

Alternative and complementary treatments for migraine



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Migraine is a chronic neurological disorder that is associated with considerable disadaptive effect on patients. Despite the development of pharmacotherapy strategies for migraine, only one third of patients are satisfied with their overall treatment. Many migraine patients turn to complementary and alternative medicine (CAM), which is not usually considered a part of conventional medicine and is not always evidence-based. In practise, however, they are often used to improve the effectiveness of standard therapy or to provide alternative treatment. In addition, in CAM methods, the patient is actively involved in the choice of treatment strategies, and they have good adherence. The basic principles and approaches of CAM are increasingly being introduced into clinical practise. This review discusses the principles of CAM in the treatment of migraine as a holistic approach using lifestyle strategies and selected non-pharmacological treatments that have been shown to be effective and rational.

Keywords: migraine; complementary alternative medicine; migraine triggers; cognitive behavioural therapy; mindfulness therapy; acupuncture; biofeedback; transcranial magnetic stimulation; supraorbital nerve stimulation; occipital nerve stimulation; vagus nerve stimulation; pterygopalatine ganglion stimulation; deep brain stimulation.

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Migraine is one of the widespread and most maladaptive neurological disorders, accounting for more than 50% of all years lost due to disease-related impaired functioning, and is the leading cause of disability before the age of 50 years [1]. Although migraine is associated with a significant burden, it can be effectively controlled with pharmacologic and nonpharmacologic approaches [2].

Pharmacologic treatment of migraine involves the use of headache medications and prophylactic treatment when indicated [3]. Despite the development of migraine pharmacotherapy strategies, only less than 30% of patients report satisfaction with treatment overall [4]. According to the analysis of semantic processing of 6566 anonymized messages from social networks and forums, in Russia, one third of patients (33% of mes-

sages) note the absence or low effectiveness of therapy [5]. About 20% of patients report using non-drug methods for migraine prevention [5].

The practical use of headache medications during a migraine attack has a number of limitations [6]. Triptans and ergot alkaloids have contraindications for use in patients with risk factors and/or cardiovascular disease [7], and nonsteroidal anti-inflammatory drugs (NSAIDs) are associated with a risk of potentially serious gastrointestinal, renal, and cardiovascular side effects [8]. On the other hand, high levels of use of analgesics, NSAIDs, triptans, and especially combination analgesics can exacerbate headaches and lead to headaches associated with medication overuse (medication overuse headache – MOH) [9, 10].

One of the significant barriers to effective treatment of patients is the low level of adherence of patients to preventive treatment [11]. It is known that only half of patients with chronic conditions are committed to following the treatment recommendations [11]. In Russia, according to an online survey, overall adherence to preventive therapy was 37.6% [12]. Among the reasons for non-compliance with therapy, dosing violations (44%) and missed dosing (43.2%) were the most frequently noted [12]. The advent of effective options for targeted biological pathogenetic therapy of migraine (monoclonal antibodies to calcitonin gene-related peptide ligand or receptor) has undoubtedly led to improved efficacy and tolerability of prophylactic treatment [13]. However, adherence to preventive therapy remains at an unsatisfactory level – only 26–29% of patients within 6 months continue the prescribed treatment, and after 12 months their percentage decreases to 17–20% [12].

Despite the development and effectiveness of pharmacotherapy, many migraine patients turn to complementary and alternative medicine (CAM). CAM in the treatment of headache include treatments that are not usually considered part of traditional medicine: massage, dry needling (DN), phytotherapy, and others. [14]. The term «complementary and alternative medicine» suggests a combination of two strategies. Complementary methods are methods used to augment the main, standard treatment, and alternative methods are methods used instead of the main, standard treatment [14]. Nevertheless, in terms of a global assessment of the role of CAM according to the position of the National Center for Complementary and Integrative Health (National Center for Complementary and Integrative Health, NCCIH), a steadily accumulating body of evidence shows that many CAM methods are effective when used in conjunction with conventional ones [15]. The basic principles and approaches of CAM are increasingly being implemented in clinical practice [15], however, estimates of their use in the treatment of headache vary widely. In a survey of European specialized headache clinics, 81.7% of respondents used CAMs [16]. A systematic review of CAM methods for headache and migraine reported overall utilization rates ranging from 28% to 82% [17]. The most commonly used methods were DN, massage, chiropractic, homeopathy, meditation, breathing exercises and yoga.

Although the evidence base for the efficacy of CAM methods for headache and migraine is growing intensively, it is extremely difficult to generalize studies or compare results because of differences in study design and difficulties in selecting adequate controls [18]. However, based on the results of current clinical trials, some of the CAM methods have strong evidence of efficacy. This review discusses evidence-based CAM methods and their role and appropriateness in the treatment of migraine.

Lifestyle modification

Lifestyle modification is one of the important strategies for migraine treatment [3, 19]. The feasibility of this approach is based on the established association between lifestyle and the frequency, severity of attacks, and burden of migraine in general [20]. Lifestyle modification can reduce the negative impact of migraine by controlling trigger factors (those that provoke the development of a migraine attack); factors predisposing to the development of a migraine attack (increasing susceptibility to

triggers and facilitating the development of migraine attacks); factors that exacerbate headache during an attack; risk factors for migraine chronicity [20, 21].

A key feature of migraine is the ability to provoke attacks by various triggering factors – endogenous or exogenous influences associated with an increased likelihood of developing a migraine attack within a short period of time, reported by up to 76% of patients [22, 23]. Triggers must be distinguished from precursor symptoms, which precede the headache phase but play no role in provoking an attack, being the earliest manifestations of an attack [20]. Identifying the real triggers and leveling their negative impact through lifestyle modification is an important approach in the treatment of migraine [24]. However, caution should be exercised with factors whose role as triggers is unclear, as encouraging active avoidance of certain factors may not be effective and may have a frustrating effect on patients.

The use of a trigger control strategy in some patients provides a preventive effect without the use of medication [26]. However, any modifications should not result in unnecessary avoidance behavior, which in itself may impair the quality of life. During a migraine attack, specific lifestyle modification approaches can help provide relief by reducing the impact of factors that exacerbate headache and maladaptation within a migraine attack.

In addition, lifestyle modification approaches may be useful in correcting some modifiable risk factors for migraine chronicity. Among them, the most studied are: stress management, optimization of the use of symptomatic remedies (use of medications recommended by the doctor, control of their quantity), physical activity, diet and sleep/wakefulness, limitation of caffeine intake [26].

Thus, to date, lifestyle modification is an important therapeutic strategy to improve the quality of life of migraine patients and reduce the use of medications [19].

Behavioral therapy

According to international and Russian recommendations, behavioral therapy is considered an effective treatment for migraine, with a high level of evidence and convincing recommendations (*level 1B*) [3]. Successful coping and displacement of emotional stress and other factors of disease chronicity contribute to migraine course relief, including the reverse transformation of chronic migraine (CM) into an episodic form [28–31]. Behavioral therapies for migraine include *educational discussion* with the patient about the causes, treatment, and prognosis of migraine, as well as specific behavioral methods such as *cognitive behavioral therapy (CBT)*, *mindfulness therapy (Mindfulness)* [3, 31, 31].

Patient education and information can be provided by a neurologist or general practitioner, either face-to-face at an appointment or in absentia using popular literature and internet resources; patient education schools are effective and widely used. The main points of such a conversation include [3, 32]: (a) discussing the role of migraine triggers and the need to avoid them; (b) explanation of the benign nature and mechanisms of migraine at a level accessible to the patient (dissuasion of an organic cause of headache, explanation of the role of pain mediators, increased activity of painful brain structures, etc.); (c) justification of inexpediency of additional studies (except for cases of suspected symptomatic migraine); (d) discussion of risk factors

Table 1. *Characteristics of lifestyle changes to overcome the negative influence of trigger factors (provocateurs of a migraine attack) [3, 20, 25–27]*

Factors	Approaches to lifestyle modification
Psychological: anxiety, crying, strong emotions, work/home stress, post-stress period	Stress management, relaxation techniques (see «Behavioral Therapy» section for details)
Sleep-related: insufficient sleep; excessive sleep; sleeping at unusual times of the day	Adherence to a sleep-wake schedule: going to bed and waking up at the same time every day, including weekends. Fixed working hours during the day, avoiding night and/or shift work with alternating day and night shifts
Nutrition-related: hunger, starvation, irregular diet; insufficient fluid intake; drinks with caffeine (coffee, cola, energy drinks), caffeine deprivation after regular use; soft drinks with aspartame; cold food, ice-cream (ice-cream migraine); certain foods (chocolate, cheese, citrus fruits, smoked meat, canned foods, dairy products), food additives (glutamate, nitrites); alcohol (especially red wine, beer, etc.).	Regular diet Drinking / adequate fluid intake (hydration). Do not abuse caffeine-containing beverages. Limit intake of soft drinks with artificial sweeteners and cold foods/iced drinks. Limit/exclude the intake of only those foods and beverages that have been linked to the provocation of a migraine attack in a particular patient
Related to physical and/or mental strain: fatigue; heavy reading or writing; working in an uncomfortable position, at a computer; intense physical activity, exercise, hard physical work; sexual activity	Prevention of excessive fatigue by observing the work and rest regime. Workplace ergonomics (prevention of musculoskeletal pain, including neck pain). Aerobic physical activity. Prevention of sudden unprepared movements and heavy lifting, contact sports with blows to the head. Modification of sexual behavior if migraine attacks are provoked by sex: decrease in the rate of movement, the degree of muscle tension for adaptation to physical load in the pre-orgasmic phase; abstain from sex if you are very tired and/or under acute severe stress
Related to external influences bright/flickering lights, glare, contrasting images; weather changes, heat, cold, rain, snowfall; noise, loud sounds; perfume, detergent, paint, gas, gasoline odors; high altitude (mountains); air travel; smoking or smoke inhalation; air pollution; severe/ prolonged vestibular strain, including train, car, water transportation, etc.	Consider the influence of external factors in the workplace and at home (lighting, odors, noise, etc.), when choosing planned vacations/travels and places of residence (motion sickness, high altitude, odors, smoke, weather conditions). Avoid artificial light from low-frequency fluorescent lamps; LED lamps are preferred. Avoid bright colors and high contrast colors in surrounding objects. TV/computer/smartphone/tablet screen with special frequency characteristics (100 Hz and above), anti-glare and light filters (adjust color to reduce exposure to blue light using an app); work with tinted glasses that block harmful wavelengths. Wear glasses with light filters to work in a room with artificial light, at a computer (with filters against blue light), in bright natural light (sunglasses), in case of flickering light from car headlights in the dark time of day. Choose household chemical and/or perfume products that do not have a pungent odor
Hormone-related (for women): «perimenstrual period» (2 days before to 3 days after the onset of menstruation); menstrual or postmenstrual period	Keeping a headache diary and menstrual cycle diary; Following the recommendations of a neurologist and gynecologist, including the use of short-term prophylaxis for menstrual-associated migraine attacks

for migraine chronicity/incidence (stress, MOH, psychiatric and other comorbid disorders) and the need to eliminate/prevent them; (e) explaining the goals of migraine treatment, the mechanisms of action of preventive medications, and the benefits of non-medication methods; (f) discussing the role of treatment adherence.

Patients who abuse pain medications should be educated about the need to limit or temporarily withdraw from them, in severe cases detoxification and ongoing lifelong monitoring of their intake [9]. Patients with comorbid disorders (sleep disorders, pain of other localizations, depression, anxiety spectrum disorders) should be explained the necessity of their treatment by doctors of relevant specialties (neurologist, somnologist, psychiatrist, psychotherapist, clinical psychologist, kinesiotherapist, etc.) [33].

Combination treatment including medication and behavioral methods can be considered a promising treatment option for refractory (resistant to traditional pharmacological treatment) migraine [34]. Patients with concomitant psychiatric (anxiety-depressive and somatoform) disorders are indicated individualized CBT, psychotherapy and psychological relaxation methods (*level of strength of recommendation A, level of evidence I*) [3].

In migraine patients, CBT is delivered in the form of sessions (individual and group), usually at a frequency of once a week and lasting 45 to 90 minutes. Classical CBT includes two methods: behavioral (aimed at activating the patient, individual prevention of migraine attacks and the ability to cope with them) and cognitive (includes work with negative thoughts and misconceptions about the disease and aims to

reduce the impact of catastrophizing pain) [28, 31, 35]. CBT focuses on identifying automatic (occurring regularly, as if «out of habit») negative thoughts, which in most cases are completely or partially inconsistent with reality and lead to negative emotions and maladaptive behavior. In therapy, migraine patients are shown how their negative, catastrophic thinking style negatively affects their psychological and physical well-being, their behavior in daily life and «internal picture of the disease» [36]. Patients are taught new, alternative and more realistic views of their illness, themselves and their future, as well as new (alternative) and more adaptive behaviors in relation to their disease. The practical significance of using CBT in patients with migraine and comorbid disorders lies in the fact that with the help of this method it is possible to form a correct «internal picture of the disease» and more active strategies for coping with headache in the patient and thus to cope not only with pain, but also with most of the patient's comorbid problems [36].

The use of CBT in migraine patients can achieve a reduction in the frequency, duration and intensity of migraine attacks, reduce the amount of pain medication taken, control symptoms of anxiety and depression, and improve self-esteem [37]. In patients with a high frequency of migraine attacks and significant symptoms of depression, CBT is more effective than educational talk alone [38]. The addition of CBT to treatment leads to a significant reduction in the frequency and intensity of headache attacks, improved emotional state, increased ability to work and contributes to the correction of concomitant sleep disorders, and in patients with CM promotes the reverse transformation to the episodic form [36]. Evidence from systematic reviews and meta-analyses on psychological methods used for migraine has led to several important conclusions: (a) CBT is significantly more effective than no therapy at all [30]; (b) the combination of CBT and relaxation is significantly more effective than either relaxation alone or antidepressant therapy alone [30]; (c) behavioral treatment was significantly superior to standard treatment in terms of reducing the number of headache days per month, reducing the frequency of headache attacks per week, and the number of patients with therapeutic effects [35]; (d) CBT is effective not only in reducing the frequency and intensity of migraine attacks, but also in increasing the functional activity of migraine patients [31].

Mindfulness is a psychological method based on meditation exercises and belongs to one of the areas of CBT [39]. The basic idea behind the technique of mindfulness is to completely shift one's attention to the present moment, without any evaluation of oneself or the surrounding reality, and without thinking about what the future may be [40]. The patient is taught how to stop intrusive, disturbing thoughts, control emotions, increase emotional resilience to stress, and enjoy life. Two of the best known and most studied Mindfulness-based psychological methods are Mindfulness-Based Cognitive Therapy and Mindfulness-Based Stress Reduction. The following conclusions have been drawn from systematic reviews and meta-analyses on the efficacy of these two directions of mindfulness for migraine [41, 42]: (a) mindfulness is a promising psychological method that can be combined with standard treatment and give more benefits than either standard treatment or mindfulness monotherapy; (b) mindfulness meaningfully improves patients' emotional well-being, reduces disease-

related suffering, and improves quality of life. In patients with migraine and MOH during the period of abusive drug withdrawal, mindfulness therapy has efficacy similar to traditional prophylactic treatment [43, 44].

Physical activity

The terms «physical activity» and «exercise» are often used synonymously. Meanwhile, exercise is a type of social and/or physical activity that can be used in various forms for the purpose of training or developing the body to promote physical health. They can be categorized into aerobic exercises, anaerobic exercises and flexibility, coordination and relaxation exercises. Aerobic exercise is designed to increase the efficiency of the oxygen transport system (e.g., long-distance running, cardiovascular training, or playing soccer) [45]. Anaerobic exercise is high-intensity work designed to increase muscular strength (e.g., weightlifting). Finally, exercises that increase flexibility, coordination, and relaxation include stretching, yoga, and tai chi [45].

The effect of exercise on migraine manifestations has been shown in several studies. Thus, in a large national cross-sectional study involving 3848 participants, L.P. Queiroz et al. [46] showed that migraine is 1.43 times more common in those who do not exercise compared to those who exercise at least one day a week. On the other hand, there are reports that physically inactive individuals are more likely to have recurrent headaches and/or migraine than physically active subjects. Moreover, regular physical exercise (more than three 30-minute sessions per week) has been associated with a reverse regression of CM to an episodic form [47].

Aerobic exercise in the preventive treatment of migraine has been studied in six randomized clinical trials (RCTs) [48]. Three of them reported a decrease (22–78%) in the average number of days with migraine per month. Long-term follow-up for at least 1 year shows that there was a statistically significant reduction in the frequency, intensity, and duration of migraine attacks compared with baseline among individuals who exercise consistently [49]. The observations also demonstrate that using a combination of 12 weeks of aerobic exercise in conjunction with treatment with amitriptyline (25 mg/day), led to a statistically significant reduction in the frequency, duration, and intensity of headache compared to the group taking amitriptyline alone [50]. Migraine patients showed a decrease in the number of days with migraine per month and duration of attacks compared to baseline after a 10-week course of aerobic running, while no statistically significant difference was found in the control group [51]. Using a 12-week cycling program in migraine patients has been shown to provide more benefits compared to a relaxation program or taking topiramate (200 mg/day) [52]. The use of anaerobic exercise for chronic pain relief suggests that it may be useful in the treatment of migraine, but evidence of its efficacy requires more in-depth study in comparative and controlled trials.

Flexibility, coordination, and relaxation exercises in the preventive treatment of migraine were investigated in four RCTs, and one RCT evaluated the use of yoga and tai chi [48]. Their results were promising and suggested that yoga and tai chi may be useful in the treatment of migraine. M.Z. Boroujeni et al. [53] conducted a small comparative study of a combination of pharmacotherapy and a 12-week

yoga and drug monotherapy program. The yoga group had three classes of 75 min per week. The combined therapy group showed a more pronounced reduction in the frequency of headache attacks, its severity and the degree of patients' maladjustment compared to the control group [53]. Similar data were obtained by P.J. John et al. [54], who compared the effects of yoga therapy and educational programs during 3 months of observation. Headache intensity, frequency, pain indices, as well as anxiety and depression indices had greater dynamics in the yoga group [54].

Although data from specific studies on the effects of different physical activity methods are limited by the limited number of studies and the lack of adequate controls, several practical conclusions can, nevertheless, be drawn with regard to aerobic exercise [48]:

1. Aerobic exercises such as cycling and walking are preferred over anaerobic exercises such as eccentric and isometric muscle work.
2. The intensity, frequency and duration of exercise should be tolerable and should not cause pain or fatigue. In general, at the initial stages of training, moderate-intensity exercises performed at 60–70% of maximum heart rate are recommended. If the participant cannot tolerate such exercises or if the headache increases, the intensity of the exercise should be reduced.
3. Based on the above-mentioned RCTs, the frequency of exercise should be two to five times per week, with each workout lasting 40 to 50 min.

Dry needling

As an important CAM component, reflexology has gained popularity as a method of palliative intervention [55]. Clinical studies have shown that DN can reduce pain intensity, pain duration, influence emotional comorbidities and the number of medications taken to manage pain episodes. However, the specific clinical efficacy of DN has not been confirmed by RCTs and the mechanisms underlying its efficacy remain unclear.

With the development of biomedical and neuroimaging techniques, the neurogenic mechanisms of DN in migraine have received increasing attention. Neuroimaging studies have shown that DN can alter the abnormal functional activity of the descending pain modulation system, the thalamus, the frontoparietal and occipitotemporal areas, and the cerebellum; reduce neuroinflammation, and regulate peripheral and central sensitization [55].

Evidence for the effectiveness of DN in controlling migraine is still limited by the low quality of published studies [55]. DN is effective in the preventive treatment of migraine (*level of evidence B*). It can be considered an effective and safe treatment option, as its use is generally not accompanied by the development of side effects [56].

DN can be used alone or in combination with pharmacologic and interventional techniques for both symptomatic and prophylactic treatment of migraine. Combining reflexology with pharmacotherapy can enhance the therapeutic benefits over taking medication or any other modality. DN may be administered to patients with poor tolerance to conventional therapy, refractoriness to treatment, or if the patient chooses non-drug therapy [57]. Preventive treatment programs for episodic migraine are described in the relevant literature [57,

58]. Practical use of DN is limited by constraints in the design of RCTs. Thus, the analysis of 15 systematic reviews conducted by Y.X. Li et al. [58], showed that 14 studies were rated as having critically low quality according to AMSTAR2. Meanwhile, the use of the GRADE tool reveals the evidence of high quality indicating that the effectiveness of DN is superior to traditional migraine treatment in some respects and reduces the number of days with headache and pain medications used [58]. However, the efficacy of DN for migraine needs further improvement.

Biological feedback

Biological feedback (BFB) is one of the most effective and well-studied behavioral therapies for various pain phenomena. The basis of BFB therapy is the ability to learn to control voluntarily the body's biological responses while utilizing feedback from various physiological processes. An important feature of BFB is the active involvement of the patient in the therapy process, which leads not only to the regression of pain manifestations, but also to the recovery of psychological and psychosocial disorders. Various modalities of BFB are used for the preventive treatment of migraine; BFB techniques using electromyography (EMG-BFB), skin temperature (tBFB) and pulse (BFB-pulse) analysis have proven to be the most effective; BFB techniques with electroencephalography (EEG-BFB) or cutaneous galvanic response assessment (CGR-BFB) are less commonly used [59]. BFB is often combined with relaxation techniques and CBT methods to increase its effectiveness [60].

Despite the long use of BFB methods, data from different studies and observations vary and sometimes contradict each other. This is primarily due to the use of different patient selection criteria, non-standardized protocols for implementing feedback, and differences in determining treatment effectiveness. Several systematic reviews and meta-analyses of the efficacy of BFB therapy for migraine and tension headache (THA) have been conducted to systematize the abundant evidence [61, 62]. Based on the findings, recommendations for the practical use of BFB in migraine and THA have been developed [63].

Y. Nestoriuc et al. [61, 62] conducted two comprehensive systematic reviews on the efficacy of BFB therapy for migraine and THA, which processed the results of BFB therapy in more than 3500 patients with migraine and THA. A significant overall sustained therapeutic effect of moderate BFB therapy was found for both migraine and THA. A separate analysis of BFB for migraine found a medium level of efficacy compared to a group of patients not treated with BFB [62]. Improvement in migraine and THA patients after BFB therapy sessions was prolonged and stable during the follow-up months of observation [62].

Based on the analysis of available data, experts of the American Academy of Neurology (AAN) published recommendations on the use of BFB and behavioral therapy methods in practice (table. 2). Recommendations are categorized into levels (A, B, C) based on the available evidence base [63].

Despite the proven medium therapeutic effect of BFB therapy for migraine and high therapeutic effect for THA, further research on the combined use of BFB and physical medicine, CBT and modern drug therapy is required to develop optimal therapeutic programs.

Peripheral nerve blocks

Currently, the use of peripheral nerve blocks for migraine is possible in two cases [64]: 1) as part of complex therapy for treatment of severe prolonged migraine attack or migraine status refractory to standard therapy; 2) in combined prophylactic therapy for CM.

Studies on the efficacy and safety of peripheral nerve blocks for the management of severe migraine attacks are few and all have been conducted on small patient samples. Blockades of occipital nerves are mainly performed for this purpose, much less frequently – of trigeminal nerve and sphenopalatine ganglion (SPG). The main indications are severe, prolonged migraine attack and migraine status refractory to standard drug therapy.

One study compared the efficacy of occipital major nerve blockade (OMNB) versus placebo treatment in patients with severe migraine attacks in the emergency department when standard parenteral therapy was ineffective [65]. In the group of patients who received bilateral OMNB blockade 31% of patients had complete regression of headache within 30 min, while in the placebo group none of 15 respondents noted such an effect. At the same time, the frequency of side effects did not differ in the studied groups [65].

A small study involving 44 patients with CM showed the efficacy of OMNB blockades using lidocaine compared to placebo. A significant reduction in the frequency of days with migraine was found in patients receiving OMNB blockades compared to the placebo group. Adverse events occurred with equal frequency in the placebo and lidocaine groups [66].

OMNB blockades have also been shown to be effective in combination therapy, in conjunction with topiramate, in patients with CM [67]. After 3 months of therapy, patients receiving OMNB blockades in combination with topiramate had a significantly greater reduction in the frequency of days with migraine per month compared to the group receiving topiramate alone [67].

Data on the efficacy of SPG blockades in migraine are quite contradictory. The efficacy of intranasal use of 4% lidocaine versus isotonic sodium chloride solution was analyzed [68]. When SPG blockade with 4% lidocaine was used, 55% of patients (n=29) experienced a pain reduction of at least 50% from baseline within 15 min, which was significantly higher than in the placebo group (n=6; 21%; $p<0,05$) [68]. In contrast, in another randomized trial, an analysis of the efficacy of

SPG blockade with 0.5% bupivacaine solution versus placebo showed no significant difference in patients with CM [69].

Neuromodulation and neurostimulation

Neuromodulation and neurostimulation provide a new alternative for migraine prevention. Vagus nerve stimulation, SPG and deep brain stimulation are invasive techniques and are only applicable in cases of severe disability and frequent, severe seizures refractory to pharmacotherapy. The development of non-invasive percutaneous stimulators has fundamentally expanded the options for neurostimulation therapy for many migraine patients regardless of disease severity and responsiveness to prior therapy. These approaches include transcranial magnetic neurostimulation techniques and percutaneous pericranial nerve stimulation techniques.

The method of transcranial magnetic stimulation (TMS) is based on the principle of electromagnetic induction and is one of the variants of neuromodulation, which is a therapeutic change in the functional activity of the central, peripheral or autonomic nervous system [70]. TMS is used to manage migraine attacks with aura and as a method of preventive therapy of the disease [71]. In order to control a migraine attack with aura, a single high-frequency pulse is used with a ring-shaped coil applied during the aura in the occipital cortex area, usually within 1 hour of its onset [72]. The efficacy of TMC for the management of headache and associated symptoms (photophobia, phonophobia and nausea) in patients with migraine with aura was demonstrated in a double-blind RPCT in parallel groups [72]. The single-pulse TMS protocol is approved by the U.S. Food and Drug Administration (FDA) as an effective method of managing migraine attacks with aura. High-frequency rhythmic TMS (rTMS; 5 or 10 Hz) has been shown to be effective in migraine prophylactic therapy. Protocols for therapeutic TMS for migraine are authorized by the FDA in the USA and by the National Institute for Health and Care Excellence (NICE) in the UK, usually using data from the clinical guidelines of the International Federation of Clinical Neurophysiology (IFCN) [73].

Among percutaneous pericranial nerve stimulation techniques, stimulation of the supraorbital nerve with the Cefaly percutaneous device has received the widest clinical use [74].

Clinical studies of the efficacy of supraorbital nerve neurostimulation using the Cefaly device for the prevention of migraine include eight studies with different designs, including

Table 2. *Practical recommendations for the use of behavioral therapy and biofeedback methods for primary headaches [63]*

Recommendations	Level of evidence
1. Relaxation techniques, BFB in combination with PIR, EMG-BFB and CPT methods can be considered as options for migraine preventive therapy	A (based on data from multiple RPCTs that support this assertion)
2. Behavioral techniques (BFB, PIR, and other relaxation techniques) can be used in conjunction with drug preventive therapy options to enhance the effectiveness of migraine treatment	B (based on the results of several RCTs, data from some studies may be contradictory)
3. The current evidence base does not allow recommending DN, manual medicine, hypnosis, bite correction, percutaneous electrical stimulation for acute or prophylactic therapy of migraine	C (expert recommendations in the absence of correct RCT data)

Observation. PIR, postisometric relaxation; RPCT, randomized placebo-controlled trial.

RCTs using a sham control procedure. In the PREMICE study [75], the analysis of the study population showed a significant reduction in the number of days with migraine headache and the total number of days with headache by the 3-rd month in the active therapy group, whereas in the control group with sham stimulation, these dynamics were not significant. An important result of the PREMICE study was the data of subjective assessment of treatment efficacy. Satisfaction with the treatment results was significantly higher in the main group (70.59%; $p=0.009$) compared to the group with simulated stimulation (51.52%) [75].

Invasive occipital nerve stimulation (ONS) is used for prophylactic therapy only for resistant forms of chronic cluster headache and CM [76], i.e. it is used only when prophylactic treatment with at least three drugs recommended for the treatment of migraine in adequate doses for at least 3 months is not effective.

The use of invasive ONS for CM shows contradictory results in RCTs. In the ONSTIM study, the response rate after 3 months was 39% in the active therapy group and 6% in the sham stimulation group [77]. In the PRISM study, differences in the rate of reduction in the number of days with headache per month with the active stimulation versus sham procedure were not significant [78]. However, among patients who did not abuse analgesics, this difference was statistically significant.

Treatment of headache by SPG neuromodulation is based on inhibition of postganglionic parasympathetic fibers, subsequent suppression of pain and cranial autonomic symptoms, and modulation of sensory processing in the caudal trigeminal nucleus [76]. The effect was achieved in 50% of patients compared to 8% with sham stimulation. The study demonstrated that stimula-

tion of the SPG region may be an alternative treatment for acute migraine attacks [78].

Percutaneous electrical nerve stimulation is performed by inserting two probes into bilateral acupuncture points. An RCT conducted in patients with episodic migraine showed a moderate but noticeable effect in the form of reduction in the number of days with migraine per month in patients receiving the active procedure compared to the sham procedure [79].

Thus, non-invasive neuromodulation may play an important adjuvant role in the abortive and prophylactic treatment of migraine, whereas invasive neuromodulation is of great importance in the treatment of patients with severe resistant chronic headache who are not helped by adequate pharmacologic modalities either as monotherapy or in combination treatment.

Conclusion

CAM, as a holistic approach, focuses more on lifestyle changes, including healthy eating, physical activity and management of stress, sleep patterns and nutrition. Because research tends to focus on the effects of individual interventions, it is difficult to assess the value of this approach as a whole. Meanwhile, the use of CAM potentially empowers patients and helps them play an active role in disease control. Many CAM methods, including physical methods, are self-selected and self-administered, which increases patient responsibility in achieving a successful outcome on the one hand, and promotes adherence to therapy on the other hand.

Although the strength of evidence for the efficacy of CAM methods in the treatment of migraine requires further research, the feasibility of their use is justified by the needs of clinical practice.

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