



# sEMG Biofeedback for Episodic Migraines: A Pilot Randomized Clinical Trial

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## Abstract

The aim of this study was to assess the feasibility and potential effectiveness of a 6-week virtual sEMG biofeedback intervention for patients with episodic migraines. Patients with episodic migraines were randomized to treatment with a novel surface EMG (sEMG) at-home biofeedback device or a treatment as usual control group; they completed validated baseline and post-intervention assessments of migraine related disability (migraine-specific quality of life, anxiety and depression). Participants also underwent a series of Quantitative Sensory Testing (QST) procedures referring to several different tests that quantitatively assess responses to mechanical stimuli during two separate visits (baseline and post intervention). No adverse events were reported during the study. Compared to the treatment as usual comparison group, patients in the sEMG biofeedback group reported lower migraine disability ( $p < 0.05$ ). Compared to baseline, participants in the sEMG biofeedback group demonstrated statistically significant reductions in anxiety ( $p < 0.01$ ), and significant increases in quality of life ( $p < 0.001$ ), and significant decreases in temporal summation ( $p < 0.05$ ) assessed by QST. No significant changes were observed in any of the outcomes in the control comparison group ( $p > 0.05$ ). No significant changes were observed in migraine frequency in either of the two groups ( $p > 0.05$ ). In addition, mediation analyses revealed that changes in migraine related quality of life mediated group effects on changes in migraine disability. Virtual sEMG biofeedback shows promise as a potential therapy for reducing disability, anxiety and depression and improving quality of life in individuals with episodic migraines. These results demonstrate the feasibility of a digital intervention for migraines and set the basis for conducting a future, larger scale randomized controlled trial to confirm these preliminary findings.

**Keywords** Episodic migraines · Digital therapeutics · Telemedicine · Biofeedback

## Introduction

Migraine is a common neurologic condition, affecting at least 15% of individuals living in the United States (Ashina et al., 2021). It causes significant disability in terms of missed life events and days of work and is incurable to date. The result is a disabling condition which is difficult to manage (Giannini et al., 2013). Biobehavioral therapies, such as cognitive behavioral therapy (CBT), can have significant

beneficial effects on the number of headache days experienced and in reducing anticipatory anxiety and catastrophizing around migraine (Klan et al., 2022).

Biofeedback, a promising adjunctive treatment for many chronically painful conditions, can be described as “operant conditioning of physiological activity”, by which “the patient learns to self-regulate his or her physiological processes with the help of feedback information” (Schwartz & Andrasik, 2016), and can comprise different sites, modalities, and procedures.

One commonly used modality of biofeedback is surface electromyographic biofeedback (sEMG-BF) which measures muscle tension and trains individuals to relax specific muscle groups. The sEMG device is used to observe and monitor skeletal and muscle tension. Relaxation training involves learning how to achieve a physical and mental state of calmness and relaxation within a few minutes. It is a systematic set of procedures usually following a specific

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protocol. Relaxation training is recommended migraine management since migraines can often be triggered by psychological stressors. sEMG-BF has been shown to reduce mean headache activity by 66% (Reeves, 1976). It has also been shown that sEMG-BF outperformed a control intervention in reducing migraine frequency and improving quality of life for patients with migraines (Nestoriuc et al., 2008; Reeves, 1976).

Grazzi et al. (Grazzi et al., 2002) compared combined biofeedback and medication to medication alone for migraine patients. Results suggested that although patients in both the biofeedback and medication group demonstrated similar effects at 1 year, at the 3-year follow up, participants receiving combined treatment showed greater and sustained improvement in headache frequency and consumption of analgesic medication.

Interestingly, most of the systematic reviews on biofeedback for headache management are outdated (Chapman, 1986). However, there has been some recent effort to provide additional evidence on the use of biofeedback for migraine management. The most recent systematic review on biofeedback and migraines showed a medium effect size for all types of biofeedback interventions that was sustained for over 17 months. Also, biofeedback was more effective than the investigated control conditions (Nestoriuc & Martin, 2007). A preliminary study conducted by Sobaniec and colleagues demonstrated that after the series of 15 sEMG-BF training sessions, headache intensity decreased in 52% of the patients and headache frequency in 66% of the patients. Another study published by Mullaly et al. 2009 (Mullally et al., 2009) comparing sEMG-BF in addition to the basic relaxation instruction or relaxation techniques alone, demonstrated that patients who completed a pain education program and relaxation techniques showed a statistically significant decrease in the frequency and severity of the headaches in the first 12 months with sustained effects at 36 months. Biofeedback provided no additional benefit, specifically no change in the frequency or severity of the headaches.

Collectively, studies using biofeedback for the treatment of migraines have shown reductions in migraine frequency and symptoms. However, there have been inconsistent findings regarding biofeedback's superiority alone over other treatments. Further, it is difficult to draw conclusions based on previous studies due to variability in sample size and characteristics, biofeedback modality, treatment conditions, and control groups. Thus, the efficacy of sEMG-BF in reducing the symptomatology of patients with migraines remains unclear. In addition, there have not been any studies utilizing portable sEMG-BF devices offering increased access to patients with migraines. The aim of this study was to assess the effects of a pilot sEMG-biofeedback virtual intervention for episodic migraines.

## Methods

We recruited 84 patients with episodic migraines aged 18–65 years old. Diagnosis was made by our study neurologist (CB) according to the ICHD criteria. If patients met criteria, they were referred to our study after confirming the diagnosis of episodic migraine. Additionally, we had access to the participants' medical records where a diagnosis of chronic migraine or medication overuse migraine was documented. Out of those 82 participants, 68 provided complete data before and after the intervention. Participants were randomly assigned to either the JOGO Digital Therapeutics sEMG-BF device or a treatment as usual control group in a 2:1 ratio. Our study was registered on clinicaltrials.gov (Identifier: NCT04607460). All patients were asked to complete self-report questionnaires assessing demographics, migraine disability and migraine frequency (primary outcomes), as well as migraine related quality of life and depression and anxiety (secondary outcome) and underwent Quantitative Sensory Testing (QST) prior to and after completing the intervention. The intervention consisted of 6 virtual weekly sessions during which participants practiced various sEMG-BF exercises with a trained biofeedback instructor. Study procedures received approval by the Institutional Review Board (IRB) of Brigham & Women's Hospital (Boston, MA, USA). Upon request, and subject to certain criteria, conditions, and exceptions, access to individual deidentified participant data can be provided.

## Eligibility Criteria

### Inclusion Criteria

- (1) Women ages 18–65.
- (2) Diagnosis of episodic migraine according to their electronic medical record and also confirmed by their treating Neurologist (with or without aura) (International Classification of Headache Disorders-II) ("The International Classification of Headache Disorders, 3rd edition (beta version)," 2013).
- (3) 4–14 days with migraine in the last month based on self-report (patients who met the criteria for chronic migraine were excluded).
- (4) No change in the type of prophylactic and psychiatric medication used within the last 3 months.
- (5) Greater than 1 year of migraines (self-reported).
- (6) Agreeable to participate, commit to all study procedures, and to be randomized to either group.
- (7) Fluent in English (required to complete self-report instruments).

## Exclusion Criteria

- (8) Any unstable medical (e.g. neurodegenerative conditions) or psychiatric conditions (e.g. psychosis) requiring immediate treatment or that could lead to difficulty complying with the protocol.
- (9) Active suicidal ideation (assessed by the clinician during initial screening).
- (10) Moderate or severe level of depression (exclude if score on PHQ-2 is greater than or equal to 3).
- (11) Psychiatric hospitalization within the past year (self-reported).
- (12) Comorbid acute or chronic pain condition that is rated by the subject as more painful than migraine.
- (13) Begins new migraine treatment during the study period.
- (14) Inability to complete study visits.
- (15) Medical condition known to influence QST or participation in the sEMG-BF intervention (e.g. HIV, peripheral neuropathy, Raynaud's syndrome).
- (16) Substance use disorder, that would interfere with study participation.
- (17) Significant medical abnormalities or conditions that in the opinion of the Practitioner would interfere either with the ability to complete the study or the evaluation of the investigational device's safety and efficacy.
- (18) Recent history of a significant medical-surgical intervention that in the judgment of the Practitioner would interfere either with the ability to complete the study or the evaluation of the investigative device's safety and efficacy.
- (19) Known allergic skin reaction to tapes and plasters.
- (20) Subject currently enrolled in an investigational drug or device study.

## Procedures

Patients were screened remotely on the phone to determine eligibility. Participants were then scheduled for a consent call with the research coordinator who obtained remote electronic consent through Partners approved procedures via REDCap. Diagnoses of episodic migraine were made by the study neurologist (CB) and confirmed by electronic medical record review.

Participants were randomly assigned to either the sEMG-BF or control group. Before the baseline in-person visit, participants filled out questionnaires regarding migraine disability, migraine related quality of life, anxiety, and depression, as well as demographics and medical history.

Upon their baseline visit, they completed a baseline assessment of Quantitative Sensory Testing. Patients randomized in the interventional group were also shown how to operate the device at home and were scheduled for virtual

therapy sessions via Partners Healthcare Secure Zoom for therapy sessions. During the second (post) visit, participants underwent the same tests as the baseline with the addition of an end-of-study questionnaire about the perceived benefit of the device.

## Self-Report Measures

### Primary Outcomes

**Headache Related Disability** HIT-6 is a 6-item assessment that evaluates the impact headaches have on a patient's life and is highly valid and reliable in patients with headaches (Kawata et al., 2005; Kosinski et al., 2003; Yang et al., 2011). Migraine Disability Assessment (MIDAS) is a 5-item questionnaire; it is the most frequently used disability instrument in migraine research and is highly reliable and valid (Stewart et al., 2001).

**Migraine Frequency** We assessed migraine frequency based on the following item: On how many days in the last 3 months did you have a headache?

In addition, diary data were collected assessing the number of days participants experienced migraines for 5 days at baseline and 5 days post intervention.

### Secondary Outcomes

**Migraine Specific Quality of Life Questionnaire, Version 2.1 (MSQv2.1)** The MSQ is a 14-item questionnaire that measures how migraines affect a patient's daily life and is a highly reliable and valid instrument (Jhingran et al., 1998; Martin et al., 2000).

**The Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983)** The HADS is a 14-item scale designed to assess the presence and severity of anxious and depressive symptoms. Seven items assess anxiety, and seven items measure depression, each scored from 0 to 3. The HADS has been used extensively in clinics and has adequate reliability (Cronbach's  $\alpha=0.83$ ) and validity, with optimal balance between sensitivity and specificity (Bjelland et al., 2002). It has been translated into many languages and is widely used around the world in clinical and research settings. Anxiety and Depression were calculated separately as subscales and explored in separate analyses.

**Standardized Quantitative Sensory Testing (QST)** QST is a non-invasive method for measuring pain sensitivity and pain modulation. Our QST testing protocol measured mechanical pain sensitivity and temporal summation of pain (reflecting pain-promoting processes). These protocols have been used in prior studies (Katz et al., 2015; Wasan et al., 2019).

The assessment of psychophysical responses includes: responses to innocuous stimuli, mechanical pain sensitivity, and temporal summation of pain, a measure of central sensitization (Sarhani & Greenspan, 2003; Staud et al., 2001). Brief descriptions of the testing methods appear below; see (Edwards, 2005; Edwards et al., 2004, 2005) for more details. All of these procedures are non-invasive, non-damaging, and have been used in studies of patients with migraines (Nahman-Averbuch et al., 2018).

**Mechanical pain and Temporal Summation of pain** Temporal summation was assessed by evaluating responses to repeated punctate mechanical stimuli, which were applied on the second and third finger on each hand using a standard set of probes. The probes are a set of weighted stimulators with fixed stimulus intensities (flat contact area of 0.2 mm diameter) that exert forces of 8–512 mN. The probe that elicits a mild degree of pain is determined for each participant (pain score 1–2/10) and used for temporal summation testing. Temporal summation (TS) refers to the increase in perceived pain from repetitive, noxious stimuli delivered at frequencies higher than 0.33 Hz (Arendt-Nielsen & Petersen-Felix, 1995). TS is also known as temporal summation of second pain (TSSP), because it is thought to represent summation of C fiber-mediated second pain. TS can be generated by a variety of noxious stimuli, such as heat, pressure, and pin-prick (Eide, 2000). In the present study we focus on TS induced by the pin-pricks. Therefore, TS served as an objective assessment of pain sensitivity in this cohort of patients (De Icco et al., 2020). The probe was applied perpendicular to the skin and was used to estimate temporal summation of pain perception by applying 10-stimulus trains at 1 Hz, with subjects giving a 0–10 pain rating after the first, 5th and 10th stimulus.

Stress affects pain processing throughout the central nervous system, including, potentially, mechanisms of TS. Since migraines can be triggered by multiple stressors, QST testing can be a particularly important assessment of migraine-related hyperalgesia.

### sEMG-Biofeedback Intervention

The portable sEMG device used in this study was a digital therapeutic product composed of wearable surface electrode-based biosensors, and an app installed on a tablet. Due to its compact size, the wireless device could be attached to the wrist or the torso of the participant using a strap and connects with the tablet via Bluetooth. The app was designed to facilitate neuromuscular retraining and muscle relaxation by using visual feedback. During the 6 weekly sessions participants were instructed on how to use the device and practiced various sEMG-BF exercises with a trained biofeedback instructor. EMG electrodes were placed across the shoulder

(trapezius muscle), the frontalis, and temporalis muscles. The EMG signal was visible on the tablet screen, which was also visible to the therapist. Each biofeedback session consisted of a series of exercises, during which the participants were taught to identify and reduce the level of tension they are feeling (tension recognition and tension discrimination exercises). Additionally, in each session, participants learnt ways to further reduce their muscle tension including relaxation techniques (e.g. Progressive Muscle Relaxation, PMR) while wearing the sEMG-BF device. PMR was practiced in the whole body while the participant had the sEMG-BF electrodes placed on the trapezius, temporalis, and frontalis muscles, alternating between muscles at each session. Further, one session was dedicated to posture training (deactivation training) using the sEMG-BF device. In each session participants had the opportunity to discuss possible difficulties using the device. Sessions lasted 40–45 min and were all conducted virtually (on a BWH encrypted Zoom platform). Patients were instructed to practice the exercises they learnt during the session at least 30 min 3 times a week and keep track of their home practice.

### Usual Care (UC) Group

Patients in this group underwent sensory testing procedures described below at baseline and 6 weeks after enrollment but received no active treatment. Participants continued their existing treatment regimens at Brigham and Women's Hospital (e.g., medication management). They were given a brochure with pain management information and psychoeducational materials.

### Data Analysis

Statistical analyses were performed using the SPSS 26.0 for the Social Sciences (SPSS Inc., Chicago, IL, USA). Descriptive statistics were used for demographic and clinical characteristics of the study sample. Baseline differences between groups were assessed by an unpaired *t*-test. For categorical variables, chi-square tests were used. Analyses were carried out on a 'per protocol' (PP) basis, which covered patients who entered the intervention ( $n = 44$ ) and control group ( $n = 24$ ) after randomization and presented values at the follow-up point.

Based on previous investigations, a sample size of 18 subjects in each group was required to detect a decrease of 25% in pain equal to the difference of one standard deviation (effect size = 0.08) with a power of 80% and  $\alpha$  of 0.05.

Initially, the normality of the scores of HIT-6, Migraine Frequency, MSQL, HADS anxiety and depression was tested through the Kolmogorov–Smirnov test. Results showed that all scores followed a normal distribution. Accordingly, we assessed within- and between-group differences regarding

the scores of all primary and secondary variables. The significance level was considered less than 0.05.

Longitudinal mediation models were constructed to test whether group allocation (sEMG-BF vs. UC) was indirectly associated with changes in HIT-6 (Migraine Disability) via the mediator of changes in Quality of Life based on past studies exploring these relationships (Dahlof, 2003; Kolytlo & Broome, 2000; Leonardi et al., 2010; Pradeep et al., 2020). In this specific instance, sEMG-BF was expected to change the outcome of interest (disability) by targeting mediating variables that are hypothesized to be causally related to the outcome (quality of life). We utilized the Preacher and Hayes' bootstrapping procedure at SPSS Process Macro (Preacher & Hayes, 2004, 2008) to conduct a series of bias-corrected bootstrapped mediation analyses using 10,000 bootstrapped resamples. This bootstrapping procedure is non-parametric and does not assume the indirect effects are normally distributed. For this model, group allocation (sEMG-BF vs. UC) was entered as the independent variable (X variable), MSQL (changes) as the mediator variable (M variable), and changes in HIT-6 (Migraine Disability) as the dependent variable controlling for baseline depression, anxiety, income, and ethnicity. The indirect effects were considered significant when the 95% bootstrap confidence interval from 5000 bootstrap samples did not include zero.

## Results

Participants in both groups were female, white, and non-Hispanic. Migraine pain was characterized as moderate in intensity and of long duration. Participants' baseline

characteristics are given in Table 1, which demonstrates no significant differences between the two groups with a randomization ratio of 2:1. Participants (n = 68) attended an average of 4.8 + 1.2 (range 4–8) of the six sessions in the EMG-BF intervention. Descriptive statistics pre and post are demonstrated for all participants in Table 2.

**Table 2** Pre-post scores of clinical outcomes (complete data)

Measure	sEMG = 39	Control = 20
	M ± SD	M ± SD
Migraine quality of life pre	84.63 ± 18.70	82.73 ± 20.87
Migraine quality of life post	92.76 ± 15.53	89.96 ± 13.54
HIT-6 Pre	62.48 ± 5.01	61.06 ± 4.91
HIT-6 Post	58.40 ± 6.21	60.0 ± 4.11
Migraine frequency pre	26.91 ± 22.67	22.26 ± 18.61
Migraine frequency post	28.28 ± 27.55	18.47 ± 14.14
HADS anxiety pre	7.55 ± 3.33	8.89 ± 4.71
HADS anxiety post	6.58 ± 3.06	7.84 ± 4.75
HADS depression pre	4.21 ± 2.71	5.26 ± 3.49
HADS depression post	3.48 ± 2.56	4.84 ± 2.65
Temporal summation pre	0.90 ± 0.99	1.06 ± 0.79
Temporal summation post	0.36 ± 0.88	0.93 ± 1.33
Diary migraine days pre (average)	1.81 ± 1.40	1.40 ± 0.69
Diary migraine days post (average)	1.45 ± 1.40	1.90 ± 1.44

*M* mean, *SD* standard deviation, *ppth* pain threshold, *HIT-6* headache impact test, *HADS* hospital anxiety and depression scale

**Table 1** Demographics and clinical profile of patients

Characteristic	JOGO baseline (n = 64)	Control baseline (n = 20)	p-value
Age	42.92 ± 11.75	44.92 ± 13.71	ns
Education	95.7%	83.3%	ns
College degree and above			
Marital status	54.3%	45.8%	ns
Married			
Race/ethnicity	4.3%	0%	ns
African American	82.6%	95.8	
Caucasian	6.5%	8.3%	
Hispanic/latino			
Employment status	63%	50%	ns
Employed full- or part-time			
Income > \$100,000	52.2%	41.7%	
Body mass index (BMI)	26.38 ± 5.84	29.54 ± 7.27	
Migraine-related variables			
HIT-6	62.48 ± 5.0	61.06 ± 4.91	ns
Migraine quality of life	84.65 ± 18.70	82.73 ± 20.87	ns
PROMIS depression	4.32 ± 2.71	5.26 ± 3.45	ns
PROMIS anxiety	7.55 ± 3.33	8.89 ± 4.71	ns

## Primary Outcomes

Participants who received sEMG-BF ( $M = 28.28$ ,  $SD 27.55$ ) compared to the control group ( $M = 18.47$ ,  $SD 14.14$ ) did not demonstrate significantly lower migraine frequency scores ( $t(48) = 2.094$ ,  $p = 0.14$ ). Participants who received sEMG-BF ( $M = 58.40$ ,  $SD 6.21$ ) compared to control group ( $M = 60.0$ ,  $SD 4.11$ ) demonstrated significantly lower migraine disability scores ( $t(51) = -1.15$ ,  $p = 0.03$ ).

Paired  $t$ -tests revealed that in the intervention group, the scores of migraine disability (HIT-6) decreased significantly, ( $M_{pre} = 62.48$ ,  $SD_{pre} = 5.01$ ,  $M_{post} = 58.40$ ,  $SD_{post} = 6.21$ ,  $t(30) = 3.70$ ,  $p < 0.001$ ) only in the sEMG-BF group. In the control group, the HIT-6 did not change significantly ( $t(19) = 1.16$ ,  $p = 0.26$ ). No significant changes were observed in migraine frequency in either the sEMG-BF group or the UC group ( $p$ 's  $> 0.05$ ).

## Secondary Outcomes

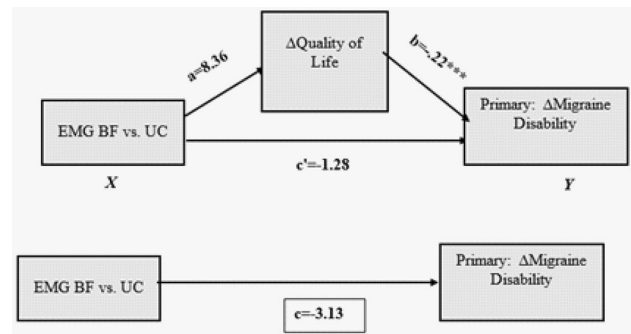
Paired  $t$ -tests demonstrated that there was a significant decrease between pre- and post-anxiety ( $M_{pre} = 7.55$ ,  $SD_{pre} = 3.3$ ,  $M_{post} = 6.58$ ,  $SD_{post} = 3.0$ ;  $t(30) = 2.27$ ,  $p = 0.03$ .) and increase in quality of life scores ( $M_{pre} = 84.63$ ,  $SD_{pre} = 18.70$ ,  $M_{post} = 92.76$ ,  $SD_{post} = 15.53$ ,  $t(38) = -3.23$ ,  $p = 0.003$ ) in the sEMG-BF but not in the control group. No significant changes were demonstrated in depression ( $t(30) = 1.70$ ,  $p = 0.9$ ).

In addition, after performing a paired  $t$ -test, significant differences were shown between pre-post temporal summation scores in the sEMG-BF group ( $t(30) = 2.07$ ,  $p = 0.04$ ) but not in the control group ( $t(30) = 0.45$ ,  $p = 0.65$ ).

Independent  $t$ -tests did not reveal any group differences in anxiety ( $t(48) = -0.11$ ,  $p = 0.9$ ), depression ( $t(48) = 0.53$ ,  $p = 0.5$ ) and migraine related quality of life ( $t(45) = 1.79$ ,  $p = 0.07$ ). The results of the final analyses are presented in Table 2.

## Quality of Life Mediating the Effects of Treatment on Migraine Disability

A mediation analysis was conducted to examine the mediating effect of quality of life (changes pre-post) between group allocation (sEMG-BF or UC) and migraine disability (changes pre-post). There was a significant indirect effect of intervention group (sEMG-BF vs. UC) on changes in migraine disability (HIT-6) through the mediator of changes in quality of life ( $b = -0.22$ , 95% CI  $[-0.31 - 0.12]$ ). The direct effect of intervention group on migraine disability was no longer significant ( $b = -1.28$ ,  $p = 0.42$ ) when changes in quality of life were included in the model (Fig. 1). These



**Fig. 1** Mediation analysis evaluating changes in quality of life scores as mediators of group differences in migraine disability. Direct and indirect effects of treatment group (X) on change in HIT-6, from baseline to 6 weeks post-intervention (Y) through change in quality of life (MSQL) from baseline to 6 weeks (M). \* $p < 0.05$ , \*\* $p < 0.01$ , \*\*\* $p < 0.001$

results suggest that the greater improvement in quality of life in the sEMG-BF group mediated the group difference in migraine disability.

## Discussion

Behavioral interventions are among the most important strategies in the prevention of migraine attacks. However, previous studies using biofeedback for the treatment of migraine have shown inconsistent results regarding reductions in migraine symptoms including difficulty in bringing significant relief to a sizeable number of headache patients (Andrasik, 2010). Therefore, the aim of this study was to evaluate the impact of a 6-week sEMG-BF intervention for episodic migraines. The main finding was that sEMG-BF significantly reduced the impact of migraines on the patients' daily life and disability. In addition, anxiety decreased, and quality of life and temporal summation improved selectively in the sEMG-BF group.

In a recent study we published, sEMG-BF for chronic low back pain produced significant changes in pain intensity and interference, as well as reductions in low back sensitivity (assessed by QST) (Lazaridou et al., 2023). The current virtual sEMG-BF intervention indicated a promising non-pharmacological therapy for reducing disability and anxiety in individuals with episodic migraines. In addition, migraine-related quality of life improved which is a significant aspect of patients living with migraines. Migraines can often last several days and disrupt individuals' ability to perform basic, daily tasks. In turn, this affects the physical, emotional, and social aspects of their life. We did not find a significant reduction in migraine days. A possible explanation for the improvements in quality of life, impact of migraines and disability (as opposed to migraine frequency)

but not the migraine days could be the length of the duration (e.g. 6 sessions) which might not have been enough to bring any changes.

Central sensitization appears to play a role in the pathophysiology of migraines (Onan et al., 2023). Further, signs of sensitization in the trigeminocervical area, as well as widespread sensitization have been reported interictally (Di Antonio et al., 2022). In the same study, increased widespread sensitization was positively correlated with the years lived with headache or the use of symptomatic drugs. This underscores the importance of interventions that have the potential of improving sensitization. Although we did not assess the trigeminocervical area, our results suggest treatment-related reductions in temporal summation in the interventional group. This could indicate that the mechanism of action of sEMG-BF in reducing migraine pain could extend beyond the reduction of muscle tension to include improvement of central sensitization. Therefore, further investigation is needed to assess this hypothesis.

Our main findings differ slightly from prior studies on sEMG-BF and tension-type headache outperforming a control intervention in reducing headache frequency and improving quality of life (Reeves, 1976) and reducing headache frequency and severity compared to a control intervention (Gauthier et al., 1994). There are several studies that explored the effectiveness of biofeedback for migraine (Nestoriuc & Martin, 2007; Vasudeva et al., 2003); recent systematic reviews also point out the effectiveness of psychological therapies for migraine management (Sullivan et al., 2016). Since individual differences in the report of pain and in the response to pain treatments are very large, some people may have different responses to the non-pharmacological pain treatments. Although the sEMG-BF intervention was not able to demonstrate changes in migraine frequency, migraine-related disability, and quality of life improved, both key areas that behavioral interventions target. Other strengths of the study include the virtual delivery of the intervention and increased access to biofeedback therapy in individuals that would otherwise have to commute to be able to receive biofeedback at a pain clinic.

Several limitations must be considered when interpreting the present findings. First, we were not able to include a sham sEMG-BF comparison group which limits our ability to control for non-specific treatment effects. However, there is significant difficulty of designing studies with credible sham sEMG-BF, which can be compared with real sEMG-BF, in assessing the efficacy of a defined biofeedback training protocol. Second, we utilized only two timepoints to assess changes in outcomes which might limit the observation of long-term therapy effects. Multiple endpoints could potentially have allowed the exploration of the effects of the sEMG-BF over time. Similarly, we utilized only 2 timepoints (5 days of baseline and 5 days of post intervention)

to assess migraine frequency via electronic diaries. It is possible that collecting daily diaries throughout the study could have provided more comprehensive information on migraine frequency, severity, and headache characteristics. Future studies may benefit from collection of an entire month of daily diaries at key study time points. Lastly, we measured temporal summation using mechanical probes on the fingers. Measurement in additional body areas including the trigeminocervical area could have potentially delivered more precise information on local and widespread sensitization. Despite these limitations, we demonstrated that 6 sessions of virtual sEMG-BF are able to bring significant changes in multiple clinical migraine outcomes.

Collectively, our findings demonstrate the feasibility of a 6-week intervention for episodic migraine management utilizing sEMG-BF. Future studies can also include other migraine samples, such as chronic migraines and add additional timepoints which can examine sustained effects over time and more granularly assess headache characteristics such as the frequency, severity, and spatial extent of migraines.

**Author Contributions** AL and MP conceived of the presented idea and research methodology. SM participated in the delivery of the intervention and data design. CB contributed to the design and implementation of the research. MC participated in the data collection and preliminary data analysis. RE was involved in planning, data analysis and interpretation and supervised the work.

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## Declarations

**Competing Interests** The authors declare no competing interests.

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