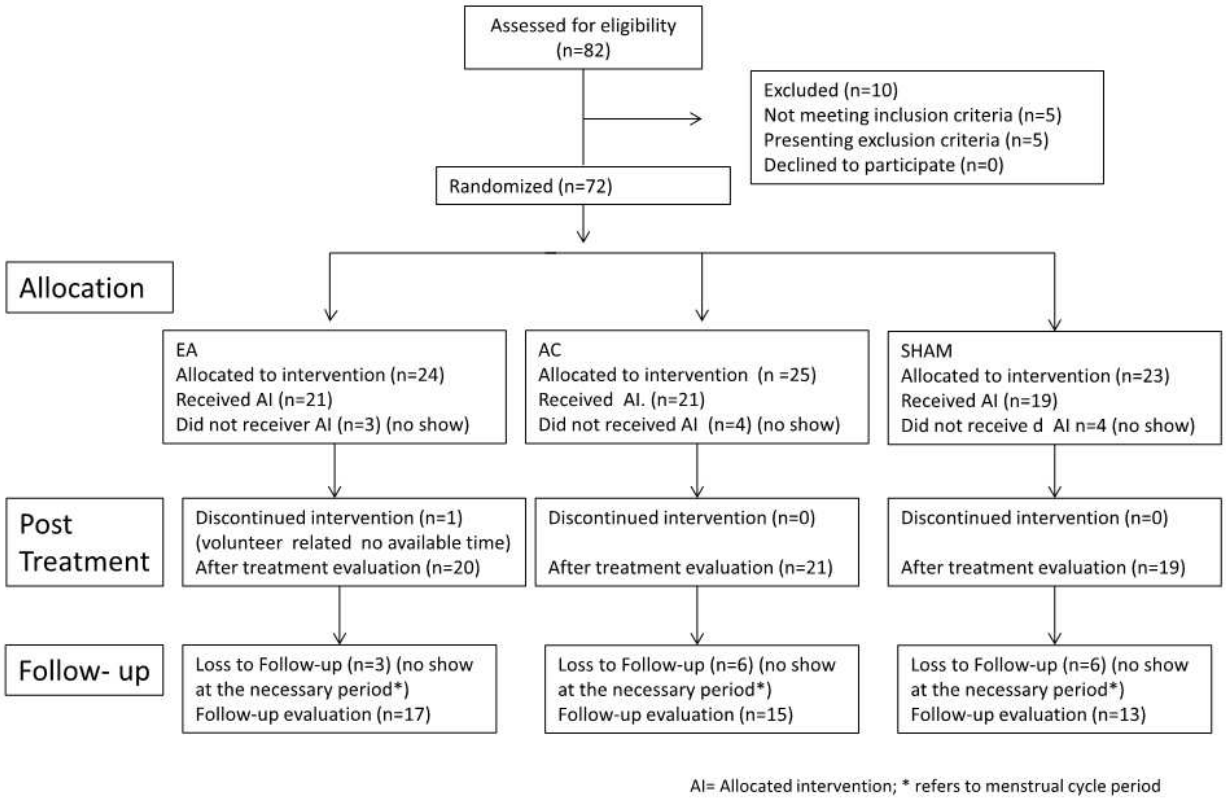

Figure 1. Enrollment of participants and study design

Procedures

The diagnosis of MTrP was based on five criteria [1,4,5]: (1) the presence of a palpable taut band in the muscle; (2) the presence of a hypersensitive tender spot in a taut band; (3) a local twitch response elicited by the snapping palpation of the taut band; (4) reproduction of the typical referred pain pattern of the MTrP in response to compression; (5) the spontaneous presence of the typical referred pain pattern and/or recognition of the referred pain as familiar. MTrP was considered active if the referred pain, whether spontaneous or evoked by compression, reproduced the subject's complaint; MTrP was

considered latent if the referred pain did not reproduce a usual or familiar pain. The volunteer remained seated in a chair during the examination.

Both VAS and fleximetry were measured pre- and post-treatment and at the follow up. Volunteers were asked to mark their pain between "no pain" and "maximum pain" on the printed VAS. Afterwards, the marked location was measured with a ruler (in centimeters) by the blinded examiner.

A fleximeter was used to evaluate the following the ranges of motion (ROM) in the head and neck: flexion (F), extension (E), inclination to the right (IR) and to the left (IL) and rotation to the right (RR) and to the left (RL). At the end of each movement, the device was repositioned. The equipment was fixed on the volunteer's head as shown in Figure 2. All movements except rotation were measured with the subjects seated in a chair with the back straight, eyes looking straight ahead and parallel to the floor, knees flexed at 90 degrees and feet flat on the floor. For the rotation movements, the volunteers had to stay in the supine position. This exception was made to keep device favorably positioned relative to the effects of gravity.

During EA application, the patient remained in the prone position. Needles were inserted bilaterally into points GB21 and GB20 and unilaterally into LI4, LV3 [20] and directly in the region of the MTrPs (a maximum of four needles). The equipment generated a rectangular pulse programmed as follows: alternating frequency F1=2 Hz (700μs), T1=5 seconds, F2=100 Hz (500μs), T2=5 seconds; total time: 30 minutes; intensity: maximum supported by the patient without pain[12,21]. The acupuncture group received the same treatment but without the connection to the alternating frequency equipment. The SHAM acupuncture group had the needles inserted 1 cm from the correct acupoints.

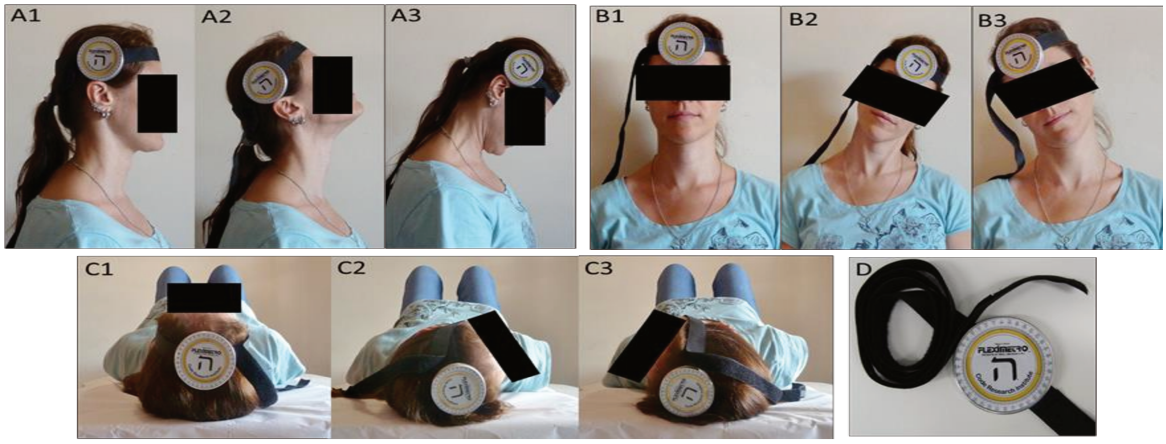

Figure 2. Fleximeter use for cervical range of motion acquisition. A1, B1 and C1 show the neutral positions for extension (A2) and flexion (A3), inclination to the left (B2) and to the right (B3), rotation to the right (C2) and to the left (C3). D shows the fleximeter.

Statistics

The assumptions of equality of variances and normal distribution of errors were checked for all variables (Shapiro-Wilk test). Intragroup comparisons were analyzed using Student's paired t-test or Wilcoxon's signed rank test, a one-way repeated measure analysis of variance or the Friedman repeated measures analysis of variance on ranks with the Student-Newman-Keuls method for *post-hoc* analysis. To identify intergroup differences, a one-way ANOVA or the Kruskal-Wallis test was used, with Dunn's Method as the *post-hoc* analysis. Moreover, an analysis of variance was applied based on a linear generalized mixed model for two factors: group (fixed) and time of evaluation as repeated measures. This analysis used the t-test adjusted with the Tukey-Kramer test. Pearson's correlation was applied. SigmaPlot (Systat Software, San Jose, CA, USA) was used for all analyses except the data linear generalized mixed model, for which SAS software (SAS Institute Inc., the SAS System, release 9.3. SAS Institute Inc., Cary, NC, USA; 2010) was used.

Results

The final sample consisted of 60 females. Their mean age was 27.33±4.95 years, and their body mass index ranged from 19 to 30 Kg/m^2 (22.55±3.24 Kg/m^2). All volunteers were diagnosed with active MTrPs bilaterally. Each side was analyzed separately. Of this sample, 45 volunteers attended the one-month follow up. Sample characteristics are presented on table 1.

Pain intensity

In pre-treatment evaluation, there were no differences among groups concerning general pain (*P*=0.493) or pain at the RTPz (*P*=0.908) or the LTPz (*P*=0.723), indicating the homogeneity of the groups. As Figure 3 presents, only the EA and AC groups showed significant decreases in general pain after treatment (EA, *P*<0.001; AC, *P*<0.001; SHAM, *P*=0.078). Significant improvement was observed in all groups for pain at the RTPz (EA, *P*<0.001; AC, *P*=0.025; SHAM, *P*=0.038) and only in the EAgroup for pain at the LTPz (*P*<0.001). Post-treatment comparisons indicated significant lower pain in both sides of the upper trapezius in the EA group compared to SHAM (RTPz *P*=0.030; LTPz *P*=0.015).

A comparison of the volunteers who attended the follow-up evaluation showed no pre-treatment difference between the groups (general pain: *P*=0.581, RTPz: *P*=0.761, LTPz: *P*=0.844). Paired data showed significant improvements in all groups, maintained until the follow-up evaluation (Figure 4). In the post-treatment intergroup evaluations, the EA showed significantly lower pain intensity on both sides of the upper trapezius (*P*<0.05). At the follow-up, there were no differences among groups.

A linear generalized mixed model analysis showed a decrease in general pain in the EA and AC groups (*P*<0.05) and a decrease in pain intensity at the RTPz and at the LTPz for

the EA group (P<0.05), but not for the AC and SHAM groups. Despite this finding, no significant intragroup difference was noted in the follow-up data.

When separated according to oral contraceptive conditions, the basal values of pain showed no differences. The results concerning pre- and post-treatment and follow-up measurements of pain are presented in Figures 3 and 4.

Table 1. Sample Characteristics

Characteristic	EA (n=20)	AC (n=21)	SHAM (n=19)
Age (mean±DP)	27.9±5.3	28.0±4.4	25.6±4.9
BMI (mean±DP)	21.6±2.6	22.2±3.1	23.6 ±3.5
WOC (%)	40.0	42.8	38.8
POC (%)	40.0	38.1	42.1
COC (%)	20.0	19.1	21.1
Pain duration (years) (mean ± SD)	6.0±4.4	4.8±4.1	5.2±3.3
Frequency of pain (times/week) (mean ± SD)	5.6±1.7	5.9±1.7	5.1±2.2
Predominant side (% right)	95	100	100
Pain at RTPz (%)	100	100	100
Pain at LTPz (%)	100	100	100
Cervical pain (%)	60.0	85.7	47.3
Occiptal pain (%)	40.0	47.6	52.6
Parietal pain (%)	15.0	28.5	10.5
Temporal pain (%)	40.0	80.9	42.1
Frontali pain (%)	35.0	28.5	47.3
Migraine (%)	45.0	47.6	26.3

Range of Motion

There were no significant differences in basal values among the 3 groups for the movements. After treatment, a significant increase in RR (P=0.049) was observed in the EA

group, and significant increases in IR (P=0.005) and RR (P=0.032) were observed in the AC group. No changes occurred in the SHAM group (Table 2). Regarding the follow-up evaluation, only the increase in IR in the AC group was maintained (P>0.05) (Table 3). A linear generalized mixed-models analysis failed to identify intragroup differences, either after treatment or at follow-up (P>0.05). Moreover, the correlations between VAS and fleximetry data were not significant (P>0.05). Correlations among cervical movements are presented at table 4.

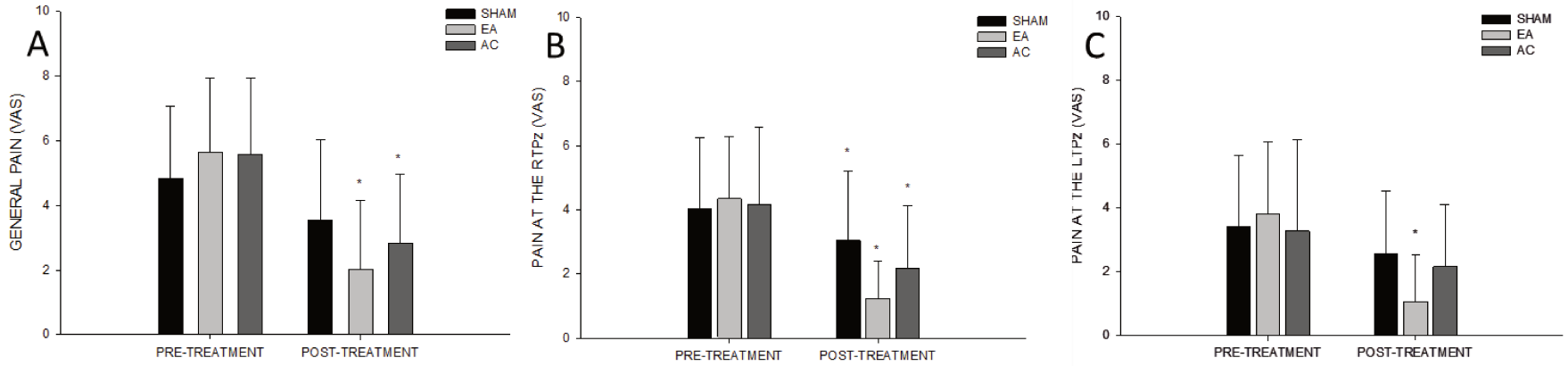

Figure 3. Means and standard deviations for general pain (A), pain at the RTPz (B) and at the LTPz (C) pre- and post-treatment. *P<0.05

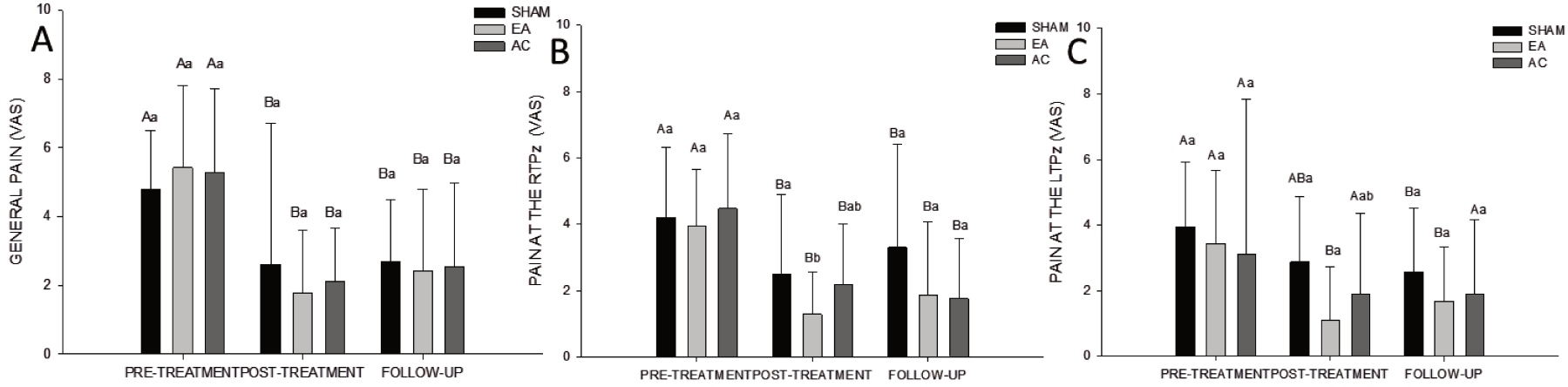

Figure 4. Means and standard deviations for general pain (A), pain at the RTPz (B) and at the LTPz (C) at pre- and post-treatment and at the follow-up evaluation. Uppercase letters above the standard deviation bars refer to intragroup comparisons: A≠B (P<0.05); lowercase letters refer to intergroup comparisons: a≠b (P<0.05).

Table 2. Intra- and intergroup comparisons of range of motion pre-treatment and post-treatment (eight sessions; means ± standard deviations)

		EA (n=20)		AC (n=21)		SHAM (n=19)	
FLEXION	PRE	53.95±7.78	*P*=0.218	*54.00±18.00*	*P=0.054*	52.63±11.39	*P*=0.213
	POST	56.15±9.04		*58.00±8.00*		55.68±5.64	
EXTENSION	PRE	64.85±10.06	*P*=0.844	66.76±12.31	*P*=0.356	*70.00±14.00*	*P=0.927*
	POST	64.40±10.63		69.05±13.59		*67.00±13.00*	
INCLINATION TO THE RIGHT	PRE	43.40±6.29	*P*=0.587	**41.81±6.20***	***P*=0.005**	41.21±7.66	*P*=0.152
	POST	44.20±6.64		**44.86±5.79***		43.26±6.89	
INCLINATION TO THE LEFT	PRE	41.65±7.11	*P*=0.220	40.67±6.92	*P*=0.060	42.79±9.67	*P*=0.751
	POST	43.95±7.78		42.95±7.58		43.37±8.01	
ROTATION TO THE RIGHT	PRE	69.50±9.43	*P*=0.051	**70.67±7.92***	***P*=0.032**	69.84±9.63	*P*=0.117
	POST	73.70±10.25		**74.00±7.73***		72.84±7.94	
ROTATION TO THE LEFT	PRE	**69.05±11.36***	***P*=0.049**	70.86±9.70	*P*=0.095	70.05±10.89	*P*=0.917
	POST	**73.30±8.29***		73.19±10.18		70.26±12.43	

PRE= Pre-treatment, POST= Post-treatment
* in the same column means intragroup differences (bold fonts)
Intergroup comparisons: no significant differences
Normal fonts: Paired t-test (means and standard deviations)
Italic fonts: Wilcoxon's signed rank test (medians and interquartile deviations).

Table 3. Intra- and intergroup comparisons of range of motion in 45 volunteers who attended the follow-up evaluation (pre-treatment, post-treatment: eight sessions; follow-up: one month)

		EA (n=17)		AC (n=15)		SHAM (n=13)	
FLEXION	PRE	53.41±7.49		52.27±9.99		52.39±12.06	
	POST	55.77±9.34	*P*=0.415	56.20±8.28	*P*=0.079	55.79±5.02	*P*=0.263
	FU	55.06±7.66		55.60±10.75		57.15±7.67	
EXTENSION	PRE	64.24±8.15		68.00±12.04		71.70±9.40	
	POST	64.18±9.11	*P*=0.997	72.60±13.30	*P*=0.244	70.62±9.20	*P*=0.853
	FU	64.06±9.89		70.87±12.80		70.00±7.82	
INCLINATION TO THE RIGHT	PRE	43.53±6.62		***40.00±9.50*** ^{A}		43.20±7.71	
	POST	44.00±7.12	*P*=0.859	***45.00±8.00*** ^{B}	***P=0.002***	44.30±7.30	*P*=0.797
	FU	44.35±4.99		***45.00±9.50*** ^{B}		44.31±6.42	
INCLINATION TO THE LEFT	PRE	41.82±6.61		41.60±6.05		45.00±10.10	
	POST	43.53±8.29	*P*=0.166	44.87±6.91	*P*=0.068	44.46±7.54	*P*=0.981
	FU	44.94±6.05		43.67±5.95		45.00±6.06	
ROTATION TO THE RIGHT	PRE	*69.00±10.00*		69.53±8.37		70.84±10.39	
	POST	*76.00±13.00*	*P*=0.079	73.47±7.93	*P*=0.100	75.46±9.63	*P*=0.081
	FU	*71.00±14.00*		73.73±7.18		76.308±6.90	
ROTATION TO THE LEFT	PRE	68.24±10.48		69.80±10.44		71.00±12.60	
	POST	72.61±6.82	*P*=0.135	72.20±10.23	*P*=0.398	71.08±3.97	*P*=0.399
	FU	72.41±9.89		72.60±9.29		74.23±12.11	

PRE= pre-treatment, POST= post-treatment, FU=Follow-up
Different uppercase letters in the same column = intragroup differences (italic bold fonts)
Intergroup comparisons: no significant differences
Normal fonts: one-way repeated measures analysis of variance (means and standard deviations)
Italic fonts: Friedman's repeated measures analysis of variance (medians and interquartile deviations).

Table 4. Pearson's correlation among cervical movements pre- and post-treatment (eight sessions)

	RL		RR		IL		IR		E	
	PRE	POST	PRE	POST	PRE	POST	PRE	POST	PRE	POST
RR	0.74	0.74	-	-	-	-	-	-	-	-
IL	0.48*	0.40*	0.45*	0.43*	-	-	-	-	-	-
IR	0.30*	0.37*	0.37*	0.36*	0.53*	0.65*	-	-	-	-
E	0.21	0.23	0.12	0.30*	0.37*	0.55*	0.23	0.53*	-	-
F	0.19	0.32*	0.14	0.26	0.48	0.20	0.27	0.06	0.03	0.16

*$P<0.05$
F= flexion; E=extension; IR= inclination to the right; IL= inclination to the left; RR=rotation to the right; RL= rotation to the left
PRE= Pre-treatment; POST=Post treatment

Additional Data Form

With respect to the monitored occurrences on previous days and between sessions, the groups presented similar patterns, as shown in Table 5. Compared with the EA and AC groups, the SHAM volunteers showed a more pronounced increase in medication use and headache frequency in the last week of treatment and before the post-treatment evaluation. While the EA and AC volunteers showed a decrease in headache frequency, the SHAM volunteers reported more headaches during the later sessions compared with the first sessions. Positive and negative life experiences remained almost unchanged for all groups. Neck and shoulder pain frequency decreased slightly in all groups, with an increase of shoulder pain between the last session and the post-treatment evaluation for the AC group.

Table 5. Percentage of volunteers who reported medication use, positive or negative life experiences, headache or neck and shoulder pain at the post-treatment evaluation (n=60)

SESSIONS		1	2	3	4	5	6	7	8	9*
MEDICATION USE	SHAM	47.46	36.84	26.31	36.84	10.53	15.79	10.53	31.58	47.46
	EAC	40.00	25.00	25.00	40.00	30.00	5.00	10.00	15.00	30.00
	AC	61.90	33.33	14.29	14.29	23.81	28.47	9.52	33.33	28.57
POSITIVE LIFE EXPERIENCES	SHAM	10.53	0	10.53	5.26	0	5.26	10.53	5.26	10.53
	EAC	15.00	5.00	0	5.00	0.00	15.00	10.00	5.00	10.00
	AC	4.76	0	9.52	9.52	9.52	0	14.29	4.76	14.29
NEGATIVE LIFE EXPERIENCEs	SHAM	42.10	26.31	15.78	26.31	21.05	31.58	21.05	36.84	31.58
	EAC	25.00	15.00	25.00	25.00	15.00	15.00	5.00	10.00	10.00
	AC	28.57	28.57	19.05	14.29	23.80	23.80	14.28	9.52	33.33
HEADACHE	SHAM	42.10	57.89	36.4	26.31	31.57	36.84	42.10	63.16	78.95
	EAC	60.00	40.00	40.00	50.00	50.00	30.00	45.00	30.00	40.00
	AC	76.19	71.43	33.33	38.09	38.09	52.38	33.33	38.09	47.61
NECK PAIN	SHAM	68.42	57.89	47.37	47.37	42.10	52.63	52.63	52.63	47.37
	EAC	65.00	55.00	65.00	55.00	50.00	30.00	40.00	55.00	40.00
	AC	76.19	57.14	47.62	61.90	52.38	61.90	47.62	52.38	61.90
SHOULDER PAIN	SHAM	100	84.21	63.16	68.42	78.95	57.89	68.42	73.68	57.89
	EAC	80.00	80.00	80.00	70.00	60.00	60.00	45.00	65.00	60.00
	AC	95.23	71.43	80.95	76.19	52.38	52.38	57.14	61.90	52.38

*post-treatment evaluation

Discussion

The aim of this study was to identify whether EA and AC are effective for treating pain and increasing range of motion in women with myofascial pain in the upper trapezius, with SHAM acupuncture as a control. Both the paired data and the results of the intergroup comparisons in this study indicated that EA and AC contribute more to the decrease in myofascial pain than SHAM acupuncture does. Moreover, the fact that EA presented significantly better results than SHAM after the respective treatments, whereas

no difference was found between AC and SHAM, suggests that EA treatment had an advantage with respect to pain intensity. Intergroup analysis showed that EA improved general pain and pain in the RTPz and the LTPz, whereas AC was effective only for general pain. In this sense, the analgesic effect of transcutaneous electrical acupoint stimulation [22], which differs from EA only by the presence of a transcutaneous electrode instead a needle, has already been described. An increase in blood flow after the use of transcutaneous electrical nerve stimulation within the upper trapezius muscle has also been reported[23]. Therefore, it is possible that the use of EA may increase blood flow and remove the chemical mediators of the MTrP area, thereby facilitating a mechanical relaxation of the MTrP taut band. Although AC showed a superior analgesic effect compared with SHAM or placebo in a study by Stux[7], the data in the present study suggest that the EA group had electrical analgesic effects in addition to the needle acupoint stimulation effect of AC, therefore presenting better results. In this way, it was demonstrated that EA reduced the use of opioid-like medication by chronic pain patients[11] and also decreased pain intensity and increased the pressure pain threshold in women with myofascial pain in the upper trapezius after eight sessions of EA applied to the same acupoints[12].

The treated groups also showed better results than SHAM with respect to ROM. Despite the expectation that the decrease in pain would lead to a decrease in muscular stiffness and an increase in range of motion, no correlation between VAS and fleximetry data was found, corroborating a recent cohort study that evaluated 4,293 subjects and found a significant difference in pain intensity but not in cervical range of motion among study groups[24.] Gemmel and Hilland[25] also found no difference concerning range of motion after treatment, despite a significant decrease in pain.

Bilateral contraction of the upper trapezius muscle extends the neck, and unilateral contraction extends the neck, inclining the head to the same side and rotating it to the opposite side[16]. Thus, the improvement of myofascial pain in the upper trapezius would

be expected to improve its function, increasing the range of motion as described above. However, the increase in IR that was observed after treatment with AC and maintained until the follow-up evaluation can be related to the shortening of RTPz fibers and the stretching of LTPz fibers[26]. Although one side's function depends on the other side's function, the expected significant improvement at the IL was not obtained, reflecting the complexity of interpreting each component of neck movements separately. Moreover, it should be noted rotation to the right almost presented significant difference for EA and flexion for AC (Table 2). In this sense, we found 3moderate positive correlations between movements related to upper trapezius at post-treatment that were absent pre-treatment. These results might suggest integrated improvement of muscle function despite the absence of significant changes in some cervical movements (Table 4).

Currently, there are not enough studies available comparing with nonspecific neck pain to the normal population to allow conclusions about any specific physical dimensions related to nonspecific neck pain[27]. Furthermore, available research comparing ROM assessment tools showed that despite the high reproducibility and reliability of some methods, average values vary greatly depending on the instrument used[28]. Often, data findings represent healthy individuals[18] in other age groups or include both genders[28].

Nevertheless, paired data presented improvements on some cervical ROM of only the two treated groups pointing to an efficacy of AC and EA, comparing to SHAM, which presented no significant changes. Despite that, intergroup analyses have failed in detecting differences between groups, setting there is no superiority of one group over another. The observed ROM improvement was subtle but present only in the treated groups, which showed significantly higher decrease on pain than the SHAM group. Thus, it is possible that both EA as AC have contributed, though subtly, to the relaxation of the contracted fibers that characterize myofascial pain. However, it is important that further studies include stretching exercises to investigate the benefits of an association between these treatments.

Finally, an additional data form was helpful for monitoring such influencing factors as the frequency of medication use, showing that the pain relief was not caused by an increased use of analgesics, for example. Although there was little variation in reported positive and negative life experiences, such experiences do not seem to have influenced the observed results either positively or negatively. Importantly, the percentage of headache complaints, possibly the referred pain from myofascial pain in the upper trapezius, was lower for the EA and AC groups and higher for the SHAM group, agreeing with data obtained in this study.

Conclusion

Both acupuncture and electroacupuncture were superiorly effective in reducing myofascial pain compared with SHAM acupuncture. Nonetheless, electroacupuncture were better than acupuncture for pain relief in the studied sample. There are indications that these treatments can assist in increasing ROM, though subtly.

Acknowledgements

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CAPÍTULO 2

Evaluation of acupuncture and electroacupuncture on pain, stress, and quality of life in women with myofascial pain syndrome: a double-blinded, randomized clinical trial

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ABSTRACT

Background: Epidemiological studies suggest that myofascial pain syndrome (MPS) is a debilitating musculoskeletal disorder and the primary cause of headache and neck pain. Moreover, chronic musculoskeletal pain is commonly associated with anxiety and stress, significantly influencing the quality of life of symptomatic patients.

Objective: The aim of this study was to evaluate the effect of acupuncture (AC) and electroacupuncture (EA) on pain, stress levels, and quality of life in women with MPS.

Method: Sixty volunteers ranging in age from 18-40 years (27,33±4,95 years) with a body mass index of 18-29.9 Kg/m^2 (22,55±3,24 Kg/m^2), regular menstrual cycle (with or without oral contraception), at least one trigger point in the upper trapezius muscle, and local or referred pain for more than six months were included in this study. Subjects were randomized into three groups: SHAM-acupuncture (SHAM), EA, and AC. All volunteers and examiners were blinded to groupings. A total of eight treatment sessions were scheduled, twice a week. An electrical current alternating between 2 and 100 Hz for 5 s each was applied to the EA group, while all groups retained needles for 30 min. Treatment effectiveness was evaluated using the visual analog scale to assess pain intensity, cortisol

awakening response (CAR) and area under the curve with respect to ground (AUC_G) to assess stress, and SF-36 questionnaire to assess quality of life. Other influential factors, including menstrual phase and medication use, were monitored. Data normality and symmetry were analyzed, and multiple statistical analyses were performed according to data distribution; statistical significance was set as $P<0.05$.

Results: A reduction in general pain was observed in both EA an AC groups post-treatment (EA, $P<0.001$; AC, $P<0.001$). Additionally, intra-group comparisons showed a significant decrease in pain when "time of evaluation" and "group" factors interacted in EA and AC groups ($P<0.05$), but not in SHAM. Although SHAM and EA groups did not present significant cortisol differences post-treatment, the AC group showed significantly enhanced AUC_G ($P=0.006$) and CAR ($P<0.001$) values. Post-treatment, the SHAM group displayed a significant increase in the bodily pain domain on the SF-36 questionnaire ($P=0.005$); EA and AC groups showed improvement in the areas of physical functioning (EA, $P=0.011$; AC, $P=0.016$), physical role (EA, $P=0.027$; AC, $P=0.13$), body pain (EA, $P=0.010$; AC, $P=0.003$), general health (EA, $P=0.017$; AC, $P=0.011$), vitality (EA, $P=0.010$; AC, $P=0.011$), mental health (EA, $P=0.018$; AC, $P=0.014$), and physical components (EA, $P=0.019$; AC, $P=0.002$).

Conclusion: In women suffering from myofascial pain in the upper trapezius muscle, those subjected to AC and EA treatments showed a significant reduction in pain intensity compared to SHAM, along with significant improvements in stress levels and quality of life.

Keywords: Acupuncture; Electroacupuncture; myalgia; quality of life; stresse, phychological; range of motion, articular.

Introduction

Myofascial pain syndrome (MPS) is a debilitating musculoskeletal disorder with an incidence range of 30-93%, depending on diagnostician subspecialty and setting (Simons et al., 1999; Skootsky et al., 1989; Gerwin, 1999). MPS is characterized by the presence of tender, hyper-irritable, firm nodules These points have been located in taut bands of skeletal muscle or fascia that radiate pain upon compression (Wheeler, 2004). These myofascial trigger points (MTrPs) give rise to characteristic referred pain, motor dysfunction, and autonomic phenomena (Simons et al., 1999). MTrPs can be latent in the absence of spontaneous pain, causing motor dysfunction such as rigidity and weakness, or active when referred or spontaneous pain at the abnormal muscle site is present (Gerwin et al., 1997; Simons et al. 1999). Referred pain due to palpation is characterized by the recognition of previously experienced pain (distant to the palpated site) and is one of the most important diagnostic criteria when palpable findings, such as the presence of taut bands and hypersensitive nodules, are present (Gerwin et al., 1997). Furthermore, MPS is considered a primary cause of headache and neck pain (Grosshandler et al., 1985), and associated chronic pain can significantly influence the quality of life of symptomatic patients (Simons et al., 1999; Gerber et al.2013).

The treatment of myofascial pain disorders requires identification of symptomatic MTrPs and muscles as primary or ancillary pain generators. Acupuncture (AC) is an alternative to more traditional clinical treatments for musculoskeletal pain that neurophysiologically and/or physically denervates the MTrP neural loop to reduce pain and stop or modulate the over-contraction of muscles (Fernández-de-Las-Peñas et al., 2007). By insertion of ultra-fine needles, AC stimulates points on the body to prevent or modify the perception of pain (nociception), alter physiological functions, or both (Stux & Pomeranz, 2007). Moreover, the passage of an electrical current through the needles, called electroacupuncture [EA], is thought to be a more effective method of pain relief than manual AC alone (Wan et al., 2001; Kim et al., 2006; Koski et al., 2009). Studies

investigating EA mechanisms of action have revealed that endogenous opioid peptides in the central nervous system mediate the analgesic effects produced by this treatment (Walling, 2006). In fact, the World Health Organization has endorsed more than 40 disorders that can benefit from AC treatment (Han, 2011).

Subjects with chronic pain frequently present traits of anxiety, tension, hopelessness or depression, and a declining quality of life (Simons *et al.,* 1999). The hypothalamic-pituitary-adrenal (HPA) axis is a key system that controls the stress response by acting through the hormone cortisol. Previous studies have shown that the cortisol awakening response (CAR) and overall cortisol secretion (the area under the curve with respect to ground [AUC_G]) are significantly attenuated in chronic pain patients compared to healthy controls (Gaab et al., 2005; Riva et al., 2010). Other valuable tools used to assess treatment efficacy include the visual analog scale (VAS), which has proven to be most effective in assessing pain intensity (Jensen et al., 1999), and the SF-36 health survey questionnaire, used to evaluate improvements in quality of life (Gerber et al., 2013; Ciconelli et al., 1999). Within this context, this study aimed to analyze the effect of AC and EA treatment of MTrPs in women with chronic pain due to myofascial dysfunction of the upper trapezius muscle by evaluating pain intensity, quality of life, and stress levels.

Materials & Methods

Patients & Parameters

This research was conducted in the Clinical Research Laboratory of the Department of Pediatric Dentistry, Piracicaba Dental School, University of Campinas (Piracicaba, SP, Brazil). The Research Ethical Committee of Piracicaba Dental School approved this project (protocol 003/2011). Informed consent was obtained from all volunteers prior to study inclusion; all subjects were informed of possible procedures, discomfort, risks, benefits, and the need to attend all sessions. The Brazilian Clinical Trials Registry number for this study is RBR-42kz9z.

Selection methods used in this study were described previously (chapter 1). Briefly, women ranging in age from 18-40 years suffering from head and neck pain were submitted to careful anamneses to assess their general health with respect to inclusion and exclusion criteria. Subjects with regular menstrual cycle (regardless of oral contraception use) and at least one MTrP in the upper trapezius muscle with local or referred persistent pain for at least six months were included in this study. Exclusion criteria were as follows: accentuated postural abnormalities, cognitive impairment or communication difficulties at screening meeting (verified by physiotherapist, C.E.E.M.), ibromyalgia, cervical radiculopathy, systemic disease, physical therapy for myofascial pain within one month prior to study launch, pregnancy, chronic pacemaker or electronic implant (as reported by the subject), or continuous use of medication to treat headache and/or muscle pain.

Pre- and post-treatment and follow-up evaluations were performed on the second and fifth day of menstruation (Greenspan et al. 2007), with 28 days between each assessment. Two sessions were scheduled per week for a total of eight sessions between pre- and post-treatment. Post-treatment re-evaluation occurred 3-6 days after the last session, coinciding with the second and fifth day of the volunteer's menstrual phase. Although session timing and evaluations were the same for all patients, for obvious reasons, continuous oral contraception (COC) users were able to start treatment at any time.

Eighty-two female subjects were assessed for eligibility, 72 were initially included, and 60 completed all eight sessions (Fig. 1). Participants had a mean age of 27.33±4.95 years, body mass index of 19-30 Kg/m^2 (average: 22.55±3.24 Kg/m^2), and were all diagnosed with active bilateral MTrPs in the upper trapezius muscle (each side analyzed separately). Volunteers were first grouped according to oral contraceptive use (paused [POC], COC, or without [WOC]), then randomly allocated into three treatment groups using the "RAND" Excel function: EA, AC, and SHAM-acupuncture (SHAM). This

classification scheme evenly distributed oral contraceptive use between the three treatment groups (Fig. 1).

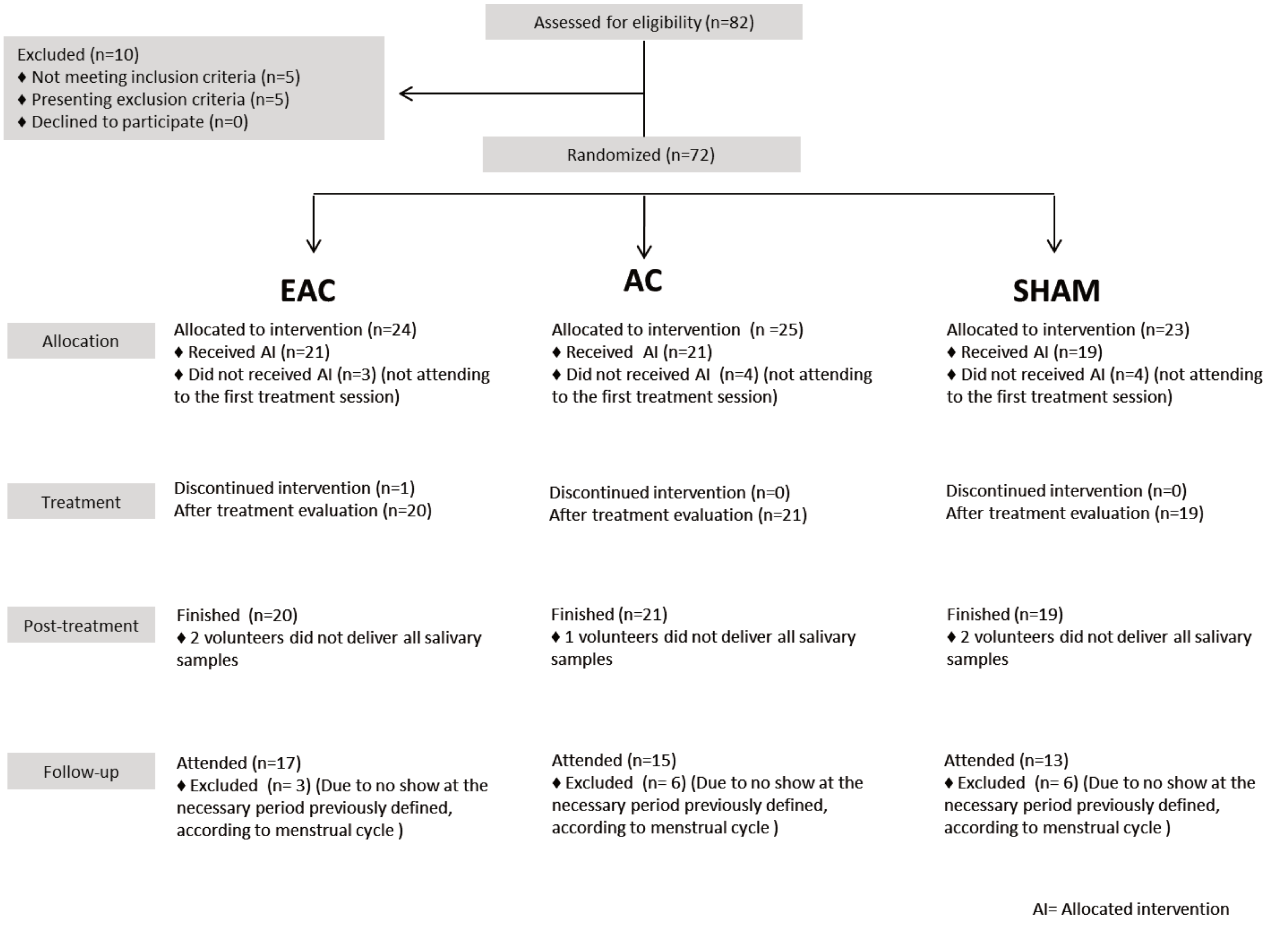

Figure 1. Participant enrollment and study design.

Instrumentation

EA, AC, SHAM, VAS, & the Additional Data Form (ADF)

EA treatments were performed using an electrostimulator (NKL, model EL608, ANVISA 80191680002) and 0.25 x 30 mm stainless steel needles (Dong Bang CO. Ltd., Korea). The VAS, consisting of a 10 cm horizontal line with extremes corresponding to zero (no pain) and 10 (maximum pain), assessed the intensity of general pain and pain in

the right (RTPz) and left upper trapezius (LTPz) muscles. At the beginning of each session, an ADF was applied to monitor influential factors such as trauma, headaches, positive or negative life experiences, neck and shoulder pain, medications (analgesics, non-steroidal anti-inflammatories, and spasmolytic drugs) and their doses, and emotional stress that could have occurred throughout treatment.

Quality of life

Quality of life was assessed by the Portuguese version of the SF-36 health survey, a questionnaire consisting of 36 questions that evaluate components of physical (PC) and mental (MC) health via eight different criteria: physical functioning (PF), physical role (RP), bodily pain (BP), emotional role (RE), general health (GH), vitality (VT), social functioning (SF), and mental health (MH). The psychometric properties of the SF-36 have been previously validated (Ciconelli et al., 1999).

Saliva collection

Saliva was obtained using Salivette® collection devices (Sarstedt, Germany) according to the manufacturer's protocol. The CAR assay was carried out using cortisol salivary immunoassay kits (Salimetrics, State College, PA, USA) according to the manufacturer's protocol. This assay has a sensitivity of 0.007 µg/dL. Inter- and intra-assay coefficients of variation were below 5% and 8%, respectively.

Procedures

MTrP diagnoses were based on five criteria previously described by Simons et al. (1999) and Gerwin et al. (1999) (for more details, please, see Chapter 1); sessions and procedures are outlined in Figure 2. All eight sessions were scheduled at the same time of the day, and VAS were completed following the ADF at the beginning of each session. The SF-36 was administered upon pre- and post-treatment evaluation and at one month follow-up on a typical weekday. Before the first and after the last session, volunteers self-

collected three saliva samples (SS) at home as instructed: SS1, immediately after awaking in the morning; SS2, 30 min after awaking; and SS3, 30 min before going to bed. Subjects were asked to awaken at the same time on both session dates (as per their usual week-day waking time) and to refrain from smoking, eating, drinking (except water), or brushing their teeth for 30 min prior to sampling. The CAR was calculated as the difference in cortisol levels between SS2 and SS1. The AUC_G was calculated using the formula outlined by Pruessner et al. (2003). Subjects were given the same sampling instructions for before and after session collection.

<table>
<tr><td>ONE DAY BEFORE S1</td><td colspan="8">TREATMENT</td><td>ONE DAY AFTER S8</td><td colspan="2"></td></tr>
<tr><td rowspan="10">SS
1, 2, 3</td><td colspan="2">WEEK 1</td><td colspan="2">WEEK 2</td><td colspan="2">WEEK 3</td><td colspan="2">WEEK 4</td><td rowspan="10">SS
12, 13, 14</td><td>WEEK 5</td><td>WEEK 9</td></tr>
<tr><td>PRE</td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td>POST</td><td>FU</td></tr>
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<tr><td></td><td>SS5</td><td></td><td>SS7</td><td></td><td>SS9</td><td></td><td>SS11</td></tr>
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Figure 2. Evaluations and sessions distributions

PRE=pre-treatment, POST=post treatment, FU= Follow-up evaluation; TS= treatment session (EAC, AC or SHAM); ADF= additional data form; SF-36= quality of life questionnaire; VAS= visual analog scale; SS= saliva samples

During EA, the patient remained in the prone position (Figure.3). Needles were inserted bilaterally in local acupoints GB21 and GB20, two Ashi points (painful points not predicted on meridians, not necessarily MTrP), and unilaterally at distal acupoints LI4 and LV3 (Lin et al., 2005). The EA equipment was programmed to generate rectangular pulses of electrical stimulation with alternating frequencies (F1=2 Hz [700 µs], T1=5 s; F2=100 Hz [500 µs], T2=5 s; total time=30 min) at the maximum intensity supported by the patient

without pain (Zhu and Polus, 2002; Aranha et al., 2011) for all EA sessions. The AC group experienced the same acupoint treatment as EA subjects without electrical stimulation, while the SHAM group had needles inserted 1 cm from the acupoints (Xue et al., 2004).

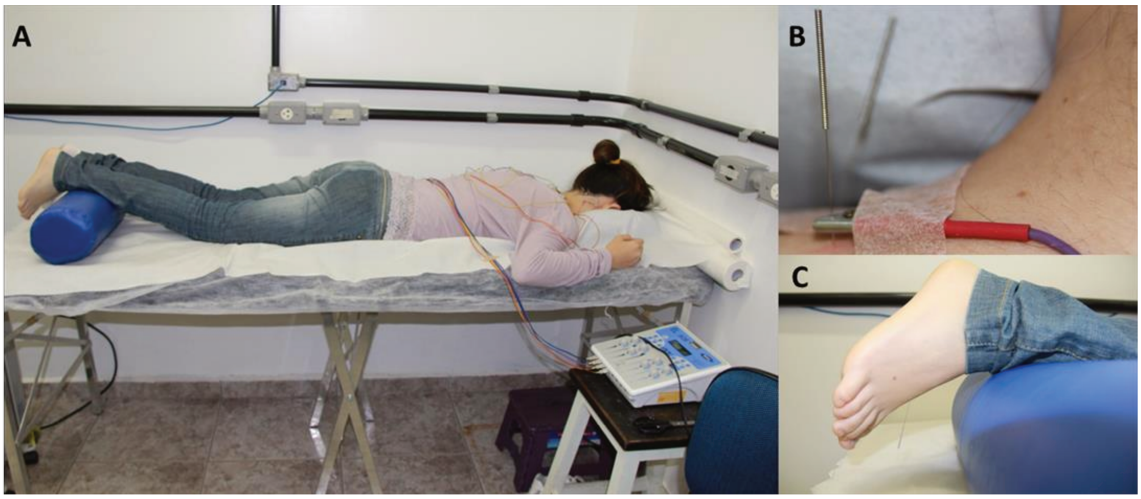

Figure 3. Treatment illustration. A- Volunteer in prone position; B- Electrode-needle connection (left upper trapezius); C- Needle (LV3) and feet position.

Statistics

Equal variance and normal error distribution were checked for all variables using the Shapiro-Wilk test. Intra-group comparisons were analyzed using a paired Student's *t*-test, Wilcoxon's signed rank test, one-way repeated measures analysis of variance (ANOVA), or Friedman repeated measures ANOVA by ranks with a Student-Newman-Keuls (SNK) *post-hoc* analysis. Inter-group differences were identified by one-way ANOVA or Kruskal-Wallis test with a Dunn's *post-hoc* analysis. An ANOVA was applied to the generalized linear mixed model (GLMM) of two factors: "group" (fixed) and "time of evaluation" (repeated measure). This analysis used the Student's *t*-test with a Tukey-Kramer adjustment. A Pearson's correlation was also applied. SigmaPlot 11.0 (Systat Software, San Jose, CA, USA) was used for all data analyses except the GLMM, which was analyzed with SAS version 9.3 software (SAS Institute Inc., Cary, NC, USA).

Results

Mean pain duration was 5.71±4.05 years with 61.67% reporting daily pain, 10% reporting pain five times per week, 11.67% four times per week, and 16.67% three times per week. All volunteers described muscular pain in both the upper RTPz and LTPz , with 65% also experiencing pain in the cervical region, 63% in the occipital, 50% in the parietal, 55% in the temporal, and 38.4% in the frontal region during this study. Furthermore, 40% of subjects reported suffering a migraine. Sample characteristics relative to group distribution are described in Table 1. From these 60 volunteers, 45 attended the one month follow-up evaluation.

Pain Intensity

There were no significant differences in general pain (P=0.493) or pain in the RTPz (P=0.908) or LTPz (P=0.723) between groups pre-treatment. However, a significant reduction in general pain was observed in both EA and AC groups after all eight sessions (P<0.001), but not in the SHAM group (P=0.078). Moreover, a decrease in pain intensity in both the upper RTPz and LTPz occurred in both the EA and AC groups post-treatment (Table 2). In fact, after most of the sessions the pain intensity decreased significantly (Table 2); intra-group comparisons before each session suggested a cumulative effect. A significant decrease was observed in the RTPz after session 5 in the SHAM group (P<0.05) and in the RTPz after session 6 (P<0.05) and LTPz after session 7 (P<0.05) in the EA group.

The AC group showed significant differences between sessions 1, 5 and 8 but not between other sessions (RTPz P<0.05).

Table 1. Sample Characteristics.

Characteristic	EA (n=20)	AC (n=21)	SHAM n=19)
Age (mean±SD)	27.9±5.3	28.0±4.4	25.6±4.9
BMI (mean±SD)	21.6±2.6	22.2±3.1	23.6 ±3.5
WOC (%)	40.0	42.8	38.8
POC (%)	40.0	38.1	42.1
COC (%)	20.0	19.1	21.1
Pain duration (years) (mean±SD)	6.0±4.4	4.8±4.1	5.2±3.3
Frequency of pain (times/week) (mean±SD)	5.6±1.7	5.9±1.7	5.1±2.2
Predominant side (% right)	95	100	100
Pain at RTPz (%)	100	100	100
Pain at LTPz (%)	100	100	100
Cervical pain (%)	60.0	85.7	47.3
Occiptal pain (%)	40.0	47.6	52.6
Parietal pain (%)	15.0	28.5	10.5
Temporal pain (%)	40.0	80.9	42.1
Frontali pain (%)	35.0	28.5	47.3
Migraine (%)	45.0	47.6	26.3

Pre- and post-treatment and follow-up pain measures are presented in Tables 3 and 4. After treatment, the GLMM identified interaction of the two factors “time of evaluation” and “group” between the EA and AC groups with regard to general pain and between RTPz and LTPz pain in the EA group only. At follow-up, no interaction between the two factors was observed in any treatment group. Furthermore, when POC, COC, and WOC were analyzed apart from treatment regimen, no significant difference in pain intensity was observed at the initial evaluation (general pain, P=0.835; RTPz P=0.501; LTPz, P=0.848; ANOVA with SNK).

Table 2. Comparison of pain intensity before and after each session for the three treatment groups.

BEFORE X AFTER SESSION		EA (n=20)						AC (n=21)						SHAM (n=19)					
		RTPz			LTPz			RTPz			LTPz			RTPz			LTPz		
1	BEFORE	4.34	(1.93)	<0.001	3.82	(2.26)	<0.001	4.16	(2.42)	0.022	*2.80*	*(5.00)*	*0.017*	4.04	(2.22)	0.013	3.43	(2.23)	0.003
	AFTER	2.06	(1.95)		1.80	(1.86)		3.22	(2.51)		*0.80*	*(4.50)*		3.16	(2.19)		2.35	(2.28)	
2	BEFORE	3.64	(2.48)	<0.001	3.50	(2.52)	<0.001	*3.40*	*(5.40)*	*0.044*	*2.80*	*(4.20)*	*0.006*	*2.60*	*(4.25)*	*0.105*	3.03	(2.03)	0.021
	AFTER	1.79	(1.61)		1.75	(1.73)		*2.90*	*(4.40)*		*1.60*	*(4.10)*		*2.00*	*(0.85)*		2.32	(2.26)	
3	BEFORE	*2.90*	*(3.68)*	*<0.001*	*3.02*	*(2.14)*	*<0.001*	3.22	(2.80)	0.053	2.40	(4.10)	0.021	2.99	(2.10)	0.014	2.30	(1.70)	0.005
	AFTER	*0.85*	*(2.40)*		*1.48*	*(1.52)*		2.47	(2.27)		2.10	(3.70)		1.87	(1.95)		1.50	(1.60)	
4	BEFORE	*1.80*	*(2.50)*	*0.003*	*2.00*	*(2.73)*	*0.005*	*2.70*	*(3.80)*	*<0.001*	*2.40*	*(2.30)*	*<0.001*	*2.30*	*(3.40)*	*0.002*	3.10	(4.00)	<0.001
	AFTER	*0.90*	*(2.28)*		*0.90*	*(3.03)*		*1.50*	*(2.80)*		*0.90*	*(2.00)*		*1.50*	*(2.70)*		1.50	(2.70)	
5	BEFORE	*2.10*	*(2.)*	*<0.001*	*1.85*	*(3.18)*	*<0.001*	*3.30*	*(3.30)*	*0.044*	2.52	(2.11)	0.099	*2.20*	*(2.90)*	*0.002*	2.40	(1.96)	0.015
	AFTER	*0.40*	*(1.73)*		*0.55*	*(2.40)*		1.30	(3.10)		1.96	(2.03)		1.10	(1.45)		1.66	(1.61)	
6	BEFORE	*1.55*	*(92.90)*	*<0.001*	*1.55*	*(3.15)*	*<0.001*	2.50	(2.90)	0.001	*2.60*	*(3.50)*	*<0.001*	*2.10*	*(1.85)*	*0.003*	1.40	(2.35)	0.001
	AFTER	*0.15*	*(1.48)*		*0.50*	*(1.58)*		1.70	(2.80)		*1.30*	*(2.60)*		*1.20*	*(1.75)*		1.20	(1.30)	
7	BEFORE	*0.75*	*(2.08)*	*<0.001*	*0.85*	*(2.38)*	*<0.001*	*2.30*	*(2.40)*	*<0.001*	*2.00*	*(2.60)*	*<0.001*	*2.17*	*(1.84)*	0.608	2.35	(1.90)	0.162
	AFTER	0	(0.90)		0	(0.73)		*1.10*	*(2.00)*		*1.00*	*(1.70)*		*1.95*	*(1.87)*		1.90	(2.09)	
8	BEFORE	0.50	(1.33)	<0.001	0.55	(1.70)	0.006	2.00	(1.42)	0.016	1.60	(1.40)	0.002	2.77	(1.92)	0.008	2.32	(1.82)	0.013
	AFTER	0	(0.35)		0.10	(0.50)		1.46	(1.37)		0.80	(1.40)		1.87	(1.58)		1.41	(1.36)	

Normal fonts: paired t-test, mean (standard deviation); Italic fonts: Wilcoxon Signed Rank Test, median (interquartile deviation)

Table 3. Intra-group comparisons of pain intensity pre- and post-treatment.

		EA (n=20)		AC (n=21)		SHAM (n=19)	
		MEAN±SD	P	MEAN±SD	p	MEAN±SD	p
GENERAL PAIN	PRE	5.63±2.29^{A}		5.58±2.37^{A}		4.84±2.20^{A}	
	POST	2.03±2.13^{A}	*P*<0.001	2.82±2.15^{A}	*P*<0.001	3.55±2.47^{A}	*P*=0.078
RTPz PAIN	PRE	4.34±1.93^{A}		4.16±2.42^{A}		4.03±2.22^{A}	
	POST	1.23±1.17^{B}	*P*<0. 001	2.75±2.07^{A}	*P*=0.025	3.04±2.16^{A}	*P*=0.038
LTPz PAIN	PRE	3.82±2.26^{A}		3.28±2.86^{A}		3.43±2.23^{A}	
	POST	1.07±1.48^{B}	*P*<0.001	2.17±1.94^{B}	*P*=0.076	2.58±1.96^{A}	*P*=0.086

Capital superscript letters in the same column mean statistical significant difference in inter-group comparisons at baseline (ANOVA) and after completed treatment (Kruskal-Wallis);
PRE=pre-treatment, POST=post treatment

Table 4. Intra-group comparison of general pain intensity and RTPz and LTPz pain in pre- and post-treatment and follow-up evaluations.

		EA (n=17)		AC (n=15)		SHAM (n=13)	
		MEAN±SD	P	MEAN±SD	p	MEAN±SD	p
GENERAL PAIN	PRE	5.42±2.38^{A}		5.29±2.44^{A}		4.80±1.70^{A}	
	POST	1.77±1.82^{B}	<0.001$^{\#}$	2.11±1.57^{B}	<0.001§	2.60±4.10^{B}	0.025§
	FOLLOW-UP	2.43±2.35^{B}		2.54±2.43^{B}		2.70±1.80^{B}	
RTPz PAIN	PRE	4.40±2.60^{A}		4.46±2.26^{A}		4.20±2.10^{A}	
	POST	1.00±1.70^{B}	<0.001§	2.17±1.83^{B}	<0.001$^{\#}$	2.50±2.40^{B}	0.025§
	FOLLOW-UP	1.30±2.20^{B}		1.76±1.79^{B}		3.30±3.10^{B}	
LTPz PAIN	PRE	3.44±2.22^{A}		3.10±4.75^{A}		3.95±1.96^{A}	
	POST	1.11±1.61^{B}	<0.001$^{\#}$	1.90±2.45^{A}	0.032§	2.88±1.99^{B}	0.048$^{\#}$
	FOLLOW-UP	1.68±1.66^{B}		1.90±2.25^{A}		2.58±1.95^{B}	

One way repeated measures Analysis of Variance (means and standard deviation)
§ Friedman repeated measures Analysis of Variances on Ranks (median and interquartile deviation)
Post Hoc All Pairwise Multiple Comparison Procedure (Student-Newman Keuls Method)
PRE=pre-treatment, POST=post-treatment

Salivary Cortisol

There were no inter-group differences in salivary cortisol levels pre- treatment (AUC_G, *P*=0.219; CAR, *P*=0.148). No significant difference was found post- treatment in the AUC_G or CAR in both SHAM and EA groups, while these stress-related measures were significantly increased in the AC group (AUC_G, *P*=0.006; CAR, *P*<0.001; Fig. 4). One-way repeated measures ANOVA showed no differences in AUC_G and CAR before and after each individual session between the three treatment groups (SHAM, *P*=0.529; EA, *P*=0.091; AC, *P*=0.675). Moreover, no interaction was found between the two factors "time of evaluation" and "group." Comparison of oral contraceptive use apart from treatment group showed no significant difference in CAR (*P*=0.379) or AUC_G (*P*=0.258) pre-treatment. Statistical analysis found no correlation between salivary cortisol levels and SF-36 or VAS results (*P*>0.05; Table 7).

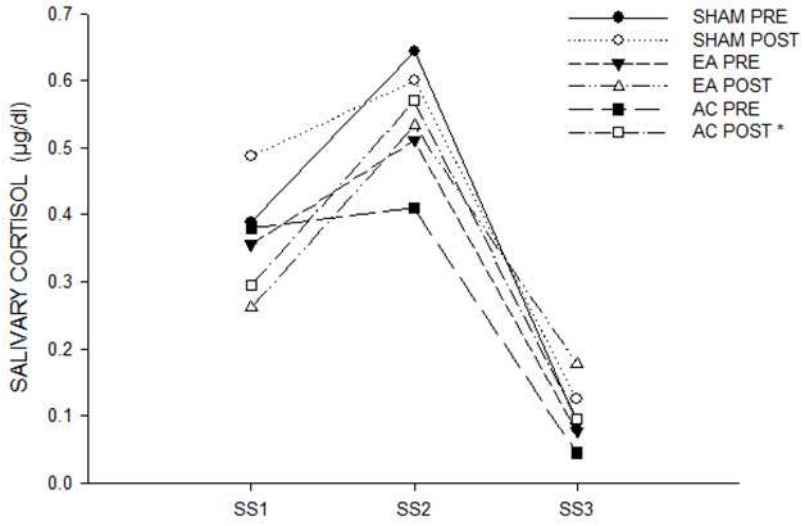

Figure 4. Concentration of salivary cortisol immediately after awaking in the morning (SS1), 30 min after awaking (SS2), and 30 min before going to bed (SS3) in the three treatment groups before and after the eight sessions (**P*<0.05). PRE, pre-treatment; POST, post-treatment.

Quality of life (SF-36)

It was found no significant inter-group differences for the SF-36 questionnaire (pre-treatment)(*P*>0.05). Post-treatment, the SHAM group showed a significant improvement in the BP domain (*P*=0.005), while the EA and AC groups both showed significant improvement in the PF, RP, BP, GH, VT, and MH domains and the PC summary (PCs) (Table 5). Comparison of quality of life pre- and post-treatment and at follow-up in the SHAM group showed an improvement post-treatment versus baseline that was maintained through follow-up for BP and GH domains. A similar improvement was observed for the EA group in the RP, BP, and MH domains and PCs; however, VT domain improvements were not maintained through follow-up. AC group post-treatment improvements maintained through follow-up were in the PF, BP, GH, VT, SF, and MH domains and PCs (Table 6).

No interaction between "time of evaluation" and "group" factors was found at post-treatment or follow-up evaluation. Moreover, baseline values were not influenced by oral contraceptive use apart from treatment (*P*>0.05). Moderately negative correlations were found between the SF-36 PCs and general pain (r=-0.333, *P*=0.002), the PCs and LTPz pain (r=-0.321, *P*=0.004), and a weakly negative correlation between the PCs and RTPz pain (r=-0.253 *P*=0.022; Table 7).

Table 5. SF-36 health survey questionnaire domain data obtained pre- and post-treatment for the three treatment groups.

SF-36		EA (n=20)		AC (n=21)		SHAM (n=19)	
		Mean±SD	P	Mean±SD	P	Mean±SD	P
PF	PRE	87.59±8.45[A]	0.011[§]	81.90±16.99[A]	0.016[§]	85.00±12.50[A]	0.463#
	POST	92.50±7.33[A]		89.52±9.60[A]		85.00±15.00[A]	
RP	PRE	62.50±81.25[A]	0.027#	50.00±100.0[A]	0.013#	55.26±35.92[A]	0.279[§]
	POST	100.0±25.00[A]		75.00±50.00[A]		65.79±37.46[A]	
BP	PRE	48.06±11.73[A]	0.010[§]	43.29±17.38[A]	0.003[§]	41.00±14.50[A]	0.005#
	POST	62.44±17.25[A]		56.09±18.07[A]		61.00±11.00[A]	
GH	PRE	74.50±20.75[A]	0.017#	72.00±20.00[A]	0.011#	72.00±22.50[A]	0.404#
	POST	87.00±15.00[A]		80.00±15.00[A]		77.00±30.00[A]	
VT	PRE	49.44±20.36[A]	0.010[§]	40.00±40.00[A]	0.011#	43.42±16.67[A]	0.061[§]
	POST	65.00±13.83[A]		55.00±35.00[A]		51.84±17.49[A]	
SF	PRE	74.31±16.87[A]	0.064[§]	61.31±28.20[A]	0.089[§]	62.50±31.25[A]	1.000#
	POST	84.03±14.73[A]		72.02±22.68[A]		62.50±37.50[A]	
RE	PRE	66.70±100.0[A]	0.322#	66.70±100.0[A]	0.492#	66.70±66.70[A]	0.067#
	POST	100.0±66.70[A]		100.0±100.0[A]		66.70±83.50[A]	
MH	PRE	62.00±29.00[A]	0.018#	58.10±18.79[A]	0.014[§]	60.84±12.83[A]	0.368[§]
	POST	76.00±16.00[A]		67.62±16.54[A]		64.21±15.80[A]	
PCs	PRE	46.64±6.49[A]	0.019[§]	44.91±7.85[A]	0.002[§]	46.23±5.03[A]	0.142[§]
	POST	51.97±6.34[A]		50.02±7.43[A]		48.15±6.36[A]	
MCs	PRE	42.69±10.85[A]	0.094[§]	46.20±20.80[A]	0.135#	39.10±13.65[A]	0.465#
	POST	47.81±8.90[A]		46.50±18.10[A]		44.70±18.20[A]	

Uppercase letters at the same line refers to intergroup differences; [§]Paired t-test; #Wilcoxon Signed test

PRE=pre-treatment, POST=post treatment

Table 6. SF-36 health survey questionnaire domains in pre- and post-treatment and follow-up evaluation.

SF-36		EA (n=17)		AC (n=15)		SHAM (n=13)	
		Mean±SD	P	Mean±SD	P	Mean±SD	P
PF	PRE	87.94±8.49^{A}	0.042§	80.67±18.69^{A}	0.007§	90.00±15.00^{A}	0.266#
	POST	92.65±7.52^{B}		90.33±10.26^{B}		85.00±15.00^{A}	
	FU	92.65±7.52^{B}		88.00±10.49^{B}		85.00±15.00^{A}	
RP	PRE	51.47±40.96^{A}	0.006§	51.67±46.74^{A}	0.190§	63.46±36.25^{A}	0.448§
	POST	82.35±32.79^{B}		75.00±34.07^{A}		76.92±31.39^{A}	
	FU	80.88±28.68^{B}		68.33±41.69^{A}		69.23±38.40^{A}	
BP	PRE	48.41±11.99^{A}	<0.001§	41.00±29.50^{A}	<0.001#	46.15±16.03^{A}	0.019§
	POST	64.29±15.83^{B}		62.00±16.00^{B}		59.46±14.52^{B}	
	FU	69.12±16.23^{B}		62.00±12.00^{B}		61.31±14.58^{B}	
GH	PRE	77.00±20.00^{A}	0.138#	62.00±21.50^{A}	<0.001#	68.77±18.32^{A}	0.005§
	POST	87.00±15.00^{A}		82.00±17.50^{B}		76.69±18.54^{B}	
	FU	82.00±15.00^{A}		77.00±22.50^{B}		78.39±14.89^{B}	
VT	PRE	49.12±20.93^{A}	0.007§	42.00±24.19^{A}	0.002§	46.92±12.17^{A}	0.126§
	POST	66.18±13.29^{B}		55.67±22.11^{B}		54.23±18.24^{A}	
	FU	58.24±20.23^{A}		60.00±23.15^{B}		58.08±19.97^{A}	
SF	PRE	75.00±25.00^{A}	0.305#	50.00±18.75^{A}	0.003#	62.50±50.00^{A}	0.368#
	POST	87.50±12.50^{A}		75.00±25.00^{B}		75.00±50.00^{A}	
	FU	75.00±37.50^{A}		87.50±37.50^{B}		75.00±25.00^{A}	
RE	PRE	66.70±66.70^{A}	0.232#	48.89±46.92^{A}	0.081§	53.86±34.82^{A}	0.201§
	POST	100.0±66.70^{A}		60.00±47.48^{A}		74.37±36.39^{A}	
	FU	100.0±33.30^{A}		73.34±40.24^{A}		56.41±36.99^{A}	
MH	PRE	60.94±17.24^{A}	0.018§	56.27±20.65^{A}	0.005§	62.15±11.50^{A}	0.252§
	POST	70.29±12.59^{B}		68.27±16.32^{B}		67.69±13.61^{A}	
	FU	72.71±16.32^{B}		68.80±19.08^{B}		68.81±14.74^{A}	
PCs	PRE	48.20±11.20^{A}	0.005#	45.33±8.63^{A}	0.010§	46.87±5.05^{A}	0.189§
	POST	53.59±8.70^{B}		51.35±7.47^{B}		49.69±5.70^{A}	
	FU	53.70±9.20^{B}		50.12±4.93^{B}		50.00±7.64^{A}	
MCs	PRE	42.76±11.18^{A}	0.137§	46.10±23.60^{A}	0.129#	41.61±7.78^{A}	0.225§
	POST	47.92±9.16^{A}		46.50±24.15^{A}		45.41±9.43^{A}	
	FU	47.36±9.95^{A}		53.00±15.55^{A}		44.49±9.23^{A}	

Uppercase letters at the same columns refers to intragroup differences; Lowercase letters at the same line refers to intergroup differences; §One-way ANOVA Repeated Measures; #Friedman Repeated Measures Analysis of Variance on Ranks: Intergroup comparisons $P>0.05$

Table 7. Pearson correlation between SF-36 health survey questionnaire PCs and MCs, VAS, and salivary cortisol levels among volunteers.

	MCs	VAS G	VAS RTPz	VAS LTPz	AUC_G	CAR
PCs	0.051	-0.333*	-0.253*	-0.321*	0.105	0.147
MCs	-	-0.259*	-0.147*	-0.178	0.131	0.126
VAS G	-	-	0.776	0.652	-0.129	-0.105
VAS RTPz	-	-	-	0.713	-0.083	-0.130
VAS LTPz	-	-	-	-	-0.051	-0.145
AUC_G	-	-	-	-	-	0.664

*P<0.05; MCs= Mental Components, PCs=Physical components, VAS= Visual Analog Scale, G= General pain, RTPz = pain at the right trapezius muscle, LTPz= pain ate the left trapezius muscle, AUC_G= Area under the curve to the ground, CAR= cortisol awaking response.

Additional Data Form (ADF)

The three treatment groups exhibited similar patterns regarding other influential factors on previous days and between sessions (Table 8). Compared to EA and AC groups, SHAM subjects had a more pronounced increase in medication use and headache frequency in the last week of treatment and prior to post-treatment evaluation. Whilst EA and AC subjects showed a decrease in headache frequency, SHAM volunteers reported more headaches in the last sessions compared to the first sessions; medication use decreased in the EA group as sessions progressed. Positive and negative life experiences remained relatively unchanged for all groups throughout all sessions. Neck and shoulder pain frequency slightly decreased in all groups, with an increase between the last session and post-treatment evaluation in the AC group.

Table 8. Percentage of volunteers who reported medication use, positive or negative life experiences, headache, or neck and shoulder pain pre-treatment till evaluation follow-up.

SESSIONS		1	2	3	4	5	6	7	8	9*	10**
MEDICATION USE	SHAM	30.77	23.08	30.77	38.46	15.38	7.69	7.69	30.77	38.46	30.77
	EA	41.18	17.65	23.53	35.29	23.53	5.88	5.88	17.65	29.41	23.53
	AC	53.33	40.00	13.33	20.00	33.33	20.00	13.33	40.00	20.00	46.67
POSITIVE LIFE EXPERIENCES	SHAM	15.38	0.00	15.38	7.69	0.00	7.69	15.38	7.69	15.38	15.38
	EA	5.88	5.88	0.00	0.00	0.00	5.88	0.00	5.88	0.00	5.88
	AC	6.67	0.00	6.67	20.00	0.00	0.00	13.33	6.67	20.00	13.33
NEGATIVE LIFE EXPERIENCES	SHAM	30.77	23.08	15.38	30.77	23.08	30.77	15.38	23.08	7.67	15.38
	EA	23.53	5.88	17.65	17.65	5.88	11.76	5.88	11.76	5.88	17.65
	AC	20.00	20.00	26.67	13.33	26.67	26.67	20.00	6.67	26.67	20.00
HEADACHE	SHAM	30.77	61.54	38.46	23.08	38.46	38.46	46.15	61.54	84.62	69.23
	EA	58.82	35.29	41.18	47.06	52.94	35.29	47.06	29.41	41.18	41.18
	AC	73.33	73.33	33.33	40.00	46.67	46.67	26.67	40.00	46.67	46.67
NECK PAIN	SHAM	69.23	46.15	38.46	38.46	38.46	53.85	53.85	46.15	46.15	69.23
	EA	58.82	52.94	64.71	52.94	47.06	29.41	35.29	58.82	41.18	52.94
	AC	73.33	66.67	53.33	73.33	53.33	66.67	53.33	46.67	53.33	33.33
SHOULDER PAIN	SHAM	92.31	76.92	53.85	69.23	76.92	61.54	76.92	69.23	61.54	84.62
	EA	76.47	82.35	82.35	70.59	47.06	58.82	35.29	70.59	58.82	70.59
	AC	93.33	73.33	86.67	86.67	53.33	60.00	66.67	60.00	73.33	60.00

*Post-treatment; **Follow-up

Discussion

The aim of this study was to evaluate the effectiveness of EA and AC in the treatment of myofascial pain. With respect to pain intensity, an interaction between "time of evaluation" and "groups" factors was found only in the EA group, suggesting EA had a greater effect on reducing myofascial pain than AC and SHAM treatments. This result corroborates a previous study regarding the analgesic effect of transcutaneous electrical acupoint stimulation (Yuan et al., 2002), which differs from EA only by the presence of a transcutaneous electrode instead of a needle. Thus, the analgesic effects of acupoint stimulation provided by the needles in AC treatments are augmented by the use of electrical stimulation. Furthermore, the alternating electrical frequency (2 and 100 Hz) releases opioid peptides, providing maximal therapeutic effects (Han, 2004).

Reduction from 60 to 45 volunteers at follow-up was basically due to no show. In addition, if a subject's oral contraceptive use changed after post-treatment evaluation they were excluded from the follow-up analysis because such changes could interfere with interpretation of results. This reduction in sample size resulted in slight statistical changes. For example, both AC and SHAM groups showed improvements after treatment when there were only 45 volunteers (follow-up), but no improvement was found in the post-treatment evaluations when there were 60 volunteers. Furthermore, none of the groups have showed significant difference between post-treatment and follow-up evaluations, suggesting that beneficial treatment effects could be maintained for at least one month (Table 4). However, further studies are needed to investigate the lasting effects of treatment with longer follow-up periods.

Interestingly, a slightly significant improvement in pain was observed in the SHAM group, supporting previous studies that found improvement in neck pain after SHAM-acupuncture (Zhu and Polus, 2002; Sun et al., 2010). Considering the level of statistical significance in this case compared to EA and AC treatments, it is possible the "placebo effect" contributed to this slight improvement (Medeiros, 2009). Indeed, this effect can significantly influence the therapeutic effects of pain treatment (MacPherson et al., 2001)

and could restrict the interpretation and strength of the present study. Therefore, the placebo effect should always be considered in the analysis of any therapeutic intervention (Medeiros, 2009). However, randomization and blinding were employed in this study to ensure results were ultimately the product of true therapeutic effects.

Although the EA group experienced superior pain relief, changes in AUC_G and CAR were only seen in the AC group, suggesting enhanced HPA axis activity in this group, as previously observed (Gaab et al., 2005; Petrelluzzi et al., 2008; Riva et al., 2010). Conversely, no difference in CAR and AUC_G were observed in women with chronic trapezius myalgia and healthy volunteers (Sjörs et al. 2010). In their study, Sjörs et al. (2012) demonstrated that significant improvements in symptom development during treatment of stress-related volunteers were not associated with CAR changes. Another study observed that subjects with fibromyalgia had slightly enhanced cortisol release throughout the day compared to healthy controls, which was associated with affective disturbances, like depression (Wingenfeld et al., 2010). Such disparities between current and previous studies may be the result of differences in patient populations and/or not controlling for menstrual phase. Although no correlation was found between CAR, AUC_G, and SF-36 MC, it should be noted that the present study did not use a specific psychological questionnaire to evaluate the degree of patient depression, which may pose a limitation to our study. Nonetheless, in order to avoid possible bias, participants underwent careful anamneses to detect any physical or emotional condition constituting inclusion or exclusion criteria.

Assessment of CAR in saliva has been shown to provide the same result whether samples were collected by patients at home or under highly controlled laboratory conditions (Wilhelm et al., 2007). Despite that, as researchers cannot completely control of the time patients awaken or other information brought by volunteers, thereby potentially limiting study methodology. Furthermore, laboratory collection of saliva from all subjects at the multiple time-points during the same time of day is not practical. Herein, these short-comings were eliminated by patient at-home sampling. Although the

CAR has been shown to be significantly affected by menstrual cycle phase (Wolfram et al., 2011), no differences in cortisol levels between POC, COC, and WOC groups were noted in the present study. This result likely stemmed from our constant monitoring and adjustment for menstrual cycle prior to treatment initiation.

Subjects with chronic pain frequently present with anxiety, tension, and/or hopelessness or depression (Simons et al., 1999), all of which can be measured with the SF-36 questionnaire. The SF-36 evaluates patient quality of life through PCs (PF, RP, BP, and GH) and MCs (RE, SF, MH, and VT) criteria; a maximum score of 100 represents a high quality of life. While both EA and AC groups showed significant improvement in six of the eight SF-36 domains (PF, RP, BP, GH, VT, and MH) and one summary measure (PCs) post-treatment, the SHAM group presented improvement in only one domain (BP) and no summary measure (Table 5). At follow-up, AC and EA groups continued to exhibit SF-36 subtle improvements relative to SHAM (Table 6). The improvement in quality of life following treatment of myofascial pain is in accordance with previous studies (Lew et al., 2008; Aranha et al., 2011; Sun et al., 2011; Gerber et al., 2013); however, to the best of our knowledge, this is the first study comparing both EA and AC treatment efficacy with quality of life.

Moderate and weakly negative correlations between general pain and SF-36 PCs and MCs, respectively, indicate that, weaker pain equates with a higher physical and mental quality of life, in agreement with Sun et al., (2010). Moreover, the lack of significant correlation between cortisol measures and pain (Table 7) agrees with previous studies which found improvement in pain but no change in CAR or AUC_G (Doepel et al., 2009). ADF-monitoring of influential factors at each session (Table 8) indicated that pain relief experienced by volunteers was due to the treatment itself, not other factors (e.g., medication). Although there was a little variation in positive and negative life experiences, they did not seem to have influenced results. Notably, the percentage of headaches, possibly a result of referred pain from upper trapezius myofascial pain, was lower in both AC and EA groups post-treatment, whereas the SHAM group remained unchanged.

Finally, with the exception to COC volunteers (i.e., no menstrual period), the first session occurred between the second and the fifth days of menstruation to reduce/eliminate the possible influence of rapid hormonal (e.g., ovulation) and/or subjective mood changes [e.g., premenstrual syndrome] (Greenspan et al. 2007). Women using POC exhibited a 28 day menstrual cycle, while WOC women had a 28.375±0.875 day menstrual cycle. These similarities between POC and WOC groups throughout the four week treatment period helped avoid potential experimental variations consequent to hormone fluctuations as opposed to therapeutic regimen.

Conclusions

EA and AC treatments were more effective at reducing myofascial pain and improving quality of life than SHAM in this study. Interestingly, there are indications that AC more effectively decreases stress and maintains a heightened quality of life post-treatment than EA. Nonetheless, further studies are needed to clarify cortisol behavior in chronic myofascial pain subjects.

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CAPÍTULO 3

Influence of acupuncture and electroacupuncture on trigger point ultrasound images after treatment of myofascial pain: A randomized controlled pilot study

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ABSTRACT

Myofascial pain (MP) can arise from an active myofascial trigger point (MTrP), wherein biochemical-associated pain and inflammation have been observed. Previous ultrasound studies have identified MTrP as focal hypoechoic areas The aim of this study was to evaluate the effect of acupuncture (AC) and electroacupuncture (EA) on the intensity of MP and 2D-ultrasound images of dysfunctional muscle tissue (due to MTrP) following treatment. Thirty-one women were randomized into three groups: EA, AC, and SHAM-acupuncture (SHAM). A decrease in pain intensity in the right (RTPz; EA, $P<0.001$; AC, $P=0.037$) and left trapezius (LTPz; EA, $P<0.001$) was observed. A decrease was also found in the hypoechoic area of the RTPz (EA, $P<0.001$; AC, $P<0.001$; SHAM, $P=0.035$) and LTPz (EA, $P=0.001$; AC, $P<0.001$). These results suggest that objective confirmation and quantification of the effects of myofascial treatments by 2D-ultrasound imaging techniques is clearly feasible. Nonetheless, further studies are needed to validate these results. (este parte está nas conclusões do estudo e está de acordo com as correções do inglês. Como eles pedem especial atenção ao aspecto das novas contribuições do estudo, achei mais adequado)

Keywords: ultrasonography, acupuncture, electroacupuncture, myalgia, musculoskeletal pain.

Introduction

Myofascial trigger points (MTrP) are defined as hyper-irritable areas within taut bands of skeletal muscle or fascia that emanate pain upon compression and give rise to characteristic referred pain, motor dysfunction, and autonomic phenomena (Simons et al. 1999). These points can be latent in the absence of spontaneous pain, causing motor dysfunction such as rigidity and weakness, or active when referred or spontaneous pain at the abnormal muscle site is present (Gerwin et al. 1997; Okeson 2006; Simons et al. 1999). Referred pain due to palpation is characterized by the recognition of previously experienced pain (distant to the palpated site) and is one of the most important diagnostic criteria when palpable findings, such as the presence of taut bands and hypersensitive nodules, are present (Gerber et al. 2013).

Among the treatments available, acupuncture (AC) is an alternative to more traditional clinical therapies for myofascial pain (MP). In general, AC neurophysiologically and/or physically denervates the MTrP neural loop to reduce pain and stop or moderate the over-contraction of muscles (Gerwin 1999). By insertion of ultra-fine needles, AC stimulates points on the body to prevent or modify the perception of pain (nociception), alter physiological functions, or both (Fernández-de-las-Peñas et al. 2007). Moreover, AC can involve the passage of an electrical current through the needles, called electroacupuncture (EA) (Stux and Pomeranz 1995).

Clinically, MP treatment should increase the function of the evaluated muscle (Gerwin et al. 1997), promoting not only a decrease in pain, but also normalization of MTrP chemical mediators and mechanical relaxation of the taut muscle band (Koski et al. 2009).

Until now, the clinical diagnosis and treatment of MTrP have mainly consisted of palpation (Aranha et al. 2011; Gerwin et al. 1997; Gerwin 1999; Lucas et al.2010; Shah and Gilliams 2008; Simons et al. 1999). However, ultrasound imaging techniques have recently been employed to improve the assessment of affected myofascial tissue and adjacent

areas. In particular, 2D-ultrasound is a real-time, objective, and non-invasive diagnostic technique that can be widely applied to visualization of soft tissues, organs, and the musculoskeletal system, such as muscle, tendons, fasciae, etc (Grassi et al. 2004; Hashefi 2011; Smith and Finnoff 2009).

Ultrasound is a low risk method used to obtain descriptive tissue information, including the presence of fat and muscle fibers, as well as mechanical properties (Whittaker and Stokes 2011), and enables the quantification of hemodynamic changes due to blood vessel compression and dynamic measures of muscle tissue performance, demonstrating correlation(s) between structure and function (Shamdasani et al. 2008). Recent studies have used 2D-ultrasound to evaluate MTrP because they appear on images as focal hypoechoic (darker) areas with heterogeneous echotexture (Chi-Fishman et al. 2004; Ballyns et al. 2012). Furthermore, a study by Shankar and Reddy (2012) reported that taut bands of muscle in MP syndrome may appear hyperechogenic (lighter) in 2D-ultrasound images. The aim of this study was to evaluate the effect of EA and AC on pain intensity and 2D-ultrasound images of MTrP in women with pain in the upper trapezius muscles following treatment.

Materials and Methods

Subjects

This research was conducted at the Electromyography and Ultrasonography Laboratory, Department of Pediatric Dentistry, Piracicaba Dental School, University of Campinas (Piracicaba, SP, Brazil), as part of the base project "Evaluation of acupuncture and electroacupuncture in the treatment of myofascial pain of upper trapezius muscles - a double-blinded, randomized, placebo-controlled trial" (Sao Paulo Research Foundation – FAPESP, process 2010/11684-0 and 2011/12659-1). The Brazilian Clinical Trials Registry number for this study is RBR-42kz9z (www.ensaiosclinicos.gov.br/rg/RBR-42kz9z/). The Piracicaba Dental School Research Ethical Committee approved this project (protocol

number 003/2011). Volunteers were asked to read and sign a consent form prior to study inclusion and were informed of any possible procedures, discomfort, risks, benefits, and the need to attend all sessions.

Sample selection methods were previously described (Aranha 2014). Briefly, women suffering from head and neck pain were submitted to careful anamneses to obtain information about their general health in order to apply inclusion and exclusion criteria, as follow: *Inclusion criteria: r*egular menstrual cycle (regardless of oral contraception use), body mass index of 18-29.9 Kg/m^2, at least one MTrP in the upper trapezius muscle with local or referred persistent pain for at least six months; *Exclusion criteria: a*ccentuated postural abnormalities and cognitive impairment or communication difficulties at the first meeting (verified by the physiotherapist, C.E.E.M.) fibromyalgia syndrome, cervical radiculopathy, systemic disease or physical therapy interventions for myofascial pain within one month before the study, pregnancy, chronic pacemaker or electronic implant use (as reported by the subject), continuous use of medications to treat headache and muscular pain. Subjects presenting with an irregular menstrual cycle were excluded. Pre- and post-treatment imaging measurements were performed on the second and the fifth day of menstruation (Greenspan et al. 2007), with 28 days between each measurement; two sessions were scheduled per week, at the same time of day, for a total of eight sessions (Sun et al. 2010). Post-treatment evaluations occurred 2-6 days after the last session, coinciding with the second and fifth day of the subject's menstrual period.

A convenience sample, composed of 31 volunteers who were participating in the above cited research, was evaluated by 2D-ultrasound before and after treatment. All subjects were diagnosed with active bilateral MTrPs, and each side was analyzed separately. Volunteers were distributed into three treatment groups: EA, AC, and SHAM-acupuncture (SHAM). Initially, subjects were coded according to oral contraceptive use as follows: paused, continuous, or without. After, subjects were randomly allocated to each treatment group using the aleatory Microsoft Excel Software function, thereby avoiding the predominance of one oral contraceptive condition in any treatment group.

Instrumentation

EA, AC, SHAM, Visual Analog Scale, & Additional Data Form

EL608 NKL (ANVISA 80191680002) was used as the electrical stimulation equipment, generating asymmetrical biphasic unpolarized waveform. Stainless steel 0.25x30 mm needles (Dong-Bang, Korea) were used for all treatments. The Visual Analog Scale (VAS), consisting of a 10 cm horizontal line with extremes corresponding to zero (no pain) and 10 (maximum pain), assessed the intensity of general pain (head, neck and shoulders) and pain in the right (RTPz) and left upper trapezius (LTPz) muscles. An additional data form (ADF) was applied at the beginning of each session to monitor inter-occurrences throughout the eight sessions and consisted of open-ended questions regarding any trauma(s), "positive" or "negative" life experiences that could have influenced their pain intensity, headaches, neck and shoulder pain, and medications (analgesics, non-steroidal anti-inflammatories, and spasmolytic drugs) and their doses; emotional stress was also considered.

2D-Ultrasound

A digital ultrasound SSA-780A–APLIO MX (Toshiba Medical Systems Corporation, Japan) machine with a 7-18 MHz linear array transducer (38 mm) was used for 2D-ultrasound image acquisition. The MTrP area on gray-scale images was acquired in DICOM format, while K-Pacs software, version 1.6.0 (DICOM Viewing Software, Alemanha), was used to convert these images to JPEG format. MTrP areas on ultrasound images were quantified using the region of interest (ROI), a standard measurement tool available in Image J version 1.45 software (National Institutes of Health, USA).

Procedures

A blinded examiner (C.E.E.M.) performed evaluations. The MTrP diagnosis was based on five criteria outlined by Simons et al. (1999) and Gerwin et al. (1997), MTrP were

considered active when subjects complained of spontaneous pain. Before the first session and also at the post-treatment evaluation, each volunteer completed an ADF and VAS of the pain experienced on each side of the upper trapezius. After, the blinded examiner (C.E.E.M.) performed the ultrasound exam, targeting the transducer to the upper resting LTPz and RTPz, longitudinal to the muscle fascicles, half-way between the seventh cervical vertebra and the tip of acromion. MTrP appeared as focal hypoechoic areas with heterogeneous echotexture in 2D-ultrasound images (Ballyns et al. 2012), and, the area of the MTrP was measured with the ROI tool in Image J (Fig. 1). If more than one MTrP where present, the most central MTrP to the image was measured. This procedure was repeated twice, and the mean values were considered for further analysis.

Eight therapy sessions, twice a week, were scheduled. The chosen acupoints were GB21, GB20, LI4, LV3 (Lian et al. 2005), and two ashi points (painful points not predicted on meridians, not necessarily MTrP). EA equipment was programmed using alternating frequencies (F1=2 Hz, T1=5 s; F2=100 Hz, T2=5 s; total time=30 min (Aranha et al., 2011) and the maximum intensity supported by the patient without pain (Aranha et al. 2011; Zhu and Polus 2002). The AC group experienced the same acupoint treatment as EA subjects without the use of alternating frequency equipment, while the SHAM group had needles inserted 1 cm from the acupoints.

Statistics

Equal variance and normal error distribution were checked for all variables with the Shapiro-Wilk test. Intra-group comparisons were analyzed using a paired Student's *t*-test, Wilcoxon's signed rank test, one-way repeated measure analysis of variance (ANOVA), or Friedman repeated measure ANOVA by ranks with a Student-Newman-Keuls (SNK) *post-hoc* analysis. One-way ANOVA or Kruskal-Wallis with the SNK method was applied for inter-group comparisons. The Student's *t*-test with a Tukey-Kramer adjustment was applied to the linear, generalized, mixed model for two factors: group (fixed) and time

of evaluation as repeated measures. A Pearson's correlation was also applied. Data was analyzed using SigmaPlot version 11.0 (Systat Software, San Jose, CA, USA) for all analyses except the linear, generalized, mixed model, which was analyzed with SAS version 9.3 software (SAS Institute Inc., Cary, NC, USA).

Results

Mean pain duration was 6.03±4.21 years with a mean frequency of 5.58±1.86 episodes of pain per week. All volunteers reported MP in both the upper RTPz and LTPz , with 70.97% also presenting with pain in the cervical region, 54.84% in the occipital, 16.13% in the parietal, 61.29% in the temporal, and 41.93% in the frontal region of the head. Also, 38.71% of subjects reported experiencing migraine. Sample characteristics relative to group distribution are presented in Table 1.

Pain Intensity

There were no significant differences in RTPz (P=0.805) or LTPz (P=0.273) pain between groups at the pre-treatment. However, at the post-treatment intragroup evaluation a decrease in pain intensity was found in both the upper RTPz and LTPz of the EA group, but only in the RTPz of the AC group (Table 2). Post-treatment comparison of pain intensity showed a significant difference between the three groups in the RTPz (P=0.018), and the *post-hoc* test identified lower pain in the RTPz of the EA group. No significant difference in LTPz pain intensity was found between the three treatment groups (P=0.068). ANOVA showed interaction of the two factors, group and time of evaluation (RTPz, P=0.011; LTPz, P=0.006), and the Tukey-Kramer test revealed a significant reduction in pain intensity following treatment in the EA group, but not in the AC or SHAM groups.

Table 1 - Sample characteristics

CHARACTERISTICS	EA (n=9)	AC (n=12)	SHAM (n=10)
Age (mean±DP)	29.1±5.5	27.6±4.8	24.9±5.6
BMI (mean±DP)	22.9±3.1	21.6±3.1	24.9±3.1
WOC (%)	33.33	25.00	30.00
POC (%)	44.44	58.33	60.00
COC (%)	22.22	16.67	10.00
Pain duration (years) (mean ± DP)	7.28±4.51	5.67±4.91	4.80±3.39
Frequency of pain (times/week) (mean ± DP)	5.89±1.76	5.67±2.02	5.10±2.03
Predominant side (% right)	100.00	100.00	100.00
Pain at RTPz (%)	100.00	100.00	100.00
Pain at LTPz (%)	100.00	100.00	100.00
Cervical pain (%)	55.55	100.00	50.00
Occiptal pain (%)	44.44	66.67	50.00
Parietal pain (%)	11.11	25.00	10.00
Temporal pain (%)	44.44	83.33	50.00
Frontali pain (%)	44.44	33.33	50.00
Migraine (%)	55.55	41.67	20.00

WOC= without oral contraception; POC = paused oral contraception; COC = continuous oral ontraception

2D-Ultrasound

There was no significant difference between the three groups at pre-treatment (RTPz, P=0.385; LTPz, P=0.188). After treatment, significant differences between groups (RTPz, P=0.010; LTPz, P=0.011) were observed; the AC group had significantly lower MTrP area in RTPz 2D-ultrasound images versus the SHAM group and in LTPz images relative to both SHAM and EA groups. Intra-group comparisons revealed a significant decrease in 2D-ultrasound image MTrP area in both the RTPz and LTPz of EA and AC groups and the RTPz of the SHAM group (Table 3). No correlation between VAS and MTrP area in the RTPz and LTPz were found. The interaction of the two factors (group and evaluation time) was

observed in the EA and AC groups, both of which also showed smaller hypoechoic areas (MTrP) in both the RTPz (P=0.003) and LTPz (P=0.001) compared to the SHAM group.

Table 2 - Means and standard deviation of intensity of pain at the RTPz and at the LTPz at pre- and post-treatment for the three groups

INTENSITY OF PAIN		EA (n=9)		AC (n=12)		SHAM (n=10)	
		MEAN±SD	P	MEAN±SD	P	MEAN±SD	P
RTPz	PRE	5.14±1.15^{A}	<0.001	4.99±2.28^{A}	0.037	4.70±1.73^{A}	0.217
	POST	1.52±1.22^{B}		3.40±1.89^{A}		3.94±2.12^{A}	
LTPz	PRE	4.83±2.07^{A}	<0.001	2.95±3.10^{A}	0.348	3.91±2.34^{A}	0.412
	POST	1.20±1.64^{A}		2.28±2.09^{A}		3.33±1.87^{A}	

Uppercase letters at the same line refers to intergroup differences; PRE= pre-treatment; POST= Post-treatment

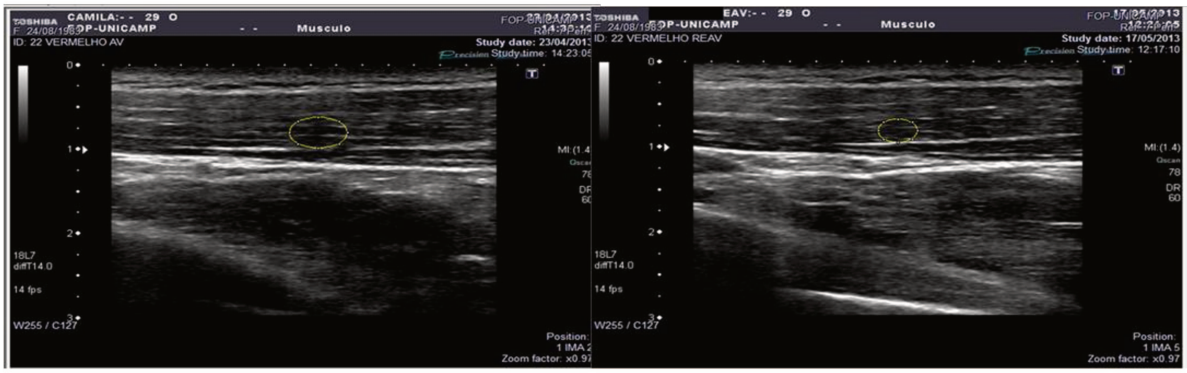

Figure 1 - Dimensional US image of the upper trapezius with the marked MTrP at pre- and post-treatment

Table 3 - Means and standard deviations of the most central MTrP area (hypoechoic area) pre and post-treatment for the three groups

MTrP AREA (Pixel)		EA (n=9) MEAN±SD	P	AC (n=12) MEAN±SD	P	SHAM (n=10) MEAN±SD	P
R	PRE	1919.44±489.35^{A}	<0.001	1679.75±554.33^{A}	<0.001	1807.60±719.20^{A}	0.035
	POST	1229.33±351.49^{AB}		1022.00±365.82^{B}		1603.10±650.06^{A}	
L	PRE	1943.00±576.02^{A}	0.001	1539.50±467.05^{A}	<0.001	1684.80±420.48^{A}	0.079
	POST	1372.05±511.89^{AC}		1002.42±358.78^{B}		1554.60±349.19^{A}	

Uppercase letters at the same line refers to intergroup differences; R=Right Trapezius; L= Left Trapezus; PRE= pre-treatment; POST= Post-treatment

ADF

Whilst the EA and AC groups showed a significant decrease in the frequency of medication ingestion and headache, the SHAM group presented an increase. Also, complaints of neck pain were less frequent after treatment in the EA and AC groups, but remained unchanged in the SHAM group. “Positive” and “negative” life experiences frequency were unchanged in all three groups. Shoulder pain was less frequently reported in all three groups after treatment (Table 4).

Table 4 - Percentage of volunteers who related medical ingestion, positive or negative living experiences, headache or neck and shoulder pain between sessions till evaluation session (n=31)

SESSIONS		1	2	3	4	5	6	7	8	9*
MEDICATION USE	EA	55.55	33.33	11.11	33.33	22.22	0.00	11.11	11.11	22.22
	AC	58.33	41.66	8.33	8.33	8.33	33.33	16.66	8.33	33.33
	SHAM	40.00	30.00	30.00	30.00	20.00	20.00	10.00	40.00	60.00
POSITIVE LIFE EXPERIENCES	EA	11.11	11.11	0.00	11.11	0.00	0.00	0.00	11.11	0.00
	AC	0.00	0.00	16.66	8.33	0.00	0.00	8.33	0.00	16.66
	SHAM	20.00	0.00	20.00	10.00	10.00	10.00	20.00	10.00	20.00
NEGATIVE LIFE EXPERIENCEs	EA	44.44	0.00	22.22	22.22	0.00	0.00	0.00	11.11	0.00
	AC	16.66	33.33	16.66	16.66	16.66	16.66	16.66	8.33	16.66
	SHAM	50.00	10.00	30.00	10.00	10.00	40.00	30.00	40.00	20.00
HEADACHE	EA	77.77	44.44	33.33	77.77	33.33	22.22	44.44	33.33	44.44
	AC	66.66	66.66	33.33	33.33	16.66	50.00	16.66	16.66	33.33
	SHAM	50.00	60.00	50.00	30.00	40.00	60.00	60.00	70.00	90.00
NECK PAIN	EA	66.66	44.44	55.55	33.33	44.44	22.22	44.44	44.44	33.33
	AC	75.00	66.66	50.00	58.33	58.33	58.33	50.00	50.00	66.66
	SHAM	70.00	60.00	50.00	50.00	50.00	70.00	60.00	70.00	70.00
SHOULDER PAIN	EA	88.88	88.88	77.77	55.55	55.55	66.66	44.44	66.66	66.66
	AC	100.00	75.00	75.00	75.00	50.00	50.00	58.33	66.66	83.33
	SHAM	90.00	90.00	60.00	70.00	80.00	70.00	80.00	80.00	70.00

*Post-treatment evaluation

Discussion

Despite a significant decrease in pain intensity in the RTPz of the AC group, the EA group showed a significant improvement relative to the AC and SHAM groups, with a significant reduction in pain intensity in both the LTPz and RTPz (Table 2). Moreover, interaction of the two factors (group and evaluation time) with respect to pain intensity was seen only in the EA group. Importantly, a significant decrease in EA group pain intensity relative to the SHAM and AC groups was found post-treatment, although no other inter-group difference was noted (Table 2). Likewise, the analgesic effect of transcutaneous electrical acupoint stimulation, which differs from EA only by the presence of a transcutaneous electrode instead of a needle, has been shown (Yuan et al. 2002). Moreover, traditional transcutaneous electrical nerve stimulation has been shown to significantly improve chronic back pain (Grant et al.1999). EA with alternating 2 Hz and 100 Hz frequencies was shown to increase the release of both dynorphin and endomorphin (Han 2004), while AC promoted activation of encephalinergic neurons within the spinal cord (Bing et al. 1991). These previous studies in conjunction with current results suggest that the EA group herein benefited from the analgesic effects elicited by electrical stimulation in addition to the needle acupoint stimulation effect (AC), thereby producing better therapeutic results.

Decreased MTrP areas in both RTPz and LTPz 2D-ultrasound images following treatment in the current study suggests enhanced therapeutic effects in the AC and EA groups versus the SHAM group, which only showed a decrease in the MTrP area of the RTPz. Furthermore, although there was initially no difference between all three groups, the AC group had a significantly smaller MTrP area in the RTPz compared to the SHAM group at post-treatment evaluation. A significantly smaller LTPz MTrP area was also noted in the AC group relative to the EA and SHAM groups, suggesting AC more effectively diminished MTrP hypoechoic areas (Table 3). However, it must be noted that the AC group presented with smaller MTrP areas at pre-treatment; though not significant, this could have affected the current results. Moreover, no significant difference in the interaction of

the two factors (group and evaluation time) between the EA and AC groups was noted, indicating neither treatment was superior to the other. MTrP 2D-ultrasound images with gray-scale degree and patterns similar to those of healthy tissue after treatment suggests therapeutically beneficial effects of EA and AC on inflammatory processes and local tissue microvascularization altered by muscle disorders prevalent in MP syndrome.

Changes observed in 2D-ultrasound image gray-scale degree and pattern in MTrP areas, as focal hypoechoic and heterogeneous echotexture regions, in the present study are in agreement with Sikdar et al. (2009) and Ballyns et al. (2012). In addition, brighter lines within muscle fascicules of dysfunctional tissue were observed in the current study, which may represent myofascial tissue thickness in MTrP-affected regions, similar to a previous study by Shankar & Reddy (2012) wherein hyperechogenic areas within taut muscle bands were observed using 2D-ultrasound diagnostic techniques. Contrary to our findings, Lewis & Tehan (1999) reported unsuccessful ultrasound diagnosis of MTrP, probably due to technical limitations of the equipment. With the development of new, more accurate technologies and equipment, myofascial tissue 2D-ultrasound diagnostics have become more reliable. Furthermore, quantification of gray-scale variations can be used to confirm results of different treatments.

Recent studies have shown that musculoskeletal system diseases exhibit alterations in mechanical properties of tissue, which can be observed using 2D-ultrasound imaging techniques (Ballyns et al. 2012; Langevin et al. 2011; Stecco et al. 2013). Using MTrP ultrasound evaluation, focal hypoechoic and heterogeneous gray-scale areas have been correlated with the local elevated inflammatory mediators, catecholamines, neuropeptides, and pro-inflammatory cytokines within these painful nodules and surrounding tissue, which are known to be associated with cases of chronic pain, myofascial tenderness, aberrant intercellular signaling, and inflammation (Koski et al. 2009; Shah et al. 2005). Therefore, a decline in the hypoechoic area on 2D-ultrasound images suggests morphological improvement of treated tissue. In the same way, if inflammation and changes in local microvascularization is substantiated by hypoechoic

findings (Shah et al. 2005), hyperechoic regions may point to fasciae thickening (Stecco et al. 2013). Therefore, further studies are necessary to better define and quantify morphological differences between normal and dysfunctional muscle associated with MTrP.

To our knowledge, no previous studies have assessed the various MTrP dimensions by 2D-ultrasound imaging pre- and post-treatment. One study, however, evaluated the thickness of sternocleidomastoid and scalene muscle fascia by ultrasound demonstrating a statistically significant decrease in fasciae average density in subjects with chronic neck pain after treatment with different conventional physiotherapy techniques (Stecco et al. 2013). Moreover, further validation studies as well as pre- and post-treatment research are required in order to confirm the possibility of using 2D-ultrasound imaging in MTrP diagnostics and monitoring. Finally, the ADF was helpful for monitoring factors influencing pain and MTrP other than treatment, especially the frequency of medication use. Our imaging results together with ADF data demonstrated that the pain relief experienced by subjects herein was not due to an increase in analgesic use. Furthermore, although there was little variation in “positive” and “negative” life experiences, they did not appear to have influenced results.

Conclusions

Although an improvement in AC volunteers was observed, EA was found to be more effective than both AC and SHAM treatment of MP in the upper RTPz and LTPz muscles. In addition, 2D-ultrasound images showed improvement of muscle tissue conditions in both the AC and EA treatment groups. These results suggest that objective confirmation and quantification of the effects of myofascial treatments by 2D-ultrasound imaging techniques is clearly feasible. Nonetheless, further studies are needed to validate these results.

Acknowledgements

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CONCLUSÕES

Os resultados observados nos estudos apresentados mostram que:

1. A EAC e a AC foram eficazes no alívio da dor miofascial da parte superior do músculo trapézio com indícios de que a eletroacupuntura tenha maior eficácia que a acupuntura em curto prazo.
2. A EAC e a AC auxiliam também no relaxamento muscular e aumento da ADC cervical, mesmo que de forma sutil.
3. A EAC e a AC se mostraram mais efetivas no aumento da qualidade de vida que a SHAM acupuntura. Apesar disso, há indícios de que a AC seja mais efetiva na diminuição do estresse e na manutenção dos resultados obtidos em relação à qualidade de vida que a EA. Nesse sentido, futuros estudos são necessários sobre o comportamento do cortisol em mulheres com dor crônica myofascial.
4. A redução da área do Pg (US), observada especialmente nos grupos que também apresentaram melhora na intensidade de dor, limitação de AMD cervical e qualidade de vida, sugere que a confirmação objetiva e quantificativa dos efeitos de um tratamento myofascial pela imagem ultrassonográfica é viável. No entanto, estudos com maiores amostra devem confirmar estares resultados.

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APÊNDICE 1

TERMO DE CONSENTIMENTO LIVRE E ESCLARESCIDO

Nº registro 003/2011

ESTUDO: **"Avaliação da acupuntura e da eletroacupuntura no tratamento da dor miofascial na parte superior do músculo trapézio"**

Você está convidado a participar da pesquisa acima citada a ser desenvolvida pelas pesquisadoras Cristina Emöke Erika Müller, Maria Fernanda Montans Aranha e Profa. Dra. Maria Beatriz Duarte Gavião. O documento abaixo é um Termo de Consentimento Livre e Esclarecido que contém todas as informações necessárias sobre a pesquisa que será realizada. As informações contidas no Termo, bem como sua apresentação e a obtenção do consentimento, serão realizadas por nós, pesquisadores responsáveis pela pesquisa. Sua colaboração neste estudo será de muita importância, mas se desistir a qualquer momento, isso não lhe causará nenhum prejuízo. Essa pesquisa se faz necessária para que possamos identificar qual das duas técnicas de acupuntura é mais eficaz no tratamento da dor no músculo trapézio proveniente de uma desordem miofascial.

Eu, abaixo assinado, concordo de livre e espontânea vontade em participar como voluntário do estudo **"Avaliação da acupuntura e da eletroacupuntura no tratamento da dor miofascial na parte superior do músculo trapézio"**. Declaro que obtive todas as informações necessárias fornecidas pelos pesquisadores responsáveis, bem como todos os eventuais esclarecimentos quanto às dúvidas por mim apresentadas.

Estou ciente que:

I) O estudo tem por objetivo identificar dentre as duas técnicas (acupuntura e eletroacupuntura) a melhor forma de tratar a dor do músculo trapézio. Serão avaliadas as possíveis alterações de postura, de intensidade da sensação dolorosa, de amplitude de movimento do pescoço, nos níveis de estresse, das imagens de ultrassonografia e elastografia ultrassonográfica do músculo trapézio, bem como da qualidade das atividades de vida diária antes e depois do tratamento.

II) A realização deste estudo pode fornecer novas informações em relação ao tratamento da dor miofascial contribuindo não apenas com a prática clínica, mas também com posteriores estudos relacionados.

III) Para a realização da pesquisa, todos os voluntários preencherão uma ficha de avaliação contendo dados pessoais e questões relacionadas à sua saúde e atividade de vida diária antes do início, e ao final do tratamento. Em cada sessão, deverão preencher a ficha de acompanhamento que consiste de questões a serem respondidas pelas voluntárias que visam acompanhar eventuais ocorrências entre as sessões, como cefaléia, dor cervical, traumas, uso de medicação e outras situações adversas influenciadoras. Antes e depois de cada sessão será solicitado ao voluntário que aponte em uma linha horizontal de 10 cm a intensidade da dor sentida no momento, sendo o início da linha o mínimo de dor e o final da linha o máximo de dor. Antes da primeira e da nona sessão serão realizados os exames de ultrassom e elastografia ultrassonográfica do músculo trapézio, assim como mensurada a sensação dolorosa com o auxílio de um aparelho que indica a máxima pressão sem dor que pode ser exercida no músculo. Para a avaliação postural, fotografias digitais serão obtidas com o voluntário em trajes de banho pré e pós-tratamento. Para quantificação do nível de estresse será realizada a análise de cortisol salivar. Para isso, as voluntárias farão coleta de saliva pela manhã e antes de dormir em três dias de cada semana. A acupuntura e a eletroacupuntura seguirão os padrões de segurança recomendados pelos Atlas tradicionais de acupuntura, com o uso de materiais esterilizados ou descartáveis.

IV) Durante o período da pesquisa, os voluntários devem manter apenas o tratamento proposto, sendo relatada na ficha de dados complementares a eventual administração de medicamento.

V) Cada voluntário será convocado a comparecer ao laboratório em dias e horários pré-estabelecidos, de modo a não comprometer suas atividades diárias. Na primeira sessão de tratamento, as próximas oito serão agendadas, sendo duas por semana, considerando a disponibilidade do voluntário. Para cada sessão, estima-se um tempo aproximado de 60 minutos, aumentando par duas horas na primeira e última sessão.

VI) As sessões deverão acompanhar todo o ciclo menstrual, iniciando na primeira semana após a menstruação ou na seguinte. A voluntária deve estar ciente de que essa é uma condição importante para a obtenção dos dados relativos à sua condição, bem como se comprometer a seguir o agendamento comparecendo às sessões previamente agendadas.

VII) Existem outros métodos para o tratamento de dor miofascial. A realização desta pesquisa se faz necessária para a obtenção de dados científicos sobre os efeitos da eletroacupuntura e da acupuntura no manejo clínico deste tipo de dor.

VIII) Este estudo inclui um grupo placebo e a alocação das voluntárias é aleatória.

IX) Os riscos e desconfortos previstos são considerados mínimos, inerentes aos procedimentos comuns de avaliação postural, intensidade de dor, limiar de dor à pressão, amplitude de movimento, coleta de saliva para análise do cortisol salivar, obtenção de imagens ultrassonográficas, aplicação de questionário de qualidade de vida, e procedimentos de tratamento pela acupuntura e eletroacupuntura; pois quando executados por profissional habilitado, como proposto pelo presente estudo, não causam efeitos colaterais negativos.

No momento da inserção das agulhas de acupuntura pode ocorrer *"de chi"* ou "sensação da acupuntura", descrita como leve desconforto, sensação de peso e/ ou dormência no local da aplicação, que passa em instantes; e, eventualmente, hematoma local.

O exame de algometria pode causar algum desconforto, porém não oferece nenhum risco previsível em sua aplicação.

A escala visual analógica (EVA), o questionário de qualidade de vida SF-36, a coleta de saliva, bem como a obtenção de imagens digitais e ultrassonográficas, são exames não-invasivos, que não provocam incômodo.

X) É possível que haja melhora da dor dos sujeitos após o tratamento.

XI) O acompanhamento e a assistência serão dados pelos pesquisadores responsáveis, para sanar qualquer necessidade relacionada à pesquisa.

XII) O contato com qualquer um dos pesquisadores responsáveis ou CEP poderá ser feito através de telefone ou endereço presente no fim desse termo de consentimento.

XIII) Quaisquer dúvidas serão esclarecidas antes, durante a após o desenvolvimento da pesquisa, entrando em contato com os pesquisadores ou com o CEP.

XIV) O voluntário tem a liberdade de desistir ou de interromper a colaboração com o estudo no momento em que desejar, sem qualquer penalidade de qualquer natureza, mediante o contato com um dos pesquisadores responsáveis.

XV) Fica garantido o sigilo de dados confidenciais ou que, de algum modo, possam provocar constrangimento ou prejuízo ao voluntário, sendo sempre preservadas sua integridade e identidade.

XVI) A participação neste projeto não acarretará qualquer custo ou ganho financeiro com relação aos procedimentos efetuados com o estudo, portanto, apenas gastos com transporte serão ressarcidos conforme a necessidade de cada voluntário, determinada na assinatura deste Termo.

XVII) Não há danos previsíveis para a realização desta pesquisa. Entretanto, se por ventura houver qualquer ocorrência nesse sentido, durante a realização das avaliações e tratamento, os pesquisadores tomarão medidas para repará-los.

XVIII) Receberei uma cópia desse Termo de Consentimento Livre e Esclarecido.

Nome:_____ Data de nascimento: ___/___/___

Endereço:_____

Telefones: _____ Celular: _____

Identidade (RG): _____ CPF: _____

Assinatura: _____ Data: ___/___/___.

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Em caso de dúvidas quanto aos seus direitos e compromissos como voluntário de pesquisa, entre em contato com o CEP/
FOP-UNICAMP
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www.fop.unicamp.br/cep

APÊNDICE 2

FICHA DE AVALIAÇÃO

DATA DA AVALIAÇÃO: ____/____/_____

NOME:

TELEFONE:

ENDEREÇO:

HORÁRIOS DISPONÍVEIS:

PROFISSÃO:

LADO PREDOMINANTE:

1) ANAMNESE

1.1) FREQÜÊNCIA, LOCALIZAÇÃO E GATILHOS DA DOR

1.2) SINTOMAS ASSOCIADOS À DOR

1.3) QUALIDADE DO SONO

1.4) ATIVIDADES FÍSICAS

1.5) HISTÓRICO FAMILIAR

2) CRITÉRIOS DE INCLUSÃO

Idade: Peso: Altura: IMC:

Dor local ou referida há quanto tempo? _____

Ciclo menstrual: Regular ◯ Anticoncepcional ◯

Data do último ciclo menstrual (1º dia) ____/____/_____

3) CRITÉRIOS DE EXCLUSÃO

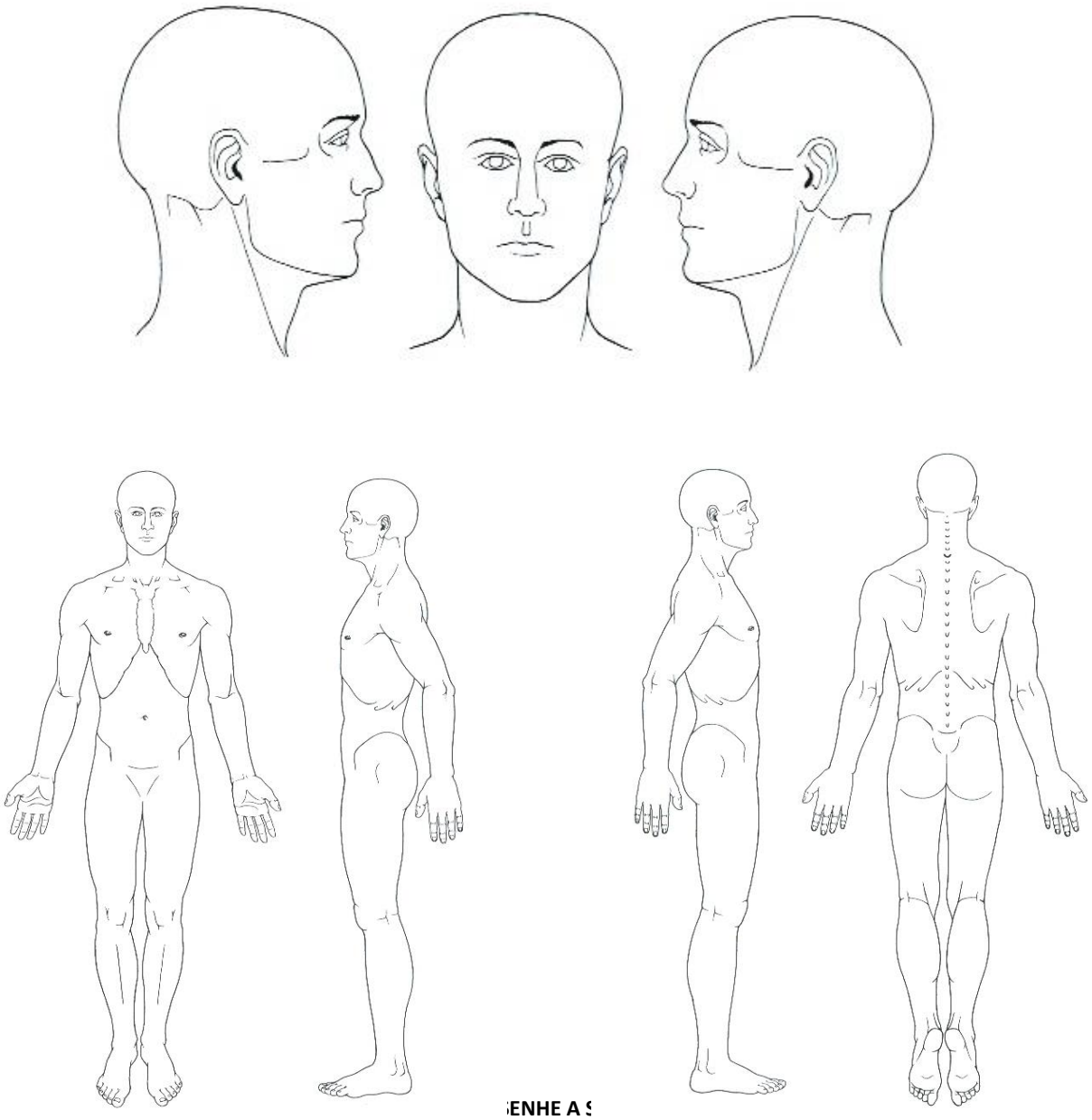
Alterações posturais acentuadas	
Fibromialgia	
Síndrome da fadiga crônica	
Radiculopatias	
Doenças sistêmicas	
Intervenção terapêutica física pra dor miofascial no último mês	
Gestante	
Marca passo ou implantes metálicos	
Medicamentos de uso contínuo	

4) EVA (marque com um traço sua intensidade de dor)

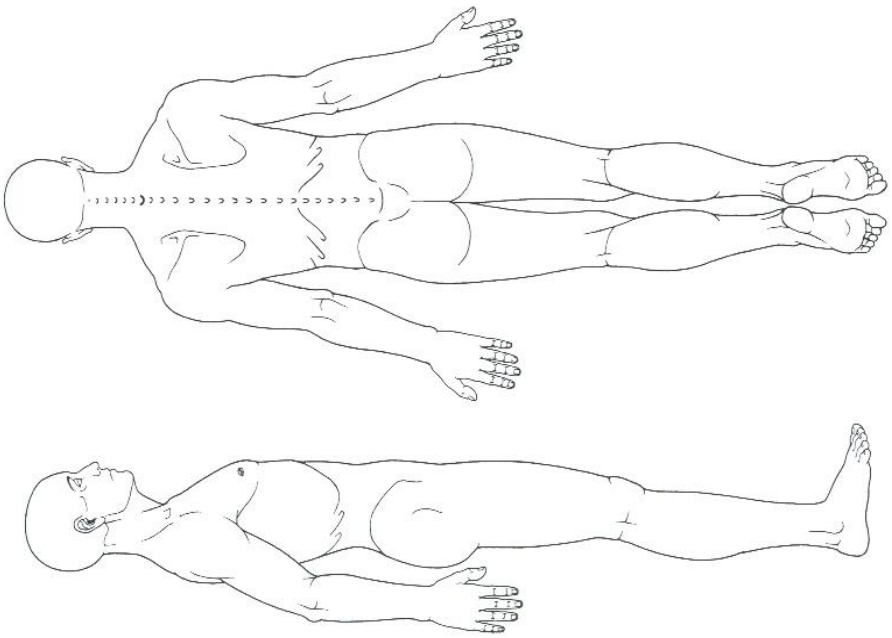
0 10

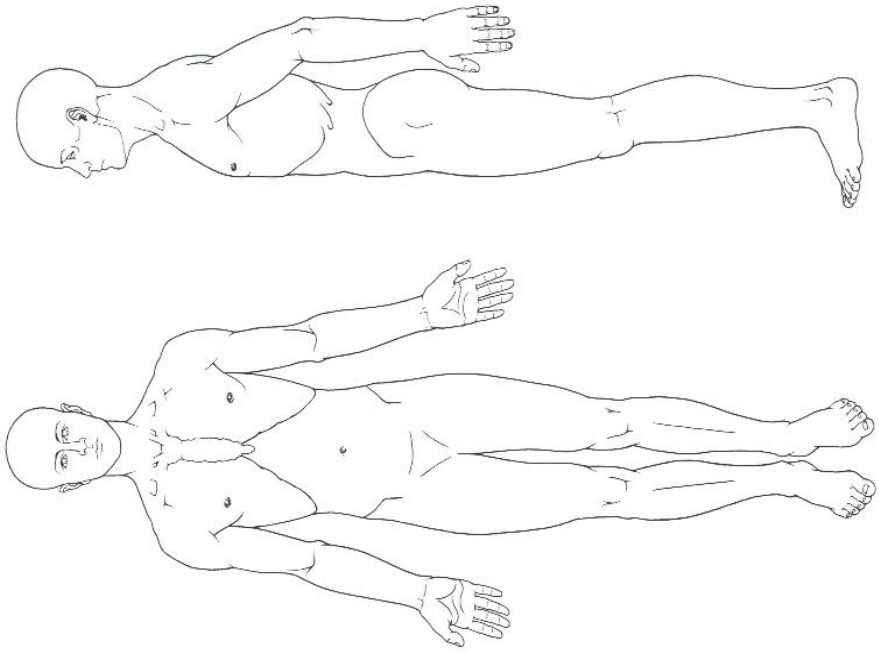
sem dor máximo de dor

5) PALPAÇÃO DO MÚSCULO TRAPÉZIO (LOCALIZAÇÃO DA DOR)



ENHE A S





APÊNDICE 3

FICHA DE DADOS COMPLEMENTARES

Nome: _____

Data:_____

Durante esta semana:

1) Você se contundiu? Qual local foi lesionado?

2) Houve necessidade da ingestão de medicamentos? Quais? Em que dosagem?

3) Vivenciou alguma situação importante, positiva ou negativa?

4) Teve cefaléia?

5) Teve dor cervical?

6) No m. trapézio?

Assinatura

_____

ANEXO 1

CETIFICADO DO COMITÊ DE ÉTICA E PESQUISA

COMITÊ DE ÉTICA EM PESQUISA
FACULDADE DE ODONTOLOGIA DE PIRACICABA
UNIVERSIDADE ESTADUAL DE CAMPINAS

CERTIFICADO

O Comitê de Ética em Pesquisa da FOP-UNICAMP certifica que o projeto de pesquisa **"Avaliação da acupuntura e da eletroacupuntura no tratamento da dor miofascial da parte superior do músculo trapézio - um estudo duplo cego, randomizado, placebo controlado"**, protocolo nº 003/2011, dos pesquisadores Maria Beatriz Duarte Gavião, Cristina EmÖke Erika MÜller e Maria Fernanda Montans Aranha, satisfaz as exigências do Conselho Nacional de Saúde - Ministério da Saúde para as pesquisas em seres humanos e foi aprovado por este comitê em 18/03/2011.

The Ethics Committee in Research of the School of Dentistry of Piracicaba - State University of Campinas, certify that the project **"Evaluation of acupuncture and electroacupuncture on the treatment of the upper trapezius myofascial pain - a double blinded randomized placebo controlled study"**, register number 003/2011, of Maria Beatriz Duarte Gavião, Cristina EmÖke Erika MÜller and Maria Fernanda Montans Aranha, comply with the recommendations of the National Health Council - Ministry of Health of Brazil for research in human subjects and therefore was approved by this committee at 03/18/2011.

Profa. Dra. Lívia Maria Andaló Tenuta
Secretária
CEP/FOP/UNICAMP

Prof. Dr. Jacks Jorge Junior
Coordenador
CEP/FOP/UNICAMP

Nota: O título do protocolo aparece como fornecido pelos pesquisadores, sem qualquer edição.
Notice: The title of the project appears as provided by the authors, without editing.

ANEXO 2

QUESTIONÁRIO DE QUALIDADE DE VIDA SF-36

INSTRUÇÕES: ESTA PESQUISA QUESTIONA VOCÊ SOBRE SUA SAÚDE. ESTAS INFORMAÇÕES NOS MANTERÃO INFORMADOS DE COMO VOCÊ SE SENTE E QUÃO BEM VOCÊ É CAPAZ DE FAZER SUAS ATIVIDADES DE VIDA DIÁRIA. RESPONDA CADA QUESTÃO MARCANDO A RESPOSTA COMO INDICADO. CASO VOCÊ ESTEJA INSEGURO EM COMO RESPONDER, POR FAVOR TENTE RESPONDER O MELHOR QUE PUDER. **(CIRCULE UMA OPÇÃO)**

1) EM GERAL, VOCÊ DIRIA QUE SUA SAÚDE É:

.Excelente 1

.Muito boa.....2

.Boa.....3

.Ruim.....4

.Muito ruim..... 5

2) COMPARANDO A UM ANO ATRÁS, COMO VOCÊ CLASSIFICARIA SUA SAÚDE EM GERAL, AGORA?

. Muito melhor agora do que há um ano atrás 1

. Um pouco melhor agora do que há um ano atrás..... 2

. Quase a mesma de um ano atrás 3

. Um pouco pior agora do que há um ano atrás 4

.Muito pior agora do que há um ano atrás 5

3) OS SEGUINTES ITENS SÃO SOBRE ATIVIDADES QUE VOCÊ PODERIA FAZER **ATUALMENTE DURANTE UM DIA COMUM. DEVIDO A SUA SAÚDE, VOCÊ TEM DIFICULDADE PARA FAZER ESSAS ATIVIDADES? NESTE CASO, QUANTO? (CIRCULE UMA EM CADA LINHA)**

ATIVIDADES	**SIM,** DIFICULTA MUITO	**SIM,** DIFICULTA UM POUCO	**NÃO,** NÃO DIFICULTA DE MODO ALGUM
a. Atividades vigorosas, que exigem muito esforço tais como correr, levantar objetos pesados, participar em esportes árduos	1	2	3
b. Atividades moderadas, tais como mover uma mesa, passar aspirador de pó, jogar bola, varrer a casa	1	2	3
c. Levantar ou carregar mantimentos	1	2	3
d. Subir vários lances de escada	1	2	3
e. Subir um lance de escada	1	2	3
f. Curvar-se, ajoelhar-se ou dobrar-se	1	2	3
g. Andar mais de um quilômetro	1	2	3
h. Andar vários quarteirões	1	2	3
i. Andar um quarteirão	1	2	3
j. Tomar banho ou vestir-se	1	2	3

4) DURANTE AS **ÚLTIMAS 4 SEMANAS**, VOCÊ TEVE ALGUM DOS SEGUINTES PROBLEMAS COM O SEU TRABALHO OU COM ALGUMA ATIVIDADE DIÁRIA REGULAR, COMO **CONSEQUÊNCIA DE SUA SAÚDE FÍSICA? (CIRCULE UMA EM CADA LINHA)**

	SIM	**NÃO**
a. Você diminuiu a quantidade de tempo que se dedicava ao seu trabalho ou a outras atividades?	1	2
b. Realizou menos tarefas do que gostaria?	1	2
c. Esteve limitado no seu tipo de trabalho ou em suas atividades?	1	2
d. Teve dificuldades de fazer seu trabalho ou outras atividades (por exemplo: necessitou de um esforço extra)?	1	2

5) DURANTE AS **ÚLTIMAS 4 SEMANAS**, VOCÊ TEVE ALGUM DOS SEGUINTES PROBLEMAS COM O SEU TRABALHO OU OUTRA ATIVIDADE REGULAR DIÁRIA, COMO **CONSEQUÊNCIA DE ALGUM PROBLEMA EMOCIONAL** (COMO SENTIR-SE DEPRIMIDO OU ANSIOSO)? **(CIRCULE UMA EM CADA LINHA)**

	SIM	**NÃO**
a. Você diminui a quantidade de tempo que se dedicava ao seu trabalho ou a outras atividades?	1	2
b. Realizou menos tarefas do que gostaria?	1	2
c. Não trabalhou ou não fez qualquer das atividades com tanto cuidado como geralmente faz?	1	2

6) DURANTE AS ÚLTIMAS **4 SEMANAS**, DE QUE MANEIRA SUA SAÚDE FÍSICA OU PROBLEMAS EMOCIONAIS INTERFERIRAM NAS **SUAS ATIVIDADES SOCIAIS NORMAIS, EM RELAÇÃO A FAMÍLIA, VIZINHOS, AMIGOS OU EM GRUPO?**

. De forma nenhuma 1

. Ligeiramente..... 2

. Moderadamente 3

. Bastante 4

. Extremamente 5

7) QUANTA DOR NO CORPO VOCÊ TEVE DURANTE AS **ÚLTIMAS 4 SEMANAS?**

. Nenhuma..... 1

. Muito leve 2

. Leve 3

. Moderada 4

. Grave 5

. Muito grave 6

8) DURANTE AS **ÚLTIMAS 4 SEMANAS, QUANTO A DOR INTERFERIU COM O SEU TRABALHO NORMAL** (INCLUINDO TANTO O TRABALHO, FORA DE CASA E DENTRO DE CASA)?

. De maneira alguma 1

. Um pouco 2

. Moderadamente 3

. Bastante 4

. Extremamente 5

9) ESTAS QUESTÕES SÃO SOBRE **COMO VOCÊ SE SENTE E COMO TUDO TEM ACONTECIDO COM VOCÊ DURANTE AS ÚLTIMAS 4 SEMANAS**. PARA CADA QUESTÃO, POR FAVOR, DÊ UMA RESPOSTA QUE MAIS SE APROXIME DA MANEIRA COMO VOCÊ SE SENTE. **(CIRCULE UMA EM CADA LINHA)**

	TODO TEMPO	A MAIOR PARTE DO TEMPO	UMA BOA PARTE DO TEMPO	ALGUMA PARTE DO TEMPO	UMA PEQUENA PARTE DO TEMPO	NUNCA
a. Quanto tempo você tem se sentido cheio de vigor, cheio de vontade, cheio de força?	1	2	3	4	5	6
b. Quanto tempo você tem se sentido uma pessoa muito nervosa?	1	2	3	4	5	6
c. Quanto tempo você tem se sentido tão deprimido que nada pode animá-lo?	1	2	3	4	5	6
d. Quanto tempo você tem se sentido calmo e tranqüilo?	1	2	3	4	5	6
e. Quanto tempo você tem se sentido com muita energia?	1	2	3	4	5	6
f. Quanto tempo você tem se sentido desanimado e abatido?	1	2	3	4	5	6
g. Quanto tempo você tem se sentido esgotado?	1	2	3	4	5	6
h. Quanto tempo você tem se sentido uma pessoa feliz?	1	2	3	4	5	6
i. Quanto tempo você tem se sentido cansado?	1	2	3	4	5	6

10) DURANTE **AS ÚLTIMAS 4 SEMANAS, QUANTO DO SEU TEMPO A SUA SAÚDE FÍSICA OU PROBLEMAS EMOCIONAIS INTERFERIRAM COM AS SUAS ATIVIDADES SOCIAIS** (COMO VISITAR AMIGOS, PARENTES, ETC.)?

. Todo o tempo 1

. A maior parte do tempo 2

. Alguma parte do tempo 3

. Um pequena parte do tempo 4

. Nenhuma parte do tempo 5

11) O QUANTO VERDADEIRO **OU** FALSO **É CADA UMA DAS AFIRMAÇÕES PARA VOCÊ? (CIRCULE UMA NÚMERO EM CADA LINHA)**

	DEFINITIVA MENTE VERDADEIRA	A MAIORIA DAS VEZES VERDADEIRA	NÃO SEI	A MAIORIA DAS VEZES FALSA	DEFINITIVAM ENTE FALSA
a. Eu costumo adoecer mais facilmente que as outras pessoas	1	2	3	4	5
b. eu sou tão saudável quanto qualquer pessoa que eu conheço	1	2	3	4	5
c. Eu acho que a minha saúde vai piorar	1	2	3	4	5
d. Minha saúde é excelente	1	2	3	4	5

DATA: ____/____/_____ PIRACICABA, SÃO PAULO.

NOME: _____

ASSINATURA: _____

ANEXO 3

CERTIFICADO DA CORREÇÃO DO INGLÊS

AMERICAN JOURNAL EXPERTS

EDITORIAL CERTIFICATE

This document certifies that the manuscript listed below was edited for proper English language, grammar, punctuation, spelling, and overall style by one or more of the highly qualified native English speaking editors at American Journal Experts.

Manuscript title:

Cervical range of motion in women with myofascial pain treated with acupuncture, electroacupuncture and SHAM-acupuncture: a double blinded, randomized clinical trial

Authors:

Maria Fernanda Montans Aranha, Cristina Emoke Erika Muller, Maria Beatriz Duarte Gavião

Date Issued:

February 1, 2014

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ANEXO 4

COMPROVANTE DA SUBMISSÃO DO ARTIGO

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Brazilian Journal of Physical Therapy

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Submission Confirmation

Thank you for submitting your manuscript to *Brazilian Journal of Physical Therapy*.

Manuscript ID:	RBFIS-2014-0059
Title:	Cervical range of motion in women with myofascial pain treated with acupuncture, electroacupuncture and SHAM-acupuncture: a double-blinded, randomized clinical trial
Authors:	Aranha, Maria Fernanda Müller, Cristina Gavião, Maria Beatriz
Date Submitted:	12-Feb-2014

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