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ORIGINAL RESEARCH

Manual therapy associated with topical heat reduces pain and self-medication in patients with tension-type headache

Associação da terapia manual e calor superficial reduz dor e automedicação em pacientes com cefaleia tensional

La terapia manual asociada con calor superficial redujo el dolor y la automedicación en pacientes con cefalea tensional

Maisa Soares Gui-Demase[1], Kelly Cristina da Silva[2], Gisely dos Santos Teixeira[3]

ABSTRACT | Tension-type headache (TTH) is a significant public health problem. The myofascial trigger points in the masticatory and cervical muscles are related to pain located in the temporomandibular joint, face, and cranium according to specific patterns. Thus, therapeutic procedures should be directed to myofascial trigger points rather than to the area of referred pain. For this purpose, the massage therapy combined with the topical heat can provide effective results due to the increase of the local microcirculation, improving tissue perfusion and promoting muscle relaxation. In this study we investigated the effects of manual therapy associated with topical heat therapy in TTH pain. This is a single-arm study composed of 13 participants with TTH (females), which were submitted to a three-month research protocol. In the first month , they filled out a pain diary and then they were evaluated. In the following month, the treatment protocol was applied (8 sessions of 45 minutes, twice a week, involving massage for skin desensitization, myofascial trigger point deactivation and stretching (friction massage) on masticatory and trapezius muscles after the topical heat). Then, in the third month (follow-up period), the participants were instructed to fill out the pain diary once again. We observed a significant decrease in pain intensity in TTH episodes, and medication intake after treatment and it keeps decreasing in follow-up. We conclude that the combination of manual therapy protocol and topical heat reduced pain and episodes related to TTH, and self-medication use in our sample.

Keywords|Tension-Type Headache; Pain; Massage.

RESUMO | A cefaleia do tipo tensional (CTT) é um relevante problema de saúde pública. Os pontos-gatilho miofasciais nos músculos mastigatórios e do pescoço referem-se a dor na articulação temporomandibular, face e crânio, de acordo com padrões específicos, e os procedimentos terapêuticos devem ser direcionados para essas áreas, ao invés de zonas de dor referida. Assim, a massagem terapêutica pode proporcionar resultados efetivos quando combinada ao calor superficial, aumentando a microcirculação local, melhorando a perfusão de tecido e promovendo o relaxamento muscular. Desse modo, investigamos os efeitos da terapia manual associada ao calor superficial na CTT. Este é um estudo de braço único, envolvendo 13 participantes com CTT do gênero feminino, as quais foram submetidas a um protocolo de pesquisa de três meses. No primeiro mês (efeito de controle), elas foram avaliadas e preencheram o diário da dor. No mês seguinte, o protocolo de tratamento foi aplicado (8 sessões de 45 minutos, duas vezes por semana, envolvendo massagem para dessensibilização da pele, alongamento e desativação do ponto de gatilho miofascial (massagem de fricção) nos músculos mastigatório e trapézio, após o calor superficial). No terceiro mês (período de seguimento), as participantes foram instruídas a preencher novamente o diário da dor. Observamos uma diminuição significativa da intensidade da dor, dos episódios de CTT e da ingestão medicamentosa após o tratamento, que persistiram no período de seguimento. Concluímos que a combinação do protocolo

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de terapia manual e do calor superficial reduziu a dor e crises relacionadas a CTT e a automedicação na amostra estudada.
Descritores | Cefaleia do Tipo Tensional; Dor; Massagem.

RESUMEN | La cefalea de tipo tensional (CTT) es un relevante problema de salud pública. Los puntos gatillo miofasciales en los músculos masticatorios y del cuello se refieren al dolor en la articulación temporomandibular, la cara y el cráneo según los patrones específicos, y los procedimientos terapéuticos deben dirigirse más a estas áreas que a las que refieren el dolor. Ante esto, el masaje terapéutico asociado con el calor superficial puede ser eficaz, aumentando la microcirculación local, mejorando la perfusión tisular y promoviendo la relajación muscular. En este sentido, investigamos los efectos de la terapia manual asociada con el calor superficial en la CTT. Este es un estudio de un solo brazo, realizado con 13 participantes con CTT del género femenino, que se sometieron a un protocolo de investigación de tres meses. En el primer mes (efecto de control), las participantes se sometieron a evaluación y completaron el diario del dolor. En el mes siguiente se aplicó el protocolo de tratamiento (8 sesiones de 45 minutos, dos veces por semana, con masaje para desensibilización cutánea, estiramiento y desactivación del punto gatillo miofascial –masaje de fricción– en los músculos masticatorio y el trapecio, después del calor superficial). En el tercer mes (periodo de monitoreo), las participantes volvieran a completar el diario del dolor. Observamos una disminución significativa de la intensidad del dolor, los episodios de CTT y la ingesta de fármacos después del tratamiento, que persistió en el periodo de monitoreo. Concluimos que el protocolo de terapia manual asociado con calor superficial redujo el dolor y crisis relacionados con la CTT y la automedicación en la muestra estudiada.
Palabras Clave | Cefalea de Tipo Tensional; Dolor; Masaje.

INTRODUCTION

Tension-type headache (TTH) is a significant public health problem[1]. Moreover, self-medication is widely practiced [2], causing risks associated with adverse effects, interactions, product, dosage or treatment duration errors, difficulty in self-diagnosis, and abuse[3]. This practice has been increased since TTH is a part of the human condition. More than 95% of all individuals experience it at some point their lifetime[4] and 10-25% of the population report weekly headaches[5].

One strategy to avoid the conversion of episodic TTH into chronic is to identify the source of peripheral nociception to prevent the development of central sensitization[6]. Excessive contraction of muscles is thought to play a major role in the pathophysiology of many myofascial disorders. Trigger points could be formed in response to increased or altered muscle demands, which include prolonged muscle contraction, such as in workplace postural errors, proximal nerve compression, and resultant muscle spasm, and post-trauma[7,8]. Thus, pain provoked by trigger points in the masticatory and cervical muscles is related to many associated symptoms, from head pain to pain in the ears, jaw, and neck[9].

Therapeutic procedures should be directed to myofascial trigger points rather than to the area of referred pain[7]. In this matter, friction massage could maintain the mobility within the soft tissue structures and cause traumatic hyperemia, which helps to produce pain triggering metabolites[10]. Stretching has also been well documented to successfully reduce myofascial pain[11,12]. Moreover, heat therapy provides analgesia, decreases muscle spasm, improves tissue healing, and facilitates a range of motion and function. Thermotherapy increases tissue temperature, blood flow, metabolism, and connective tissue extensibility[13].

Although studies with manual therapy showed positive results, including a reduction in headache intensity and/or frequency[14-16] and improvement in quality of life[14], the effectiveness of manual therapy for TTH is not completely clear due to the heterogeneity in studies design, outcome measures, and different treatments[17]. Moreover, the true cause of TTH is still unknown, which underscores the need for a manual therapy program addressing each of the many problems associated with TTH[18].

If thermotherapy and skin desensitization technics promote pain relief[15], increase blood flow[19] and deactivation of trigger points and muscle stretching, release muscle spasms[16], our main hypothesis is that researching physical therapy protocol could decrease pain related to TTH and reduce TTH episodes and self-medication. Moreover, with associated technics able to enhance these benefices, it could also improve quality of life and sleep (secondary hypothesis).

Given this background, this study aims to determine if a massage therapy program associated with topical heat and muscle stretching could have beneficial effects on the self-medication, frequency, and intensity of pain associated with TTH. We also aimed to evaluate the quality of life and sleep.

METHODOLOGY

This experimental study was designed as a single-arm trial, composed of a three-month research protocol, with effective control period and follow-up, aiming to test the viability of a treatment protocol for TTH.

Female participants with headache complaints were recruited from the community surrounding the Physical Therapy Clinics and who responded to the invitation by social networks. After screening these patients using inclusion and exclusion criteria (anamnesis), they were physically examined (manual palpation) by a physical therapist.

The inclusion criteria were gender (female) and the presence of headache and trigger points in trapezius, the sternocleidomastoid masseter or temporalis muscles, individuals aged from 18 to 60 years. Exclusion criteria were headache originating from a secondary cause (e.g., injury), systemic diseases, temporomandibular disorder diagnosis, migraine treatment, polyarthritis, exposure to macro facial trauma, dislocated joints, use of orthodontic braces, dental pain, the presence of sinusitis, ear infections, cancer, hormonal disorders, and illiterate individuals.

These data were obtained from the anamnesis, which was performed according to The International Classification of Headache Disorders, 3rd edition (ICHD-3)[20], which was also used on a similar study[15]. During an initial evaluation, we noticed that participants meeting "frequent episodic tension-type headache" subtype, according to ICHD-3 diagnostic criteria (at least 10 episodes of headache occurring on 1–14 days per month on average for >3 months (>12 and <180 days per year), lasting from 30 minutes to 7 days and at least two of the following four characteristics: (1) bilateral location; (2) pressing or tightening (non-pulsating) quality; (3) mild or moderate intensity; (4)not aggravated by routine physical activity such as walking or climbing stairs. (5) Neither nausea nor vomiting, and no more than one episode of photophobia or phonophobia.

After a verbal presentation of the project, the participants gave their written informed consent. The study is registered in one of the Clinical Trial Records under identification number RBR-4n73hw, according to the criteria established by the World Health Organization (WHO) and the International Committee of Medical Journal Editors (ICMJE).

Research protocol

The research protocol was composed of three steps: Control, Treatment, and Follow-up periods. The same (blind) investigator performed all evaluations.

Firstly, the participants were submitted to the initial evaluation, where they were screened by the inclusion and the exclusion criteria and complete the quality of life and sleep questionnaires. Then, they received guidance about filling the pain diary. Thus, for 30 days before treatment, they filled the diary when they had pain related to headache, the intensity of pain, whether they took any pain relievers, and menstrual period information.

In the next month, a physical therapist applied the standardized treatment protocol. It was composed of eight sessions of 45 minutes, applied twice a week, involving the following technics, in this order:

1) Skin desensitization: application of thermotherapy (topical heat with hot water bottle over muscles with trigger points for 15 minutes), followed by effleurage techniques (skin gliding on trapezius, masseter, temporalis, and sternocleidomastoid muscles);
2) Myofascial trigger point deactivation (deep transverse friction massage was applied up to three points per session); the massage is deep, and it was applied transversely to the fiber orientation[10]. The physical therapists kept their finger joints slightly flexed during the transverse friction massage. The two-phase movement was done: active phase with more pressure (movement of the structure for 15 seconds) and relaxation phase, without pressure, both applied until release (or reduction) of the myofascial trigger point. The massage was interrupted if the pain was unbearable (or if the structure is too tender on palpation) and resumed at the next session.
3) Manual and passive stretching followed by gliding (desensitization). Manual stretching was performed for 60s, three times for each movement (passive range of neck flexion, extension, and lateral inclination was performed with the participant on lying position and passive range of mandible depression, with the participant on sitting position).

In the last month (follow-up), they filled the pain diary again, and answered the quality of life and sleep questionnaires, once more.

To test the study first hypothesis, pain, self-medication, and TTH episodes were evaluated by applying a pain diary. To test the second hypothesis, The ShortForm-36v2® Health Surveys (SF-36) and Pittsburgh Sleep Quality Index (PSQI) were used.

Pain diary – similar to that used by Moraska et al. (2015)[15] – consists of a table with 15 columns (two tables for one month). They were instructed to complete the dates of occurrence of TTH episodes, the medication used, and the dates of the menstrual period. The participants were also advised that if it was necessary to take an analgesic (of their regular use), they would write it down in the specific field (type and quantities). They were instructed to not to change the type of medication used during the research.

Pain intensity was evaluated by pain reported on TTH episodes on the pain diary. In the specific field, the participants classified their pain (1=weak; 2=moderate; 3=severe) at the moment of the TTH episode. Then, pain index was estimated—sum of the values of reported pain.

A generic multidimensional instrument was used to assess quality of life: Medical Outcomes Short-Form Health Survey (SF-36). This questionnaire measures eight health domains: Physical Functioning, Role-Physical, Bodily Pain, General Health, Vitality, Social Functioning, Role-Emotional, and Mental Health. The score for each scale varies from 0 to 100, and the higher the score, the better the quality of life. The SF-36 is widely used in research with excellent metric properties (sensitivity, validity, and reliability), and it was translated into and validated for the Portuguese language.[21]

Quality of sleep was assessed by PSQI, validated for the Brazilian population[22], which provides a score of severity and nature of sleep disorders during the preceding months. The highest score is 21 points, and scores above five indicate that sleep quality has been compromised. PSQI contains 19 self-rated questions, combined to form seven components score, each of which ranges from 0 to 3 0-3 points. In all cases, zero indicates no difficulty, while a score of three indicates severe difficulty.

Statistical analysis

The GraphPad Prism7 software was used for data analysis. The data presented a normal distribution (Kolmogorov-Smirnov test) and, thus, the paired Student's T-test, or one-way ANOVA analysis of variance was used with Tukey-Kramer post-test for multiple comparisons, both considering 95 % confidence interval.

The number of TTH episodes decreased from 8.61(7.03) on the control period to 1 (1.70) on the follow-up period (95% CI: 1.484 to 13.29, p=0.0151). Based on this data, a large effect size was found (Hedges g=1.4410) – which could mean that 93% of the participants after experimental treatment will exceed the mean value of a control period.

RESULTS

Participants

Among the 30 patients with tension-type headache complaints, 21 female patients agreed to participate. After screening these patients using inclusion and exclusion criteria, 17 were recruited, examined, and then, they answered the questionnaires in the initial evaluation, but only 13 participants completed the study protocol (Fig.1).

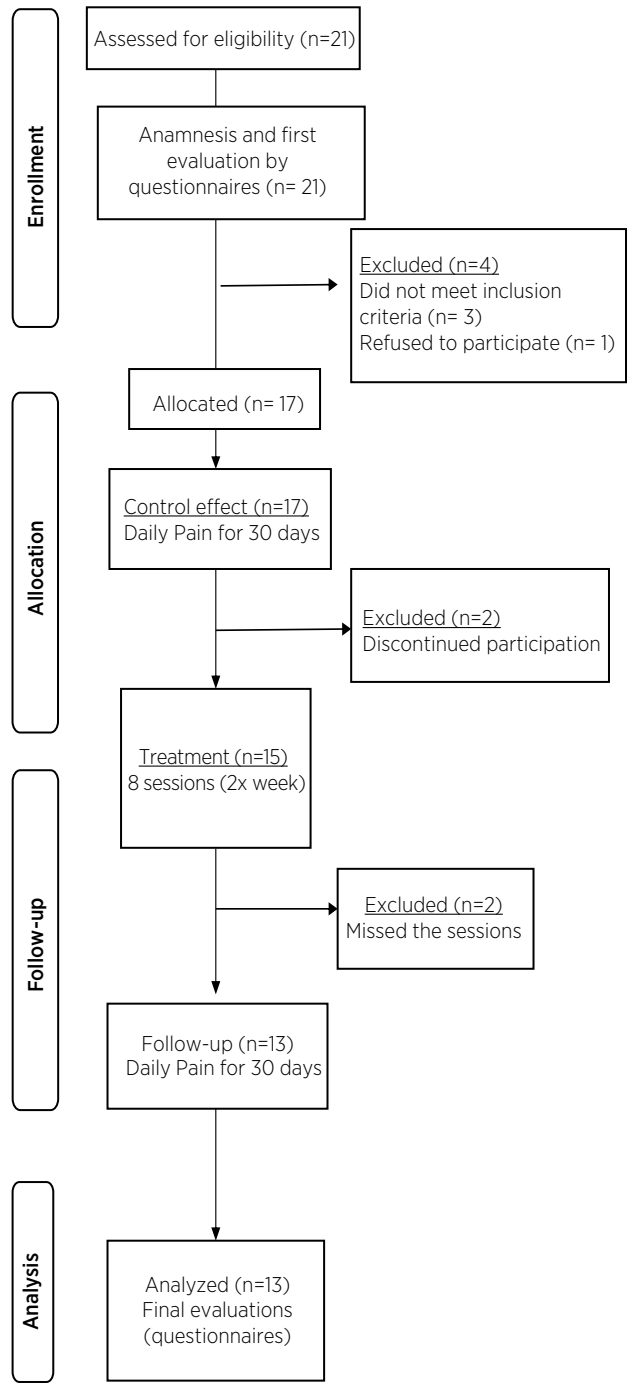

Figure 1. Flowchart of subjects' enrollment

Participants and their relatives were recruited from the Physical Therapy Clinics of the Faculdades Integradas Einstein de Limeira from November 2015 to August 2016. Our single-arm study compared treatment protocol results with the previous control phase and follow-up, bringing preliminary pieces of evidence of the efficacy of the treatment.

The baseline characteristics of participants of the study (n=13) were female with 31.5 (6.57) years, 46.1% presented higher education. Body Mass Index was 22.7 (23.12) Kg/m^2. Regular physical activity was reported by 53.8%. In total, 13.5% subjects self-reported depression, 100% had a self-report of anxiety, and 84.61% had poor sleep quality (PSQI>5).

Also, they have presented TTH pain for 109.5 (99.50) months, and we found 8.0 (2.74) trigger points on evaluated muscles, 76.9% have a family history of headache and 53.8% had headache in childhood. Somatic symptoms (e.g., tingling, dizziness, nausea) were found in 69.2% of participants. No one reported smoking or drinking habits.

Pain, self-medication, and TTH episodes

We found a significant decrease in TTH pain reported on the pain diary. After treatment, we observed a mean decrease of 15 points on pain intensity sum values (95% CI:1.822 to 28.18), and 18 points on pain intensity sum values after the follow-up period (95% CI:5.291 to 30.71), when compared to the control phase (Fig. 2). The same change was observed on self-medication, i.e., five days of self-medication reduction when compared Control vs Intervention (95% CI: 1.96 to 8.963), and six days of self-medication reduction compared Control vs Follow-up (95% CI: 2.883 to 9.887), as shown in Fig.3.

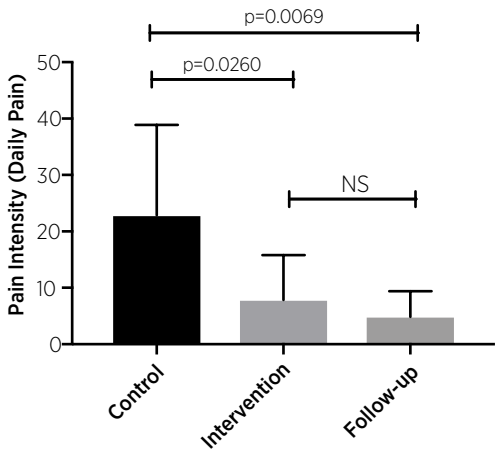

Figure 2. Mean (SD) of values of pain intensity sum reported by the participants on pain diary. Repeated measures one-way ANOVA and Tukey-Kramer multiple comparations test.
NS: non-significant (p>0.05); 1: weak; 2: moderate; 3: severe.

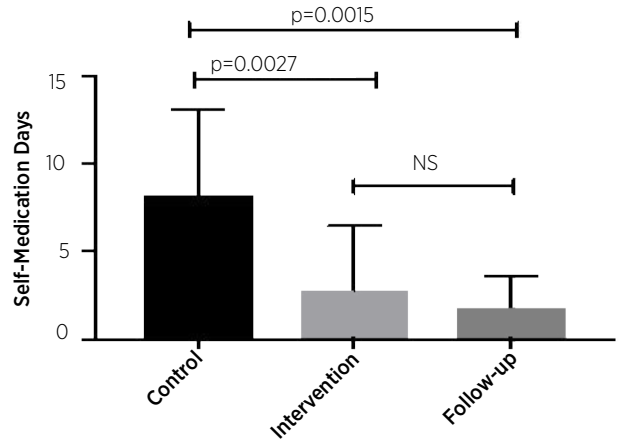

Figure 3. Mean (SD) of the number of days of self-medication for pain related to TTH (pain diary). Repeated Measures one-way ANOVA and Tukey-Kramer multiple comparations test.
NS: non-significant (p>0.05).

Furthermore, we observed a significant decrease in the number of ingested pills for pain, after treatment (4.0 (6.23) and p=0.0169), and after follow-up (3.7 (6.52) and p=0.0075), when compared to the control pain diary (11.7 (7.34) pills). Between treatment and follow-up, the difference was not significant (Repeated Measures one-way ANOVA and Tukey-Kramer multiple comparations tests).

On follow-up, we also observed an improvement of TTH episodes marked in the diary of pain, i.e., a mean reduction of seven pain episodes at follow-up period when compared to control phase, out of menstrual period (After follow-up, there were 1 (1.70) episodes when compared to control pain diary 8.61 (7.03) tested by Repeated Measures One-Way ANOVA and Tukey-Kramer multiple comparations test (95% CI: 1.484 to 13.29, p=0.0151). The menstrual period was considered from two days before and two days after the period.

Quality of life and sleep

We observed improvement in physical functioning, bodily pain, social functioning, and mental health domains of the SF-36 questionnaire in four weeks after the proposed treatment (Fig. 4).

We did not observe differences (p=0.3268 Paired Student T-Test) on PSQI global measures before (6.9 (2.30)) and after treatment (6.2 (2.41)), i.e., impairment of sleep pattern (PSQI>5). However, when we analyzed the PSQI components, we found significant improvement in Sleep Disturbance after the research protocol (Table 1).

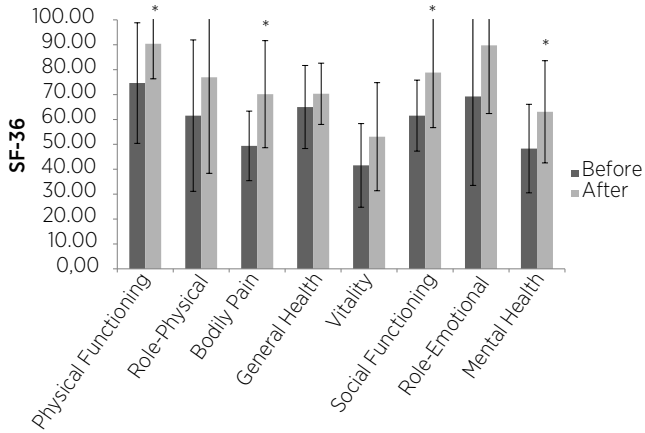

Figure 4. Mean (SD) of eight SF-36 domains before and after research protocol applied on studied subjects (n=13). The higher the score, the better the quality of life. Paired Student T-test, *p<0.05.

Table 1. Mean (SD) of PSQI components before and after the research protocol. Score zero indicates no difficulty and three, severe difficulty.

Components (0-3)	Before	After
Subjective sleep quality	1.4 (0.62)	1.2 (0.42)
Sleep latency	1.7 (1.07)	1.3 (0.72)
Sleep duration	0.8 (0.66)	0.6 (0.62)
Habitual sleep efficiency	0 (0.0)	0.2 (0.80)
Sleep disturbances	1.5 (0.63)	1.2 (0.42)*
Use of sleeping medication	1.4 (0.63)	0.5 (1.08)
Daytime dysfunction	1.2 (0.66)	1.1 (0.83)

*Paired Student T Test, p=0.0395.

DISCUSSION

The myofascial pain syndrome was the target of our intervention protocol on TTH (presence of trigger points), which could cause headache pain. The combination of manual therapy protocol, stretching, and thermotherapy reduced tension-type headache pain, headache episodes, and self-medication, also improving quality of life and reducing sleep disturbances.

Some studies also provided pieces of evidence about manual therapy on TTH pain and episodes. Quinn, Chandler and Moraska (2002)[16] used a 4-week treatment program, and Moraska et al., (2015)[15], a six-week treatment compared to placebo (detuned ultrasound). Both observed headache pain reduction. Espí-López(2014)[14] divided participants into three treatment groups (manual therapy, manipulative therapy, a combination of manual and manipulative therapy). All three treatment groups showed significant improvement in the different dimensions of pain perception.

Our findings also showed that these benefits persist after treatment and the main point reduces self-medication. One possible explanation is that thermoreceptors and mechanoreceptors initiate nerve signals that block nociception (the pain signal processing that results from a noxious stimulus) within the spinal cord. The activation of these receptors within the spinal cord reduces muscle tone, relaxes painful muscles, and enhances tissue blood flow[19].

Myofascial pain may also involve peripheral pain mechanisms that over time may initiate central changes[6]. Pressure pain thresholds significantly decreased bilaterally over trigeminal, extra-trigeminal, and distant points in the TTH group compared with controls[22]. Therefore, early intervention prevents pain chronification and central sensitization.

According to the gate control theory of pain, tactile stimuli (whether heat or light pressure) may help to decrease the perception of pain within the brain by stimulation of large diameter fibers. This results in the closure of the "pain gate" in the spinal cord thus inhibiting the transmission of these impulses to the brain and their perception as a painful sensation within the brain[12].Improvement in sleep quality could also interrupt this pain chronification process, interrupting the cycle pain-sleep disorders[24]. Participants with baseline of poor sleep quality developed first-onset Temporomandibular Disorders (myofascial type) at twice faster than the rate of participants with good sleep quality[25], i.e., our study protocol could improve sleep disturbances, leading to less pain and vice-versa, as well as the improvement in the quality of life.

Moreover, some studies protocols were not performed by a physical therapist, osteopath, or another health professional with knowledge in anatomy and physiology. Herein, we noticed that structured physical therapy can incorporate these techniques along with stretching and relaxation techniques, massage[11], thermotherapy safety application[19,] and the trigger points correctly diagnosis[18]. However, we cannot rule out that participants have another type of headache, as well as secondary headache, since the diagnosis was performed according to subjective information provided by the participant.

To the best of our knowledge, this was the first study that observed a reduction in medication intake and pain symptoms after the physical therapy program for TTH. A systematic review[17] showed that reduction in

analgesic use was assessed in five studies, although all of them reported changes, these were not statistically significant in all cases.

Limitations

This was a single-arm study, with a small sample size (with a large effect #g=1.4410), that could not confirm the efficacy of treatment. On the other hand, we found that our approach can be safely administered, and then, we can test this hypothesis with a randomized controlled trial (RCT), reducing bias associated with medication use. We will have an ethical endorsement when asking patients not to use pain medication during future RCTs, which are needed in order to draw definitive conclusions about the roles of massage, stretching, and topical heat in the treatment of myofascial trigger points related to TTH.

CONCLUSION

The combination of manual therapy protocol and topical heat, not only reduced TTH pain, episodes, and self-medication, but also improved quality of life and reduced sleep disturbances on studied participants.

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