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Effect of progressive muscle relaxation on headache-related disability in patients with multiple sclerosis: A Quasi-Experimental Study

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Abstract

Background: Headache is common in multiple sclerosis and is associated with greater functional disability. We aimed to determine whether a structured progressive muscle relaxation (PMR) program reduces headache-related disability in multiple sclerosis.

Methods: We conducted a parallel-group, quasi-experimental pretest–posttest study at Multiple Sclerosis Society clinics in Zahedan, Iran (2023). Adults with MS and recurrent headaches were allocated to PMR (n = 30) or usual care (n = 30). The PMR intervention comprised three 20 - 30-minute group sessions on consecutive days plus daily home practice for six weeks; adherence was supported by weekly phone calls. The primary outcome was the Headache Disability Inventory (HDI; 0 - 88), measured at baseline and at 3-month follow-up. Analyses were conducted using SPSS version 24 and employed χ^2 tests and ANCOVA, adjusting for baseline HDI and disease duration ($\alpha = 0.05$).

Results: Sixty participants completed the trial (30 in the PMR group and 30 in the control group). The groups were comparable in age and gender at baseline; however, disease duration was significantly longer in the PMR group ($p = 0.014$). At the 3-month follow-up, HDI scores showed a significant decrease in the PMR group (21.5 ± 15.6) and a significant increase in the control group (45.1 ± 16.9), resulting in a significant between-group difference ($p < 0.001$). An analysis of covariance (ANCOVA), controlling for baseline HDI scores and disease duration, confirmed a significant treatment effect ($F = 25.07$, $p < 0.001$) with a large effect size (partial $\eta 2 = 0.305$).

Conclusion: A six-week progressive muscle relaxation program significantly reduced headache-related disability at 3-month follow-up in multiple sclerosis and appears to be a feasible, low-cost adjunct to routine care. Larger randomized trials with longer follow-up and objective adherence tracking are warranted.

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Highlights

What is current knowledge?

- Headache is common in multiple sclerosis (MS) and contributes substantially to functional disability; scalable non-pharmacological adjuncts are needed.
- Relaxation-based behavioral therapies, including progressive muscle relaxation (PMR), are guideline-supported in primary headache populations.
- Evidence specifically evaluating PMR in people with MS is limited, and real-world implementation data are sparse.

What is new here?

- A brief, nurse-led PMR program (With 6-week home practice) produced a significant reduction in Headache Disability Inventory at 3-month follow-up versus usual care in adults with MS.
- The between-group effect was large ($t=5.63$, $p<0.001$; partial $\eta^2 \approx 0.30$; Cohen's $d \approx 1.46$) and robust after adjustment for baseline Headache Disability Inventory and disease duration (ANCOVA).
- The intervention was low-cost and feasible for routine services; findings support larger randomized trials with longer follow-up and objective adherence tracking.

Introduction

Multiple sclerosis (MS) is a chronic, immune-mediated disease of the central nervous system characterized by focal inflammatory demyelination and neurodegeneration, typically beginning in early adulthood and affecting women more than men (1,2). Beyond motor and visual deficits, recurrent headaches - most commonly migraine and tension-type headache - affect a substantial proportion of people with MS and contribute to functional disability (3). Population-based and clinic studies suggest that roughly one-third of individuals with MS experience headache, with higher rates reported among younger women (4). Headache disorders are among the leading causes of years lived with disability globally, underscoring the need for scalable, safe, and acceptable non-pharmacological adjuncts that can be integrated into routine care without increasing medication burden (5).

Contemporary guidelines endorse behavioral therapies-such as relaxation training, biofeedback, and cognitive-behavioral therapy-as effective adjuncts in primary headache management (6). Within this spectrum, progressive muscle relaxation (PMR), which targets somatic tension and autonomic arousal through a structured sequence of contraction–release coupled with diaphragmatic breathing, is inexpensive, simple to teach, and amenable to home practice (7,8). Trials in primary headache populations (Randomized and quasi-experimental) indicate that PMR can reduce headache frequency and severity and attenuate disability; feasibility work has also explored digital delivery to enhance access (9). However, evidence specific to MS remains limited, leaving uncertainty about effectiveness, practicality, and effect size in this population and care context (10).

Mechanistically, PMR may modulate pain perception and stress reactivity by reducing muscle tension, normalizing breathing patterns, and influencing autonomic balance and cortical excitability - pathways relevant to migraine and central sensitization - and thus may plausibly impact headache-related disability (11). In pragmatic service settings, full randomization and blinding can be constrained by ethical and operational considerations; a quasi-experimental design with baseline-adjusted analyses offers a feasible approach while acknowledging residual selection and performance biases (12).

Accordingly, we aimed to evaluate whether a brief, nurse-led PMR program, reinforced by daily home practice over six weeks, reduces headache-related disability - measured by the Headache Disability Inventory - in adults with multiple sclerosis and recurrent headaches, hypothesizing greater improvement with PMR than with usual care after adjustment for baseline values.

Methods

Study design

This was a two-arm, quasi-experimental study with a parallel control group using a pretest-posttest design. Assessments were conducted at baseline and at 3 months after enrollment (≈6 weeks after completion of the 6-week home-practice phase).

Setting and study period

The study was conducted at the Zahedan Multiple Sclerosis (MS) Society and neurology clinics across Zahedan, Iran, in 2023 (May - August 2023).

Population and sampling

The study population comprised all patients with multiple sclerosis (MS) who were members of the Zahedan MS Society or attended collaborating neurology clinics in Zahedan during the study period. Using consecutive convenience sampling based on a priori eligibility criteria, potentially eligible adults were approached and enrolled until the target sample size (n = 60) was reached.

Eligible participants were ≥18 years of age, had neurologist-confirmed MS, reported recurrent headaches, and provided written informed consent. Individuals were not enrolled if they had a substance use disorder/addiction or an active psychiatric disorder that could interfere with the intervention or with valid outcome assessment. Participants were excluded post-enrollment if they withdrew consent, missed ≥1 training session, were unable to perform or maintain the technique for two consecutive days, experienced an MS relapse or clinical deterioration during follow-up, or initiated another headache-reduction intervention (Behavioral/educational/rehabilitative or similar) during the study.

Sample size

The required sample size was calculated using the two-sample means formula for quasi-experimental designs. Based on parameters from the study by Dhyani et al. (13) for headache-related disability, the following values were used: A two-sided significance level (α) of 0.05 (Z_1 - α/2 = 1.96), statistical power of 80% (β = 0.20, Z_1 - β = 0.84), and an effect size (d) of 0.80. Applying these values yielded a requirement of 25 participants per group. To account for an anticipated attrition rate of 15%, the sample size was adjusted to 30 participants per group, resulting in a total sample of 60 participants.

Allocation and masking

After eligibility confirmation and baseline assessment, participants were assigned 1:1 to the PMR intervention or usual care using a computer-generated random sequence (Simple randomization, no stratification or blocking). The sequence was produced by an independent researcher not involved in recruitment, intervention delivery, or outcome assessment and was encoded as "A" (PMR) and "B" (Control). Allocation concealment was ensured using sequentially numbered, opaque, sealed envelopes (SNOSE). Identical, tamper-evident envelopes were prepared off-site by the independent researcher according to the random sequence and stored securely. For each eligible participant, the enrolling nurse opened the next lowest-numbered envelope only after baseline data collection, thereby revealing the assignment.

Given the behavioral nature of the intervention, blinding of participants and facilitators was not feasible; outcomes were self-reported. To minimize analytical bias, group codes were masked to the data analyst until the primary analyses were finalized.

Participant information, consent, and baseline assessment

All eligible adults received standardized oral and written information about the study aims, procedures, potential benefits/risks, the voluntary nature of participation, confidentiality of data, and their right to withdraw at any time without penalty. Those who agreed provided written informed consent. Before any allocation or intervention, participants in both the intervention and control groups completed a demographic/clinical information form and the Headache Disability Inventory (HDI).

Intervention, control, and follow-up assessments

Participants allocated to the PMR group (Accompanied by a family caregiver) attended three nurse-led group sessions of 20 - 30 minutes on three consecutive days, during which Jacobson-based progressive muscle relaxation was taught under standardized conditions (Low ambient light, quiet room, semi-sitting posture, comfortable clothing). The protocol comprised guided tension-release across 14 muscle groups - face (Forehead, eyelids, jaw, lips), neck, fingers and palms, forearms, arms, shoulders, upper back, lower back, chest, abdomen, buttocks, thighs, calves, and soles - paired with diaphragmatic breathing (Eyes closed; five breathing cycles per block; ~4 s inhalation / ~6 s exhalation; ~5 s contraction then ~10 s relaxation per muscle group), ending with whole-body relaxation and five additional deep breaths. Session 1 included brief education on multiple sclerosis, primary/chronic headache, and an introduction to PMR; session 2 followed the scripted sequence with supervised practice; session 3 emphasized supervised repetition, Q&A, and troubleshooting.

After training, participants completed daily 20-minute home practice for 6 weeks; adherence was supported by weekly telephone follow-ups, and a Persian booklet plus an audio file (CD) was provided. Because training occurred in the presence of a caregiver, caregiver oversight of home practice was encouraged using a researcher-provided checklist. The control group received usual care during the study period; for ethical reasons, PMR materials were offered after completion of follow-up. The post-intervention assessment at 3 months consisted of repeating the Headache Disability Inventory (HDI) in both groups.

Instruments and outcome measures

1. Demographic/clinical form: Age, sex, marital status, occupation, education, residence, MS duration, disease stage/type, and headache type.
2. Primary outcome – Headache Disability Inventory (HDI): The HDI is a condition-specific instrument for assessing headache-related disability, developed in 1994 by Jacobson et al. It comprises 25 items across two domains - emotional and functional - and evaluates the extent to which headaches interfere with daily roles and emotional well-being. Responses are scored on a three-point scale (Yes = 4, Sometimes = 2, No = 0); thus, the total score is the sum of item scores, with higher scores indicating greater disability (14). The Persian version was culturally adapted and psychometrically evaluated by Jabbari et al. (2021) using a standard forward-backward translation procedure and expert review. During internal validation, several items were removed due to cross-loading/shared variance, yielding a total score range of 0 - 88 for the Persian version. Internal consistency (Cronbach's α) for the total scale has been reported in the range of 0.86 - 0.89 (15).

In both groups, baseline assessments included the demographic/clinical form and the HDI. The intervention was then delivered as described above, while the control group continued usual care. Follow-up at 3 months comprised repeat HDI administration. Confidentiality was maintained, and participants were informed that they could withdraw at any time.

Statistical analysis

Analyses were conducted using SPSS v24. Descriptive statistics (Mean, standard deviation, frequency, percentage) were used to summarize the data. Normality (e.g., Shapiro-Wilk) and homogeneity of variances (Levene's test) were examined. Between-group comparisons used independent-samples t-tests for continuous variables and χ^2 tests for categorical variables. We conducted the primary analysis using ANCOVA, specifying post-test HDI as the dependent variable and entering baseline HDI and disease duration as covariates; effects are reported as partial η^2 (≈0.01 small, 0.06 medium, 0.14 large), and statistical significance was set at two-sided $p < 0.05$.

Results

A total of 60 participants completed the study (30 PMR; 30 control). As shown in Table 1, the groups did not differ significantly at baseline in age (p = 0.057) or gender distribution (p = 0.531); however, MS duration was longer in the PMR group (7.0 ± 4.3 vs. 4.4 ± 3.4 years, p = 0.014). Baseline headache-related disability (HDI) was numerically lower in the PMR group (30.6 ± 19.8) than in controls (39.1 ± 19.7), but this difference was not statistically significant (p = 0.10). At 3 months, HDI decreased in the PMR group (21.5 ± 15.6) and increased in the control group (45.1 ± 16.9); the between-group difference was significant (t = 5.64, p<0.001). Within-group change was significant for PMR (Paired t = 2.62, p = 0.01) and not significant for controls (Paired t = 1.21, p = 0.23), as summarized in Table 2. In the adjusted analysis (ANCOVA with post-test HDI as the outcome and baseline HDI plus MS duration as covariates), the group effect remained significant and large (F = 25.07, p<0.001; partial η2 = 0.305). Adding within-group change lines for completeness, Table 3 displays the adjusted comparison alongside the paired pre-post results.

Table 1. Baseline demographic and clinical characteristics (PMR vs. Control)

Variable	PMR (n=30)	Control (n=30)	Test statistic	P-value
Age (Years) , Mean ± SD	35.2±6.4	31.9±6.6	t=1.94*	0.057
Female , n (%)	25 (83.3)	22 (73.3)	χ^{2}**	0.531
Male , n (%)	5 (16.7)	8 (26.7)	–	–
MS duration (Years) , Mean±SD	7.0±4.3	4.4±3.4	t=2.54	0.014
HDI (Baseline) , Mean±SD	30.6±19.8	39.1±19.7	t=1.67	0.100

Abbreviations: HDI: Headache Disability Inventory (0 - 88; higher = worse), PMR: Progressive Muscle Relaxation.
* Continuous: Independent-samples t-test.
** Categorical: χ2 test.

Table 2. Headache Disability Inventory (HDI) at baseline and 3 months - between-group and within-group results

Timepoint/Analysis	PMR Mean ± SD	Control Mean ± SD	Δ (PMR−Control) ± SD-pooled**	P-value
Baseline	30.6±19.8	39.1±19.7	−8.5 ± 19.75	0.10
3 months	21.5±15.6	45.1±16.9	−23.6 ± 16.26	< 0.001
Within-group change (Paired t*)	***Δ=−9.1 → t=2.62	Δ=+6.0 → t=1.21	–	**0.01** (PMR) / **0.23** (Control)

* Between-group at each timepoint: Independent-samples t-test.
Within-group change: Paired t-test (Pre vs. 3 months).
** SDpooled = pooled standard deviation for between-group difference.
*** Δ = "change". For the within-group row, Δ denotes post − baseline in that arm (Negative = improvement, because lower HDI indicates less disability). In the Δ (PMR−Control) column, Δ denotes the between-group mean difference at that timepoint (PMR mean - Control mean; negative = lower HDI in PMR).

Table 3. Post-intervention HDI -Adjusted Between-Group Comparison (ANCOVA) with baseline HDI and MS duration as covariates, plus within-group tests

Source / Analysis	SS***	df	**F	P-value	Partial η²
Group (PMR vs Control)	6704.21	1	F=25.07	< 0.001	0.305
***Baseline HDI (Covariate)**	316.85	1	F=1.18	0.281	0.014
***MS duration (Covariate)**	2.58	1	F=0.01	0.922	0.001
Residual	14977.31	56	–	–	–
Within-group change (Paired t)	–	–	PMR: t=2.62 Control: t=1.21	0.01 0.23	–

* ANCOVA outcome: Post-test HDI; covariates: Baseline HDI, MS duration.
** Within-group change lines show paired pre-post tests for each arm (Reported alongside the adjusted comparison for completeness).
Interpretation of partial η 2: ≈0.01 small; 0.06 medium; 0.14 large.
*** SS = Sum of Squares: A measure of variability attributable to each source in ANCOVA (e.g., Group, Covariates, and Residual). In general, SS Total = SS Model + SS Residual. Larger SS indicates that the term explains more variance in the outcome (Units: HDI score squared).

Discussion

In adults with multiple sclerosis and recurrent headaches, a brief, nurse-delivered progressive muscle relaxation (PMR) program supported by six weeks of structured home practice produced a greater reduction in headache-related disability at the 3-month follow-up compared with usual care.

The between-group post-test difference was significant, and the ANCOVA - adjusting for baseline HDI and disease duration - confirmed a robust treatment effect. The adjusted mean difference (PMR - control ≈ -22.5 points on the 0-88 scale) reflects a large effect size. Although an anchor-based minimum clinically important difference (MCID) for the Persian HDI in adults with multiple sclerosis has not yet been established, a change of this magnitude is plausibly meaningful for daily functioning and participation.

Ailani et al. (16) and Eigenbrodt et al. (17) recommend incorporating behavioral therapies - including relaxation training - into routine headache care to improve functional outcomes. Our findings are consistent with these recommendations by demonstrating a substantial reduction in disability through a low-risk behavioral adjunct. In a controlled trial, Meyer et al. (18) found that PMR reduced migraine burden and normalized contingent negative variation (CNV). Our results are aligned in both direction and clinical benefit: Supervised PMR supplemented by sustained practice improves headache outcomes. Any partial divergence is attributable to methodological differences; Meyer et al. examined electrophysiological changes in primary migraine, whereas our focus was functional disability (HDI) in a multiple sclerosis cohort.

Two pragmatic studies by Minen et al. - a randomized primary-care trial (2021) and a single-arm feasibility study (2019) - reported that smartphone-delivered PMR reduces migraine-related disability (19,20). Our findings correspond with their demonstrated clinical benefit and feasibility despite differences in delivery modality (In-person vs. digital). Where our effect size appears larger, probable contributors include a more clearly defined behavioral dose (Three supervised sessions plus six weeks of home practice), adherence support via weekly calls, and the use of disability as the primary outcome.

The systematic review by Noser et al. (21) and the narrative synthesis by Chen and Luo (22) conclude that digital behavioral and self-management interventions can reduce headache burden. Our results are consistent with this overall trend, though they also reflect the heterogeneity highlighted in those reviews (Platforms, adherence, and outcome measures). Several included studies reported modest or nonsignificant between-group differences; our comparatively larger effect likely reflects a more structured dose, adherence reinforcement, and the use of a disability-focused endpoint.

Turning to multiple sclerosis-specific literature, Abdollahi et al., Mrabet et al., and Gebhardt et al. document that headache - particularly migraine and tension-type headache - is common in MS and interacts with mood, autonomic reactivity, and musculoskeletal tension. Although these are not PMR trials, they support our rationale: Behavioral interventions that reduce tension and arousal and cultivate self-regulatory skills are particularly well-suited for individuals with MS (23-25).

1. Dose/structure: Three supervised sessions followed by six weeks of daily practice mirrors higher-dose behavioral regimens associated with stronger effects (18-21).
2. Endpoint selection: Prioritizing HDI captures role functioning and participation; behavioral therapies often yield larger gains on disability than on attack counts when coping, pacing, and self-efficacy improve.
3. Context and coaching: Weekly follow-up calls and caregiver presence during training likely sustained adherence, a known moderator in digital and hybrid programs (19-22).
4. The multiple sclerosis outpatient profile: Down-regulating autonomic arousal and muscle tension may produce spillover benefits across fatigue, mood, and activity management, amplifying perceived disability reductions. Taken together, these features help explain why our effects are comparatively large.

Beyond statistical significance, the magnitude of the adjusted difference and partial η2 suggests real-world relevance. PMR plausibly operates through convergent pathways - reducing skeletal-muscle tension, attenuating autonomic arousal, normalizing breathing patterns, and enhancing self-efficacy - consistent with models of migraine and central sensitization. Evidence that applied relaxation can modulate stress physiology (e.g., cortisol), as reported by Kische et al. (26), aligns with these pathways, although we did not collect biomarkers. Given the substantial global burden summarized by Stovner et al. (27), even moderate HDI reductions likely translate into improved daily functioning, social participation, and adherence to concurrent multiple sclerosis therapies.

We prespecified adjustment for baseline HDI and accounted for the baseline imbalance in disease duration; the group effect remained large and significant, and neither covariate independently predicted post-test HDI. Core assumptions (Normality, homogeneity of variances) were examined a priori. While additional sensitivity analyses (e.g., age, sex, headache subtype) would be informative in larger datasets, the present adjusted model offers a conservative estimate of the treatment effect within a quasi-experimental framework.

Strengths include a standardized, low-cost, nurse-led protocol; a clear supervised plus home-practice sequence; and explicit reporting of adjusted effect sizes. Limitations include quasi-experimental allocation without randomization (Risk of selection bias), lack of blinding of participants/providers/assessors (Performance and measurement biases), unmeasured confounders (e.g., analgesic use, mood fluctuation, treatment changes), absence of objective adherence logging (e.g., app-based minutes), single-center recruitment, and a 3-month assessment window that limits inferences about durability.

Limitations include baseline differences in age and MS duration, which reflect chance imbalance in a modest sample and do not, by themselves, indicate a failure of random allocation. Because the prespecified analysis could not be modified post hoc, residual confounding - particularly by age - cannot be fully excluded.

In sum, our nurse-led PMR program produced a large, adjusted reduction in headache-related disability at three months - findings that align with guideline-endorsed behavioral care (16,17), echo PMR-specific benefits in primary-headache trials (18-20), and are consistent with digital/self-management syntheses (21,22), while motivating definitive randomized studies to confirm effect size, durability, and value in real-world multiple sclerosis services.

Conclusion

In adults with multiple sclerosis and recurrent headaches, a brief progressive muscle relaxation program with 6-week home practice resulted in significantly lower headache-related disability at 3 months compared with usual care. The effect remained robust after adjustment for baseline Headache Disability Inventory and disease duration and was of large magnitude.

Given its low cost, safety, and ease of delivery by nurses, progressive muscle relaxation is a pragmatic adjunct to routine care that may translate into improved daily functioning, social participation, and treatment adherence. Embedding progressive muscle relaxation within Multiple Sclerosis services - and leveraging mobile/digital supports for training and follow-up - could enhance access and scalability.

Priorities include multicenter randomized controlled trials with extended follow-up, blinded assessment, objective adherence tracking, anchor-based determination of the Headache Disability Inventory minimum clinically important difference in Multiple Sclerosis, and comparative-effectiveness/cost-effectiveness studies contrasting progressive muscle relaxation with other behavioral packages to guide health-system decisions.

For practice, PMR appears feasible, safe, and scalable within multidisciplinary multiple sclerosis care when paired with six weeks of home practice and optional digital supports for training and follow-up. For research, priorities include multicenter randomized controlled trials with longer follow-up, blinded outcome assessment, objective adherence monitoring, prespecified stratification/adjustment (Disease duration; headache subtype/severity), comparative-effectiveness designs contrasting PMR with other behavioral packages, and cost-effectiveness analyses. Establishing an anchor-based MCID for the HDI in multiple sclerosis will enhance clinical interpretability.

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Ethical statement

This interventional, quasi-experimental study was reviewed and approved by the Ethics Committee of Zahedan University of Medical Sciences (IR.ZAUMS.REC.1402.439). All participants were adults (≥18 years) and provided written informed consent after receiving oral and written information about the study's aims, procedures, potential benefits/risks, and the voluntary nature of participation. Confidentiality was ensured by assigning coded identifiers, removing personal identifiers from analytic files, and storing study materials on secure, access-restricted systems. Participants were informed of their right to withdraw at any time without penalty and without any effect on their routine care. The study was conducted in accordance with the ethical principles of the Declaration of Helsinki and applicable local regulations. This quasi-experimental study was not prospectively registered; we acknowledge this as a limitation.

Conflicts of interest

The authors declare no competing interests.

Author contributions

A. S. and Z. P. Conceived and Designed the study; M. R. Acquired data; N. Y. and M-R. Analyzed and Interpreted data; A. S. and Z. P. Drafted the manuscript; All authors critically revised and approved the final manuscript.

Data availability statement

Data will be made available upon reasonable request, subject to review by the research team and consideration of data confidentiality.

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