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Effect of Structured Non-Pharmacological Counselling on Migraine-Related Disability and Quality of Life: A Randomised Interventional Cohort Study in a Tertiary Care Hospital.

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Abstract

Background

Migraine can cause substantial disability and reduce everyday functioning. Structured counselling on lifestyle and self-management may complement pharmacological treatment, but local evidence on its effects on disability and migraine-specific quality-of-life measures remains limited.

Objective

To assess the effect of structured non-pharmacological counselling added to pharmacological treatment on migraine-related disability and migraine-specific quality-of-life measures among adult patients attending a tertiary care hospital.

Methods

This Randomised Interventional Cohort Study included 60 adults with migraine recruited from the Neurology inpatient and outpatient services at KMCH, Coimbatore, from April to September 2026. Participants were allocated to a control group receiving pharmacological treatment alone (n = 30) or an intervention group receiving pharmacological treatment plus one-to-one structured counselling (n = 30). Allocation followed the recruitment week: weeks 1 and 3 were assigned to the intervention group and weeks 2 and 4 to the control group. Outcomes were assessed at baseline and 2 months using the Migraine Disability Assessment (MIDAS) and recorded MSQ V2.1 domain scores. Within-group change, between-group change, baseline-adjusted follow-up MIDAS, and a 50% MIDAS responder analysis were evaluated.

Results

Mean baseline MIDAS scores were 19.67 ± 7.55 in controls and 24.43 ± 17.38 in the intervention group ($p = 0.441$). Scores decreased in both groups at 2 months: by 2.63 ± 2.80 points in controls (19.67 ± 7.55 to 17.03 ± 6.04; $p < 0.001$) and by 5.67 ± 5.49 points in the intervention group (24.43 ± 17.38 to 18.77 ± 12.76; $p < 0.001$). The between-group difference in MIDAS reduction was significant (Mann-Whitney $U = 280.000$; $Z=-2.531$; $p = 0.011$), as was the group effect after baseline adjustment ($F(1,57) = 7.894$; $p = 0.007$). A reduction of at least 50% occurred in one intervention participant and no controls ($p = 1.000$). Several recorded MSQ-coded domains changed statistically, but their interpretation as validated MSQ V2.1 quality-of-life scores remains uncertain because scoring requires verification.

Conclusion

Adding structured non-pharmacological counselling to pharmacological care was associated with a greater reduction in MIDAS scores over 2 months than pharmacological care alone. The responder analysis was not significant, and quality-of-life findings should be interpreted cautiously until the MSQ scoring is confirmed.

Introduction

Migraine is a primary headache disorder characterised by recurrent headache attacks, often accompanied by nausea, photophobia, phonophobia, and interference with daily activity. Diagnostic classification is based on clinical features and the criteria set out in the International Classification of Headache Disorders, 3rd edition. [1] The burden of headache disorders remains substantial worldwide, with migraine contributing importantly to years lived with disability and functional impairment.[2] Current understanding of migraine involves altered sensory processing and trigeminovascular pathways; the condition should not be regarded as simply an isolated episode of head pain. [3]

Assessment of migraine management therefore needs to include the effect of the condition on functioning and quality of life in addition to headache symptoms. The Migraine Disability Assessment (MIDAS) questionnaire measures days of lost or reduced productivity attributable to headache across work or school, household, and social activities.[4] The Migraine-Specific Quality of Life Questionnaire (MSQ) assesses migraine-related restrictions, prevention of usual activities, and emotional effects. Its standard Version 2.1 scoring requires correct item mapping and rescaling before domain scores can be interpreted. [5, 6]

Pharmacological treatment remains central to acute and preventive migraine management, but education and behavioural or lifestyle strategies may be used as complementary measures. Lifestyle approaches can address regular meals and hydration, individual triggers, sleep routines, physical activity, relaxation, and self-management behaviours. [7] Trials and reviews have evaluated behavioural migraine management, smartphone-delivered behavioural therapy, progressive muscle relaxation, breathing-based practices, cognitive behavioural therapy, and mindfulness approaches, with effects varying by intervention and outcome. [8–13] Patient education has also been evaluated in primary care, while studies of yoga-based approaches provide additional context for multimodal behavioural care. [14, 15]

Because counselling is intended to be used alongside established medical treatment, it is important to evaluate it without implying that lifestyle advice replaces prescribed therapy. The present study examined a structured, multicomponent counselling package in adult migraine patients in a tertiary-care setting. MIDAS was used to quantify disability, and MSQ V2.1 domain data were collected to assess migraine-specific quality-of-life outcomes. The analysis compared pharmacological treatment alone with pharmacological treatment plus counselling over a 2-month follow-up period.

Aim and Objectives:

Aim

To assess the effect of non-pharmacological intervention on migraine-related disability and quality of life among patients with migraine.

Objectives:

- To evaluate changes in MIDAS and recorded MSQ V2.1 domain scores after structured non-pharmacological counselling, compared with pharmacological treatment alone.

Methods

Study design and setting:

The study was described as a **Randomised Interventional Cohort Study** and was conducted in the Neurology inpatient and outpatient services of Kovai Medical Center and Hospital (KMCH), Coimbatore, Tamil Nadu, India. The overall project period was April to September 2026.

Sixty participants were included in the final analysis.

Participants:

Eligible participants were adults aged 18 years or older presenting with migraine, willing to participate and provide informed consent, able to understand and complete the questionnaires, and attending the outpatient or inpatient services during the study period. Exclusion criteria were age below 18 years; severe neurological disorders such as epilepsy or brain tumours; serious psychiatric illness expected to affect questionnaire responses; unwillingness to participate; or inability to understand the counselling instructions or questionnaires.

Sample size and group allocation:

The sample-size calculation used expected proportions achieving a 50% reduction in MIDAS of 68.9% in the intervention group and 34.6% in the control group, based on Aguirrezabal et al. [14] with a 95% confidence level and 80% power; the estimated requirement was 29.4 participants per group; this was rounded to 30 per group (total n = 60). Allocation followed the weekly method used in the study: participants recruited in the first and third weeks were assigned to the intervention group, and those recruited in the second and fourth weeks were assigned to the control group.

Intervention and comparison:

The control group received pharmacological treatment alone. The intervention group received pharmacological treatment plus structured, one-to-one non-pharmacological counselling. Counselling covered lifestyle modification (regular sleep-wake timing, physical activity, hydration, and identification or avoidance of personal triggers), dietary advice (regular meal timing and discussion of commonly reported triggers, including caffeine, alcohol, and processed foods), stress-management and relaxation strategies, sleep hygiene, and demonstrated stretching and breathing exercises. Each counselling component was delivered in a one-to-one interaction lasting approximately 10–15 minutes per patient.

Outcome measures and follow-up:

Migraine-related disability was assessed using MIDAS. Migraine-specific quality-of-life outcomes were recorded under the Role Restrictive (RR), Role Preventive (RP), and Emotional Function (EF) domains associated with MSQ V2.1. Baseline assessments were compared with assessments obtained at 2 months. Clinical information was also collected from participant interviews, questionnaires, and medical records.

Ethics and trial registration:

The study protocol was approved by the Institutional Human Ethics Committee, KMCH Institute of Allied Health Sciences, Coimbatore (reference 26/IHEC/38; 22 July 2026). Written informed consent was obtained in English or Tamil, and participants were informed of the voluntary nature of participation, confidentiality, and their right to withdraw. The study registration was reported as Clinical Trials Registry-India (CTRI/2026/07/114543).

Statistical analysis:

Data were entered into Microsoft Excel and analysed using IBM SPSS Statistics. Continuous variables were summarised as mean ± standard deviation and categorical variables as frequency and percentage. Within-group baseline-to-follow-up MIDAS comparisons used the Wilcoxon signed-rank test; between-group MIDAS reduction was compared using the Mann-Whitney U test. Analysis of covariance (ANCOVA) compared follow-up MIDAS scores after adjustment for baseline MIDAS. Fisher exact testing was used for the proportion achieving a reduction of at least 50% in MIDAS. Recorded MSQ-coded domain values were compared within groups, and between-group comparisons of raw change scores used the Mann-Whitney U test. A p-value below 0.05 was considered statistically significant.

Results

Participant characteristics

All 60 participants included in the final analysis were distributed equally between the control and intervention groups (30 per group). The measured baseline demographic characteristics did not differ significantly between groups. Female participants accounted for 83.3% of the control group and 93.3% of the intervention group (Table 1).

Table 1
Baseline demographic characteristics.

Characteristic	Control (n = 30)	Intervention (n = 30)	p-value
Age, years, mean ± SD (range)	44.3 ± 14.3 (18–75)	43.6 ± 13.7 (23–75)	0.854
Body weight, kg, mean ± SD (range)	61.4 ± 10.3 (45–86)	63.5 ± 12.1 (43–99)	0.488
Sex, n (%)	Female: 25 (83.3) Male: 5 (16.7)	Female: 28 (93.3) Male: 2 (6.7)	0.424

Change in migraine-related disability:

MIDAS scores decreased from baseline to 2-month follow-up in both groups. In the control group, the mean score decreased from 19.67 ± 7.55 to 17.03 ± 6.04, a mean reduction of 2.63 ± 2.80 points (Wilcoxon Z=-3.784; p < 0.001). In the intervention group, the score decreased from 24.43 ± 17.38 to 18.77 ± 12.76, a mean reduction of 5.67 ± 5.49 points (Wilcoxon Z=-4.635; p < 0.001). The between-group comparison of MIDAS reduction was significant (Mann-Whitney U = 280.000; Z=-2.531; p = 0.011; Table 2).

Table 2
MIDAS values and between-group analyses. ANCOVA was adjusted for baseline MIDAS; Levene's test p = 0.259; partial eta-squared = 0.122.

MIDAS outcome	Control (n = 30)	Intervention (n = 30)	Test/result
Baseline, mean ± SD	19.67 ± 7.55	24.43 ± 17.38	Between-group p = 0.441
2-month follow-up, mean ± SD	17.03 ± 6.04	18.77 ± 12.76	—
Mean reduction ± SD	2.63 ± 2.80	5.67 ± 5.49	Mann-Whitney U = 280.000; Z=-2.531; p = 0.011
Within-group Wilcoxon test	Z=-3.784; p < 0.001	Z=-4.635; p < 0.001	Both within-group changes significant
Adjusted follow-up mean	18.760 (95% CI 17.900-19.619)	17.040 (95% CI 16.181–17.900)	ANCOVA group effect: F (1,57) = 7.894; p = 0.007

The ANCOVA model was statistically significant (F (2,57) = 506.562; p < 0.001). Baseline MIDAS was a significant covariate (F (1,57) = 1004.839; p < 0.001), and the adjusted group effect was significant (F (1,57) = 7.894; p = 0.007). The adjusted follow-up mean was 1.72 points lower in the intervention group

than in the control group. In the responder analysis, no control participant achieved a reduction of at least 50% in MIDAS, compared with one participant (3.3%) in the intervention group; Fisher exact p = 1.000.

MSQ-coded domain results:

The recorded domain values changed from baseline to follow-up in both groups (Table 3). In the control group, the only statistically significant within-group change was in Role Preventive (10.07 ± 2.02 to 9.00 ± 1.44; p = 0.033). Role Restrictive (18.13 ± 3.34 to 17.23 ± 2.49; p = 0.102) and Emotional Function (9.23 ± 1.70 to 9.17 ± 1.53; p = 0.889) did not show statistically significant within-group changes. In the intervention group, statistically significant pre-post changes were reported for Role Restrictive (18.10 ± 5.01 to 15.60 ± 3.16; p < 0.001), Role Preventive (10.07 ± 2.24 to 8.67 ± 1.65; p = 0.003), and Emotional Function (9.57 ± 2.54 to 8.67 ± 1.52; p = 0.016).

Table 3
Recorded MSQ-coded domain values (mean ± SD) and within-group p-values. Score direction and item mapping require verification before clinical interpretation.

MSQ-coded domain	Control baseline	Control follow-up	Control p	Intervention baseline	Intervention follow-up	Intervention p
Role Restrictive (RR)	18.13 ± 3.34	17.23 ± 2.49	0.102	18.10 ± 5.01	15.60 ± 3.16	< 0.001
Role Preventive (RP)	10.07 ± 2.02	9.00 ± 1.44	0.033	10.07 ± 2.24	8.67 ± 1.65	0.003
Emotional Function (EF)	9.23 ± 1.70	9.17 ± 1.53	0.889	9.57 ± 2.54	8.67 ± 1.52	0.016

Table 4
Between-group comparison of recorded MSQ-coded domain change scores.

MSQ-coded domain	Control raw change, mean ± SD	Intervention raw change, mean ± SD	Mann-Whitney U	p-value
Role Restrictive (RR)	-0.90 ± 3.01	-2.50 ± 3.88	625.5	0.009
Role Preventive (RP)	-1.07 ± 2.41	-1.40 ± 2.27	496.5	0.493
Emotional Function (EF)	-0.07 ± 2.12	-0.90 ± 1.97	539.5	0.183

A weak correlation was observed between MIDAS reduction and Role Restrictive change (Spearman rho=-0.258; p = 0.046); correlations with Role Preventive (rho=-0.148; p = 0.258) and Emotional Function

(rho=-0.118; p = 0.369) were not statistically significant. These correlations are reported descriptively because the domain scoring direction remains unresolved.

Discussion

In this single-centre study of 60 adults with migraine, both groups demonstrated lower MIDAS scores at the 2-month assessment. The group that received structured non-pharmacological counselling in addition to pharmacological treatment showed a greater mean reduction in MIDAS score than the group that received pharmacological treatment alone. The between-group comparison of MIDAS change was statistically significant (p = 0.011), and a significant group effect remained after adjustment for baseline disability using ANCOVA (p = 0.007). These findings supported an association between the addition of structured counselling and a greater reduction in migraine-related disability during the observed study period.

The findings were consistent with the broader rationale for incorporating behavioural and lifestyle support into migraine management, although the intervention used in the present study consisted of multiple components and the contribution of any individual component could not be isolated. Behavioural approaches to migraine management have been evaluated in combination with pharmacological treatment, while smartphone-based behavioural therapy and progressive muscle relaxation have provided examples of structured self-management strategies. [8–10]

Randomised studies evaluating yoga-based breathing and relaxation, mindfulness-based stress reduction, and patient education have also demonstrated beneficial effects on selected headache-related outcomes; however, the magnitude and consistency of benefit have varied according to the intervention and outcome assessed. [11–14].

In the present study, the mean reduction in MIDAS score was 5.67 points in the intervention group and 2.63 points in the control group. However, responder analysis did not demonstrate a statistically significant difference between groups. Only one participant in the intervention group and none in the control group achieved a reduction of at least 50% in MIDAS score (Fisher’s exact p = 1.000).

Therefore, the continuous-score findings should not be interpreted as evidence of a significant increase in the proportion of clinically meaningful responders. The difference between the significant comparison of mean or ranked change and the non-significant responder analysis was plausible because the two analyses evaluated different aspects of the outcome distribution, and only one participant met the predefined responder threshold.

The quality-of-life findings required particular caution. Although changes were observed across the three MSQ domains, the recorded domain scores decreased in the intervention group. Under the standard MSQ V2.1 scoring system, domain scores are conventionally rescaled such that higher scores represent better migraine-specific quality of life. [5, 6]

Therefore, the item mapping and scoring algorithm required verification before the results could be interpreted definitively. As the scoring direction had not been confirmed, the observed decreases were not interpreted as improvements in quality of life. The statistically significant between-group difference was limited to the raw Role Restrictive change ($p = 0.009$), whereas no significant between-group differences were observed for Role Preventive or Emotional Function. The administered questionnaire and scoring workbook therefore required verification before the findings were reported as validated MSQ V2.1 outcomes.

The counselling intervention addressed migraine triggers, regular meals, adequate hydration, sleep, physical activity, relaxation, and self-management strategies. These components had a plausible supportive role in migraine management; however, the strength of evidence differed between individual components and should not be generalised across all lifestyle measures. Reviews have described lifestyle modification as an adjunctive strategy in migraine management, while evidence concerning hydration, sleep interventions, and aerobic exercise has varied in study design, intervention intensity, and certainty.[7, 18–20] Previous studies evaluating patient education and yoga-based interventions also provided supportive context, although differences in patient populations, settings, intervention intensity, duration, and outcome definitions limited direct numerical comparison with the present findings. [14, 15]

From a pharmacy-practice perspective, structured counselling provided a defined framework for addressing lifestyle modification and self-management while continuing appropriate pharmacological treatment. Professional statements have recognised the potential role of pharmacists in headache education, appropriate medicine use, patient support, and referral within structured healthcare services. [17]

Nevertheless, the present study did not establish which individual counselling component contributed most to the observed MIDAS change and did not evaluate effects on healthcare utilisation or cost-effectiveness.

The findings should also be interpreted in the context of the study design. The study involved a relatively small, single-centre sample with predictable week-based group allocation, no blinding, self-reported outcome measures, and the possibility of changes in concomitant pharmacological treatment during follow-up. These factors may have introduced bias and limited the ability to establish a causal relationship between counselling and the observed improvement in disability. In addition, MIDAS assesses disability based on a 3-month recall period, whereas the present study used a 2-month follow-up. Consequently, the baseline and follow-up recall periods overlapped, which may have influenced the interpretation of change over time. The allocation procedure and the difference between the MIDAS recall period and follow-up duration therefore required transparent consideration when interpreting the study estimates.

Overall, the present study demonstrated that the addition of structured non-pharmacological counselling to pharmacological treatment was associated with a significantly greater reduction in migraine-related

disability than pharmacological treatment alone over the observed 2-month period. However, the absence of a significant responder difference, uncertainty regarding MSQ scoring, the multicomponent nature of the intervention, and the limitations of the study design indicated that the findings should be interpreted as supportive rather than definitive evidence of treatment effectiveness.

Further studies with larger samples, concealed and less predictable allocation, longer follow-up, standardised intervention components, verified MSQ scoring, and assessment of healthcare and economic outcomes would be valuable for confirming and extending these findings.

LIMITATIONS

The study had several limitations. It was a **single-centre, hospital-based study** conducted in a tertiary-care hospital, limiting generalisability to other healthcare settings and populations. The **small sample size of 60 participants (30 per group)** limited statistical power for secondary outcomes and subgroup analyses. **Predictable week-based allocation** may have introduced selection or allocation bias. The **2-month follow-up** limited assessment of long-term sustainability of treatment effects. The study was **non-blinded**, which may have introduced performance, reporting, or detection bias. As the intervention was **multicomponent**, the individual or synergistic effects of each component could not be determined. **MIDAS and MSQ were self-reported measures**, making them susceptible to recall and reporting bias. Changes in **concomitant pharmacological treatment** were not completely restricted and may have confounded the observed outcomes. The intervention was delivered by a **single investigator**, limiting assessment of inter-provider variability and generalisability to other healthcare professionals or practice settings. The **MIDAS 3-month recall period did not correspond with the 2-month follow-up**, resulting in overlapping assessment periods that may have affected interpretation of temporal changes. **MSQ scoring required verification of item mapping and scoring algorithms**, limiting definitive interpretation of changes in migraine-specific quality of life. Finally, the study did not assess **cost-effectiveness, healthcare utilisation, or resource requirements** associated with integrating structured non-pharmacological counselling into routine migraine management.

Conclusion

Among 60 adults with migraine, structured non-pharmacological counselling added to pharmacological treatment was associated with a greater reduction in MIDAS scores at 2 months than pharmacological treatment alone, with a significant between-group change comparison ($p = 0.011$) and baseline-adjusted group effect ($p = 0.007$). The proportion achieving a 50% or greater MIDAS reduction did not differ significantly between groups ($p = 1.000$). Recorded MSQ-coded domain changes cannot yet support a reliable conclusion about improved quality of life because the score mapping and direction require confirmation. These findings support further evaluation of structured counselling in larger, multicentre studies with a clear allocation process, verified outcome scoring, and follow-up measurements aligned with the instruments' recall periods.

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