Parameters and results of non-invasive neuromodulation in the management of chronic pelvic pain: integrative literature review

Parâmetros e resultados da neuromodulação não invasiva no manejo da dor pélvica crônica: revisão integrativa da literatura

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ABSTRACT

BACKGROUND AND OBJECTIVES: Chronic Pelvic Pain (CPP) is characterized by persistent pain in the pelvic region for more than six months, affecting both men and women and causing significant impairment in quality of life (QoL). Two of the main non-invasive approaches are Transcranial Magnetic Stimulation (TMS) and Transcranial Direct Current Stimulation (tDCS). These techniques aim to modulate neural activity and promote pain relief. In this context, this research conducted an integrative literature review to summarize the results of relevant studies, aiming to identify the key parameters used in TMS and tDCS for CPP treatment. The objective was to assess the effect and efficacy of non-invasive neuromodulation as a therapeutic intervention for CPP.

CONTENTS: For this integrative review, electronic searches were conducted in Pubmed, Scielo, PEDro, Medline, Cochrane, and Scopus databases, examining studies in Portuguese, English, or Spanish. The keywords "pelvic pain," "transcranial direct current stimulation," and "transcranial magnetic stimulation" and their derivatives were searched in the three languages in studies from 2013 to 2023. Seven studies were included for analysis. Both techniques showed positive effects in managing CPP, improving pain levels and quality of life to a relevant extent. However, there is still no consensus on the parameters applied in TMS and tDCS techniques for CPP.

CONCLUSION: Non-invasive neuromodulation improves pain levels and quality of life in patients with CPP. Further studies are needed to establish more reliable parameter relationships, and the limited number of studies restricts definitive conclusions on the subject.

Keywords: Chronic pain, Non-invasive neuromodulation, Pelvic pain, Transcranial magnetic stimulation, Transcranial direct current stimulation.

RESUMO

JUSTIFICATIVA E OBJETIVOS: A dor pélvica crônica (DPC) é caracterizada pela persistência da dor na região pélvica por mais de 6 meses, afetando tanto homens quanto mulheres e causando prejuízos significativos na qualidade de vida. Duas das principais abordagens não invasivas são Estimulação Magnética Transcraniana (EMT) e a Estimulação Transcraniana por Corrente Contínua (ETCC). Nesse contexto, esta pesquisa realizou uma revisão integrativa da literatura com o intuito de resumir os resultados de estudos relevantes, buscando identificar os principais parâmetros utilizados no tratamento da DPC. O objetivo foi fornecer uma visão abrangente sobre essas técnicas de neuromodulação e suas aplicações específicas no controle da dor pélvica crônica.

CONTEÚDO: Para esta revisão integrativa, as buscas eletrônicas ocorreram nas bases de dados Pubmed, Scielo, PEDro, Medline, Cochrane e Scopus, verificando estudos em português, inglês ou espanhol. "Dor pélvica", "estimulação transcraniana por corrente contínua" e "estimulação magnética transcraniana" e suas derivações foram pesquisadas nos três idiomas em estudos entre 2013 e 2023. Sete estudos foram incluídos para análise. Ambas as técnicas apresentaram efeitos positivos no manejo da DPC, melhorando os níveis de dor e a qualidade de vida em proporções relevantes. Entretanto, ainda não há um consenso sobre os parâmetros aplicados nas técnicas de EMT e ETCC para DPC.

CONCLUSÃO: A neuromodulação não invasiva melhora os níveis de dor e a qualidade de vida em pacientes com DPC. São necessários mais estudos para que relações mais confiáveis de parâmetros possam ser preestabelecidas e a ausência de um maior número de estudos limita conclusões acerca do assunto.

Descritores: Dor crônica, Dor pélvica, Estimulaçao magnética transcraniana, Estimulaçao transcraniana por corrente contínua, Neuromodulaçao não invasiva.

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HIGHLIGHTS

- There is a need for standardization and consensus on the parameters of neuromodulation techniques for chronic pelvic pain.
- The stimulation area includes the motor cortex and the dorsolateral prefrontal cortex.
- Neuromodulation techniques, such as Transcranial Magnetic Stimulation and Transcranial Direct Current Stimulation, have shown potential in addressing not only pain but also other aspects such as sleep, cognitive complaints, fatigue, catastrophizing, depression, and mood in patients with chronic pelvic pain.

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INTRODUCTION

Chronic pelvic pain (CPP) is pain in the pelvic area persisting for at least six months, affecting both genders and diminishing overall well-being, daily functionality, and emotional health. It may also induce symptoms of anxiety and depression[1]. Approximately 4% to 16% of women have CPP, with a third requiring medical aid due to severe symptoms[2]. The prevalence of CPP surpasses that of ailments like asthma or migraines, presenting significant public health concerns[3].

The pathophysiology of CPP is intricate, often tied to multiple disorders including neurological, neuroendocrine, and stress disorders. Several pelvic pain conditions can coexist, with symptom overlap attributed to mechanisms such as viscero-visceral cross-sensitization, where activity in one organ may hypersensitize another. This long-term exposure to pain stimuli can lead to central sensitization, an altered central nervous system (CNS) pain perception due to neuroplasticity[4,5].

CPP's multifactorial nature includes gynecological, urological, gastrointestinal, and psychological dimensions[6]. A comprehensive approach is vital, yet about 60% of affected women never receive a definitive diagnosis[3]. Current CPP treatment prioritizes symptom management. Non-invasive neuromodulation, part of the expanding field of neuromodulation, emerges as a promising therapeutic avenue[7].

According to the International Neuromodulation Society (INS), neuromodulation acts directly on the Central Nervous System (CNS), generating an alteration or modulation of neural activity through the distribution of electrical or pharmacological agents in a specific area. Among the types of neuromodulation, noninvasive brain stimulation (NIBS) techniques are considered promising therapies[8], used in the treatment of various pain conditions, such as neuropathic, inflammatory, trigeminal and nociplastic pain[9], including chronic pelvic pain. This technique involves modulating neural activity through the application of an electrical or magnetic current to a target area[10].

The main non-invasive techniques are Transcranial Magnetic Stimulation (TMS) and Transcranial Direct Current Stimulation (tDCS)[11]. The mechanism of both techniques is not fully understood, but it is suggested that they modulate brain function, inducing neuroplasticity in the CNS by modifying the resting membrane potential and altering neuronal activity through the direct application of an electrical current or the creation of an electric field with magnetic induction on the scalp[4]. TMS promotes depolarization, while tDCS alters the membrane potential. The affected sites include the prefrontal cortical network, including the dorsolateral prefrontal cortex (DLPFC), and the primary motor cortex (M1)[12].

TMS is a safe neuromodulatory technique based on Faraday's law of electromagnetic induction. A coil placed on the scalp generates a perpendicular magnetic field that reaches the targeted region, making it non-invasive. Due to its time-varying characteristics, it generates an electric field and electric currents at the target site[13]. This tool uses an electromagnetic field to alter neuronal electrical activity and modify firing patterns, resulting in various connectivity modifications[8]. Furthermore, low-frequency TMS with a frequency of 1 Hz, pulse width of 1 ms, and intensity of 200 mT (millitesla) has demonstrated analgesic effects due to its inhibitory effects on the brain[9].

A guideline[14] mentioned the promising effects of TMS in different cases of chronic pain (CP), focusing on the two main targets of TMS in the pain domain, namely M1 and DLPFC. Studies have shown that TMS has been successfully used when applied to M1 and DLPFC in cases of CP, including migraines, headaches, and low back pain. The results demonstrated a significant reduction in persistent pain intensity after applying the technique, with long-lasting effects for several weeks. Research on low back pain also showed a significant analgesic effect after a 5-day application protocol on the right M1. However, data are still scarce for other CP syndromes to recommend specific TMS parameters[15-17].

The physiological effects of tDCS in pain management have been studied since the 1960s. This intervention induces changes in the neuronal membrane potential by altering extracellular ion concentrations. Therefore, tDCS is seen as a purely modulatory intervention by promoting synaptic plastic changes and positive regulation in M1, potentially and indirectly modifying pain perception through thalamic nuclei[11].

In evidence-based guidelines[18], tDCS targets M1 or DLPFC in cases of CP, with most studies applying anodal stimulation to the M1 of the contralateral hemisphere (for focal or lateralized pain) or to the M1 of the dominant hemisphere (for more diffuse pain). Studies have shown that a single session of tDCS can provide significant pain relief[18].

Reliability for applying the intervention is evaluated based on factors such as safety, tolerability, cost, and, most importantly, adverse effects. tDCS, in particular, has an adverse effects rate of 10-40% among individuals undergoing neuromodulation, with the main side effects being itching, headache, burning sensation, discomfort, and tingling[19]. On the other hand, TMS may induce non-severe symptoms such as headache, discomfort, and pain at the stimulation site. All reported symptoms are mild and transient[20].

The parameters used are one of the factors directly influencing the therapeutic effect of NIBS. In TMS, these measures can be exemplified and modulated based on the type of magnetic field, amplitude, coil type, frequency, and number of sessions. The parameters used play a significant role in influencing the therapeutic effects of NIBS. In the case of repetitive Transcranial Magnetic Stimulation (rTMS), these measures include the type of magnetic field, amplitude, coil type, frequency, and number of sessions[21]. Previous studies have shown that different rTMS protocols can either increase or suppress neural activity, as well as affect the duration of stimulation effects[8]. Conversely, in tDCS, parameters such as amplitude, duration, electrode size, and number of sessions are considered.

Despite the increasing number of publications addressing the role of NIBS in the management of CPP, a notable variability persists in both outcomes and methodological approaches across studies. This inconsistency underscores the imperative for a review and synthesis of the existing literature. Consequently, the primary aim of the present study was to assess the effect and

efficacy of non-invasive neuromodulation as a therapeutic intervention for CPP.

CONTENTS

This study is an integrative literature review with the purpose of summarizing the results of a set of research studies on a specific topic. This approach aims to link research evidence with healthcare practices, with the potential to contribute for healthcare assistance. To organize the information and conduct the study, six steps of the integrative review process were followed[22].

The first step involved identifying the topic and formulating the research guiding question. The second step was establishing inclusion and exclusion criteria, followed by a literature search in the selected databases. In the third step, the objective was to identify the selected studies. The fourth step involved categorizing the selected studies. The fifth step consisted of analyzing and discussing the results. Finally, in the sixth step, the integrative review was presented[23]. The search for the studies occurred in the following order: search of the databases using MeSH terms and keywords, reading of the titles, selection and reading of the abstracts of the pre-selected studies.

The guiding question for this review was: "What are the parameters used in transcranial magnetic stimulation (TMS) and transcranial direct current stimulation (tDCS) available in the literature for the treatment of chronic pelvic pain"?

The searches were conducted in six databases: Pubmed, Scielo, PEDro (Physiotherapy Evidence Database), Medline, Scopus (SciVerse Scopus), and Cochrane. The search terms used were "Pelvic Pain" for pelvic pain, "Transcranial direct current stimulation" for tDCS, and "Transcranial magnetic stimulation" for TMS, based on the Health Sciences Descriptors (DeCS) from the Virtual Health Library (BVS). The Boolean operator "AND" was used to combine the search terms.

Articles that presented duplicates between databases, were outside the 10-year period (January 2013 to May 2023) and were not clinical trials were excluded. The eligibility criteria included articles related to the topic and available in full text in Portuguese, English, or Spanish (figure 1 for tDCS and figure 2 for TMS). The extraction of data from the full reading was performed to fill a table with the eligibility criteria; after the final selection of studies, an integrative review with critical analysis of the results was performed.

RESULTS

The search yielded a total of 50 articles. However, after applying the eligibility criteria, only 7 articles were included in this review: 3 related to tDCS and 4 related to TMS. Among these, there were 2 pilot studies, 1 case study, 1 cross-sectional observational study, and 3 clinical trials. Several reasons led to the exclusion of the remaining articles, including their involvement with topics that did not align with the scope of this review, lack of significant relevance to the theme, studies that were already reviews themselves, studies that had not been conducted yet, as well as articles with restricted access or availability in languages other than Portuguese, English, or Spanish.

To present the findings, the included articles were grouped and structured. Table 1 contains the articles covering tDCS, while table 2 includes the articles selected for TMS.

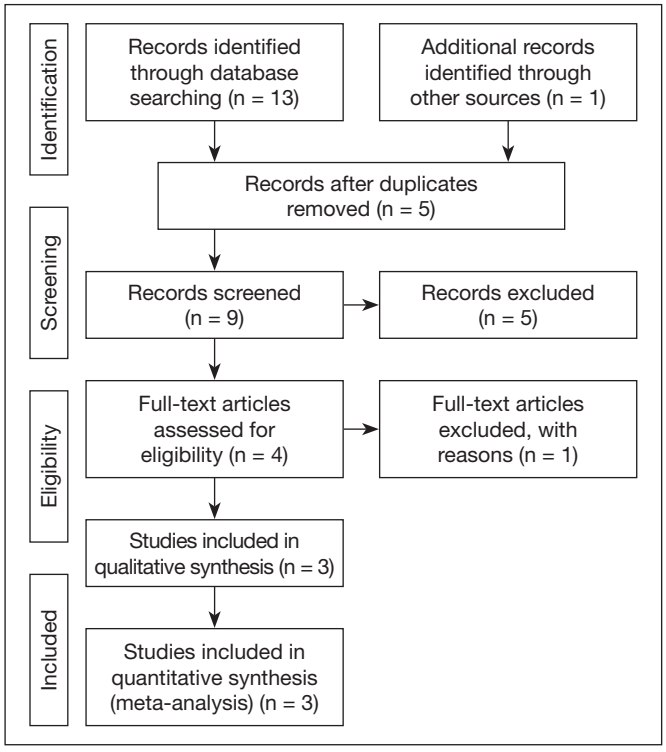

Figure 1. Eligibility criteria included articles - tDCS

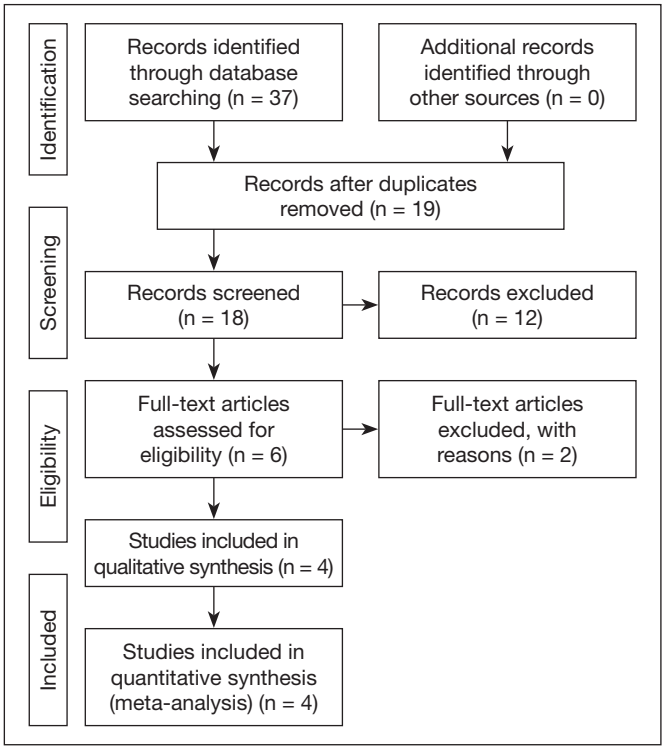

Figure 2. Eligibility criteria included articles - TMS

Table 1. Data from selected Transcranial direct current stimulation articles

Authors	Type of Study	Sample	Stimulated Area	Parameters (Amplitude, Electrode Size, Number of Sessions, and Duration)	Primary Outcome	Secondary Outcome	Conclusion
Divandari et al.[1]	RCT	16 women between the ages of 20 and 50 who were diagnosed with CPP and were not in the postmenopausal period	Left M1 and DLPFC	Amplitude: 0.3mA Electrode Size: 1.5 x 2cm (0.1mA/cm^2) Number of Sessions: 2 Duration: 20 minutes Reference Electrodes: Two reference electrodes (2 x 6 cm) were positioned in the supraorbital area	tDCS was found to be effective in reducing pain levels.	Real tDCS showed improvement in quality of life and disability but did not demonstrate an effect on depression.	Real tDCS treatment was effective in reducing CPP and improving quality of life.
Simis et al.[27]	RCT	11 male and female patients, aged between 18 and 24 years, who were diagnosed with CPP and reported a minimum pain level of 3 on the visual analog scale (VAS).	Anode: Left M1 (contralateral to the more painful side or where the symptoms started). Cathode: Contralateral supraorbital area.	2mA; electrode size: 35cm^2; 10 consecutive sessions; 20 minutes each.	Significant increases were found in sensory and pain thresholds after 2 weeks of active ETCC compared to sham.	Biochemical changes in neural circuits related to pain are associated with the pain levels measured by quantitative pain tests.	A significant increase in pain thresholds was observed after active tDCS compared to sham conditions, but further testing of neuromodulatory interventions for DPC is needed.
Harvey et al.[28]	RCT	9 male and female patients who were diagnosed with CPP.	tDCS: Anode: Contralateral M1 to the more painful side; Cathode: Contralateral supraorbital area. TENS: Lower abdominal and/or lumbar region + Tibial region.	TENS: Frequency of 3Hz, pulse duration of 400ms, intensity at the pain threshold, and duration of 30 minutes. TENS+tDCS: tDCS applied with an intensity of 2 mA, electrode size of 5 x 7cm, and duration of 30 minutes.	There was a slight decrease in pain during the treatment, but it was not clinically significant in both groups.	One session of TENS, either alone or in combination with ETCC, can slightly reduce pain in patients with CPP.	The combination of TENS and tDCS did not provide additional benefits in patients with CPP (based on the analysis of one session).

tDCS = transcranial direct current stimulation; TENS = transcutaneous electrical nerve stimulation; CPD = Chronic Pelvic Pain; RCT = randomized controlled study; DLPFC = dorsolateral prefrontal cortex; TMS = transcranial magnetic stimulation.

Table 2. Data from selected tramscranial magnetic stimulation articles

Authors	Type of Study	Sample	Stimulated Area	Parameters (Amplitude, Electrode Size, Number of Sessions, and Duration)	Primary Outcome	Secondary Outcome	Conclusion
Pinot-Monange et. al.[24]	Pilot Study	12 women with Endometriosis and CPP	left M1	80% of the resting motor threshold (LMR); 8-shaped coil; 10-second pulses every 50 seconds, 10Hz up to 1500 pulses per session; 5 sessions; not reported.	Pain improvement.	9 women reported pain improvement and a reduction in its interference with their quality of life.	TMS appeared to be an interesting alternative for patients with endometriosis and CPP.
Nikkola et al.[26]	Pilot Study	11 patients (both male and female) with CPP	Left and right M1 in the corresponding locations to the pelvic area.	110% do LMR; B8; pulsos de 5s a cada 26s até 1500 pulsos/sessão; 5 sessões; 20min.	Reduction in pain levels was observed after treatment and at the first and eighth week.	NIBS patients reported an overall improvement in pain levels, and six patients were able to reduce their medications.	rTMS appeared to be a safe and well-tolerated therapy for prostatic pain and CPP. It may be an alternative for pain that is resistant to other conventional therapies.

Continue...

Table 2. Data from selected TMS articles – continued

Authors	Type of Study	Sample	Stimulated Area	Parameters (Amplitude, Electrode Size, Number of Sessions, and Duration)	Primary Outcome	Secondary Outcome	Conclusion
Louppe et. al.[30]	Case study	2 women with CPP	M1	Patient 1: 1 session, 20 minutes, 2 electrodes stimulating M1r, 20 trains of 10 seconds, 10 Hz, 80% of the resting motor threshold (LMR), interval between trains of 50 seconds (2,000 stimuli). Amplitude 2.5 V, pulse width 60 ms, frequency 40 Hz. Patient 2: 3 sessions, 1 placebo session, except for the Amplitude (2V), all parameters remained the same.	Conventional neuromodulation techniques previously performed failed in the mentioned cases, making rTMS a promising treatment for them.	Conventional neuromodulation techniques previously performed failed in the mentioned cases, making rTMS a promising treatment for them.	Motor Cortex stimulation via rTMS was an effective technique in the treatment of refractory chronic pelvic/perineal pain. However, further comprehensive studies in this field are needed.
Zakka et al.[25]	Cross-sectional observational	20 females with CPP	M1	80% of RMT; Coil position B8; 10 Hz; 10-second pulses every 20 seconds up to 3,000 pulses per session; 2 sessions; 15 minutes.	Reduction in the mean scores of all items on the Brief Pain Inventory was observed in patients initially treated with rTMS.	rTMS induced analgesic effects independent of improvements in quality of life or mood in the included patients.	rTMS is feasible and constitutes a safe procedure and a good therapeutic alternative for CPP.

CPD = Chronic Pelvic Pain; NIBS = non-invasive brain stimulation; TMS = transcranial magnetic stimulation; tDCS = direct current cranial stimulation; rTMS = repetitive transcranial magnetic stimulation; LAR = motor threshold at rest.

DISCUSSION

This study involved gathering data on the treatment of CPP using NIBS techniques: tDCS and TMS. The presented results highlight the scarcity of studies concerning the relationship between NIBS techniques and CPP. This scarcity may be attributed to the complex nature of CPP, which is a multifactorial condition with a challenging diagnosis of its etiology.

According to a study[21], addressing patients with CPP poses a challenge for healthcare professionals. It is often claimed that women with CPP have to live with the pain, and many professionals, unable to resolve the issue, become frustrated and label the patient's pain as an emotional problem, subsequently abandoning the case. In this study, neuromodulation was considered as a potential intervention, as previous studies have suggested its potential to address not only pain but also other aspects such as sleep, cognitive complaints, fatigue, catastrophizing, depression, and mood[21].

The parameters of the most commonly used NIBS techniques for CPP are still subject to debate, and there may be divergent findings in the published studies. Regarding the stimulation area in TMS, a study[18] mentioned the application on M1 and DLPFC, while another study[21] presented potential parameters for CPP treatment using an eight-shaped coil positioned over the M1 region. DLPFC plays a crucial role in cognitive and emotional processing, including pain modulation. It is involved in the cognitive control of pain, regulating attention, emotion, and pain-related cognitive processes.

Stimulation of the DLPFC can modulate the brain's pain network, influencing pain perception and reducing pain intensity. The motor cortex is involved in the generation and modulation of pain signals. Stimulation of the M1 can modulate the excitability and activity of neural networks involved in pain processing and modulate the transmission of pain signals, altering pain perception. Two researchs[24,26] conducted pilot studies and determined M1 as the target area for CPP treatment, supporting the guidelines proposed by another author[14]. Additionally, a study[25] conducted an observational cross-sectional study using the M1 area and reported analgesic effects in the management of CPP.

Regarding the frequency used in TMS, the studies [24-26] reached a consensus on using 10Hz for the management of CPP. As for determining the pulse width, two studies[24,26] used 1,500 pulse trains per session, while another study[25] opted for double that amount. All studies found positive effects on pain thresholds in their respective samples. Another parameter to consider is the pulse train duration and the intertrain interval. Two studies[2,26] provided values for these parameters, with a ratio of 5s to 26s and 10s to 20s, respectively. Lastly, the resting motor threshold (RMT) and session duration were not specified by all authors, only by one[25], who determined an RMT of 80% with a session duration of 15 minutes. In summary, all articles support the effectiveness and safety of TMS therapy as a viable alternative for the treatment of CPP.

Regarding tDCS, standardizing the target area is crucial to ensure the desired effects on pain thresholds. A double-blind controlled clinical study[1] used M1 and DLPFC as target areas for CPP treatment, which resulted in a positive outcome in reducing pain thresholds. Additionally, a randomized clinical trial from 2016 used M1 and the contralateral side of the supraor-

bital area in a population with CPP, resulting in a significant and positive impact on sensory and pain thresholds[27]. Also, a research[28] combined tDCS with transcutaneous electrical nerve stimulation (TENS), with the application of tDCS in the contralateral M1 region to the pain and TENS in the lower abdominal and/or lumbar regions along with the tibial region. This combination did not yield additional benefits in patients with CPP based on the analysis of a single session.

Regarding amplitude, a study[1] opted for 0.3mA, while another studies[27,28] chose 2mA. In terms of application time, only one study[28] differed, with a session duration of 20 minutes, while the other authors utilized sessions of 30 minutes. Some of these findings align with the recommendations published in a study[21], which suggests targeting the contralateral M1 or the dominant side as the target areas, using an amplitude of 2mA, and a session duration of 20 to 30 minutes.

The outcomes of the assessed studies often coincide, with the mentioned techniques showing potential for improving pain symptoms and enhancing the quality of life of participants, with minimal side effects. These findings underscore the relevance of NIBS techniques for CPP and emphasize the need for more randomized clinical trials involving larger populations.

NIBS is an innovative approach in the realm of neuroscientific research and treatment. This technique offers the capability to modulate brain activity without requiring surgical interventions or implantation of electrodes. While it holds immense promise, it's essential to recognize its associated side effects. The most severe side effects reported are seizures and neurocardiogenic syncope. Minor side effects include headache, scalp discomfort, twitching, fatigue, and tinnitus. However, in the broader context, it's worth noting that these side effects are relatively few and most are transient[26].

The studies included in this review were limited in scope and sample size, often involving only a single session of NIBS. It is necessary to conduct more well-designed, large-scale randomized controlled trials with broader populations, multiple treatment sessions, and long-term follow-ups to establish more reliable parameter relationships. In addition, a limited number of publications on the theme was identified, making this review difficult to carry out, even considering the limitations inherent in the methodology used in an integrative review.

CONCLUSION

NIBS techniques, particularly when targeting the M1 cortex, emerge as a promising avenue for alleviating CPP. The studies reviewed in this paper demonstrate significant improvements in pain levels and overall QoL for patients. Specifically, the M1 cortex has been frequently utilized, underlining its potential relevance in managing CPP. However, despite these encouraging results, there remains a lack of consensus on the precise parameters for using techniques like TMS and tDCS specifically for CPP. As the field advances, further research is imperative to optimize and standardize these parameters, ensuring both efficacy and safety for patients.

AUTHORS' CONTRIBUTIONS

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