

Study Details	Patients	Interventions	Outcome measures	Effect size	Comments
<p>Author & Year: John et al, 2007⁴⁰¹</p> <p>Study design: RCT</p> <p>Setting: Health care clinic</p> <p>Duration of follow-up: 3 months</p>	<p>Patient group: Patients with migraine without aura.</p> <p>Inclusion criteria: 20-25 years. Willing to be randomised and attend sessions regularly. No prophylactic medication for the previous 2 months. 4-15 (and no more) attacks a month. Literate in English. Included patients with mild depression and anxiety.</p> <p>Exclusion criteria: >15 attacks/month. Co-morbid condition. Unstable medical/psychiatric condition (including those on antidepressants, pregnant women headaches related to diet /allergy or menstruation). Receiving other treatments for migraine. Participated in yoga program in the 6 months prior to enrolment in study. Those unwilling to participate and practice regularly.</p> <p>All patients N: 72 Age (mean): NR Drop outs: 7</p>	<p>Group 1- yoga Treatment phase 12 weeks. Patients taught a self administered set of practises under the guidance of a trained yoga therapist. Participants were given handouts of techniques to practice during the prodromal stage of migraine when possible. Patients told not to practice during headache, resolution, and postdrome stage.</p> <p>An integrated approach to yoga therapy was used including yoga postures, breathing practices yoga breathing, relaxation practices and meditation for 5 days per week for 60 minutes.</p> <p>Kriya taught once a week with deep relaxation</p> <p>Group 2 –self care Treatment phase 12 weeks</p>	<p>Mean change in migraine frequency ± SD (days) Per month</p> <p>Mean change in migraine intensity ± SD (McGill Pain Questionnaire) 0-10 numerical scale</p> <p>Mean use of acute pharmacological treatment ± SD (prescribed by neurologist but not use of any other symptomatic medication)</p>	<p>Baseline Group1: 10.22 ± 2.59 Group 2: 9.82 ± 2.31 Follow up Group 1: 4.56 ± 1.79 Group 2: 10.18 ± 2.14 p value: 0.001</p> <p>Baseline Group1: 2.94 ±0.91 Group 2: 3.33 ±0.92 Follow up Group 1: 1.69 ±0.47 Group 2: 3.97 ±0.58 p value: 0.001</p> <p>Baseline Group1: 2.69 ± 1.31 Group 2: 2.91 ± 1.13 Follow up Group 1: 1.37 ± 1.01 Group 2: 3.94 ± 0.94 p value: 0.001</p>	<p>Funding: NMP medical research institute Jaipur Rajasthan, India</p> <p>Limitations: Allocation concealment NR. Participants and investigators not blinded. Participants in the intervention group charged registration fee to participate. Mean headache frequency is patient reported outcome. Migraine frequency: baseline doesn't state whether this is no. of attacks per week in the previous month.</p> <p>Additional outcomes: Migraine duration Hospital anxiety depression scale</p> <p>Notes: * Average age is given for the patients who completed the study excluding drop outs.</p> <p>A random number generator (version1) computer programme was used for randomisation.</p> <p>Patients in the intervention group</p>

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	<p>Group 1 mean (SD) N: 36 Age (mean): 34.38 (8.74)* Drop outs: 4 Male/ female: 10/22 Non prescribed medication: 2.69 (1.31) Average pain: 7.32 (1.03) Frequency of attacks in last month: 10.22 (2.59)</p> <p>Group 2 mean (SD) N: 36 Age (mean): 34.21 (9.66)* Drop outs: 3 Male/ female: 6/27 Non prescribed medication: 2.92 (1.13) Average pain: 7.62 (0.91) Frequency of attacks in last month: 9.82 (2.31)</p>	<p>Participants contacted 1 per month for an educational session on migraine, its types, causes and triggering factors given by a healthcare provider. Also handouts provided with info on self care strategies such as avoiding triggers, life style modifications in diet and sleep. Patients asked to make entries in a headache diary.</p>			<p>were charged a registration fee and asked to acquire the necessary equipment</p> <p>Patients allowed to take similar acute medications prescribed by neurologists. Not to use other symptomatic medications including over the counter drugs.</p> <p>Outcome data calculated on ACA basis- Group 1 n=32, Group 2 n=33</p>

Abbreviations: NR=not reported, NA=not applicable, M/F=male/female, N=total number of patients randomised, SD=Standard deviation, SE=Standard error, ITT=Intention to treat analysis

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<p>Author & Year: Varkey et al, 2011⁸¹⁹</p> <p>Study design: RCT</p> <p>Comparison: Exercise vs topiramate vs relaxation</p> <p>Setting: Specialist headache clinic, Sweden</p> <p>Duration of follow-up: 3 and 6 months after treatment.</p>	<p>Patient group: Patients with migraine recruited from newspaper adverts and headache clinic.</p> <p>Inclusion criteria: Aged 18-65; migraine with or without aura according to ICHD-II criteria; frequency of 2-8 attacks per month; had migraine for at least 1 year before participating in the study and before the age of 50.</p> <p>Exclusion criteria: Interval headaches not distinguishable from migraine; medication overuse headache; regular exercise (once or more per week during the 12 weeks prior to the study); earlier practice of relaxation, pregnancy, breastfeeding or use of daily migraine prophylaxis in the 12 weeks prior to the study; inability to understand Swedish; use of antipsychotic or antidepressive medication in the 12 weeks prior to the study; drug or alcohol abuse;; topiramate intolerance.</p> <p>All patients N: 91 Age (mean): 44.4 (11.3) Drop outs: 44</p>	<p>Group 1 - Exercise Trained with a registered physiotherapist for 40 minutes three times/ week. Exercise programme based on indoor cycling and the rate of perceived exertion was used to set the intensity of the exercise programme. Training session included 15 min warm up, 20 min exercise programme, 5 min cool down. There was opportunity to discuss the exercise programme with the therapist after the session. If participant was absent they exercised at home or a local gym. All forms of continuous aerobic exercise were then accepted, participants instructed to reproduce same intensity and duration of exercise used in the programme. Participants who exercised 1/ week at clinic and >2/ week were considered adhering to treatment.</p> <p>Group 2 - Topiramate Visited neurologist before starting a course of topiramate. Dosage was increased by 25mg/week until the dosage</p>	<p>Responder rate (50% reduction in migraine attack frequency) at 3 months</p> <p>Change in patient-reported migraine days (n/month, least squares mean (SE)) **[SD] Change from baseline at 3 months</p> <p>Change in patient-reported migraine frequency (attacks†/month, least squares mean (SE)) **[SD] Change from baseline at 3 months</p> <p>Change in patient-reported migraine intensity (VAS 0-100, least squares mean (SE)) **[SD] Change from baseline at 3 months</p> <p>Headache specific QoL Swedish version of</p>	<p>Group 1: 9/30 Group 2: 8/31 Group 3: 7/30 p value: NR</p> <p>Group 1: -2.23 (0.55) **[3.01] Group 2: -2.08 (0.54) **[3.01] Group 3: -1.47 (0.55) **[3.01] p value: NR</p> <p>Group 1: -0.98 (0.58) **[1.53] Group 2: -0.68 (0.28) **[1.56] Group 3: -0.94 (0.28) **[1.53] p value: NR</p> <p>Group 1: -7.1 (3.5) **[19.17] Group 2: -13.7 **[18.93] Group 3: -5.1 (3.5) **[19.17] p value: NR</p> <p>Group 1: 5.0 (2.3) **[12.60] Group 2: 2.4 (2.3)</p>	<p>Funding: Swedish research council, Gothenburg research and development council, Swedish association of physiotherapists, Renee Eander fund, Neurological research foundation, Olle Engkvists Byggmastare foundation, Glaxosmithkline, Astrazeneca.</p> <p>Limitations: Single blind (evaluator only). >10% dropped out of study at 3 month follow up, but similar in all groups. Unclear for how long patients trained with a physical therapist-reads as though only at the beginning then participant took control of exercise programme for at least 2 of the 3 sessions per week. Study based on a self selected sample. Patients who already undertook regular exercise were excluded.</p> <p>Additional outcomes: Body weight VO₂max Data at 6 months</p>

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	<p>Group 1 – Exercise N: 30 Age (mean): 47 (10.8) Drop outs: 8 at 3 months, 5 withdrew (1 lack of time, 4 non-compliance) 3 no data, 14 at 6 months. M/F: 5/ 25 Disease duration (years): 28.8 (11.0) Migraine frequency (days/month): 7 (3.8) Migraine frequency (attacks[†]/month): 4.3 (2.0) Frequency of headache medication used (doses/month): 6.9 (4.1) Intensity of pain (median, IQR): 50 (26-64) MSQoL (median, IQR): 60 (43-77)</p> <p>Group 2 - topiramate N: 31 Age (mean): 44.4 (9.2) Drop outs: : 11 at 3 months, 10 withdrew (7 refused drugs, 3 adverse events) 1 no data, 14 at 6 months. M/F: 2/29 Disease duration (years): 25.1 (11.4) Migraine frequency (days): 7.5 (3.9) Migraine frequency (attacks): 3.6 (1.6)</p>	<p>reached the highest dose that the individual could tolerate, maximum of 200mg/day. Allowed to call neurologist any time of day during the treatment period to book a scheduled visit if needed. At least 1 follow up visit was scheduled. Adherence defined as using the medicine for > 2 months in accordance with prescription and was measured using self reports.</p> <p>Group 3 – Relaxation Scheduled individual appointment with a registered physiotherapist once a week. The programme was based on common forms of relaxation, breathing and stress-management techniques (described by Larsson and Andrasik) and includes a series of 6 exercises, each of which is based on the one before. Each lasted between 5-20minutes and verbal and written information was given before the introduction of a new relaxation exercise. After each session there was an opportunity to discuss their progress with the</p>	<p>the migraine specific QoL questionnaire [Scale 1- 100] least squares mean (SE) **[SD]</p> <p>Use of acute pharmacological treatment (doses/ month) least squares mean (SE) **[SD]</p> <p>Incidence of adverse events (%) NB none were serious</p>	<p>**[12.81] Group 3: 3.1 (2.4) **[13.15] p value: NR</p> <p>Group 1: -2.72 (0.55) **[3.01] Group 2: -2.71 (0.54) **[3.01] Group 3: -2.84 (0.54) **[2.96] p value: NR</p> <p>Group 1: 0/30 Group 2: 3/31* Group 3: 0/30 p value: NR</p>	<p>Notes: ANCOVA used to adjust for baseline differences (these results are reported) ** SD calculated by NCGC</p> <p>ITT analysis undertaken with last observation carried forward for missing data.</p> <p>*3 patients state AE as reason for withdrawal. 8 patients reported AEs in total. No serious AEs reported.</p> <p>Participants randomised after the baseline period. Randomisation by independent person by a lottery method.</p> <p>[†]Migraine attack defined as concomitant days with migraine headache and distinct attacks were counted if separated by ≥24 hours.</p>

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	<p>Frequency of headache medication used (doses): 7.1 (5.3)</p> <p>Intensity of pain (VAS) (median, IQR): 40 (29-58)</p> <p>MSQoL (median, IQR): 60 (48-73)</p> <p>Group 3 – relaxation (N=30) N: 30 Age (mean): 41.5 (11.4) Drop outs: 7 at 3 months, 4 withdrew (2 not satisfied, 1 lack of time, 1 unexplained) 1 no data, 16 at 6 months. M/F: 2/28 Disease duration (years): 22.2 (11.8) Migraine frequency (days/month): 7.6 (3.8) Migraine frequency (attacks⁺/month): 4.2 (1.6) Frequency of headache medication used (doses/month): 6.5 (4.6) Intensity of pain (median, IQR): 39 (26-55) MSQoL (median, IQR): 58 (51-67)</p>	<p>physiotherapist. Between sessions they practised at home every day with a CD. Adherence was defined as participating in 6 or more sessions at the clinic. Verbal confirmation of practice at home was also required.</p> <p>All groups 4- 12 week baseline period, followed by 12 week treatment period. All participants were allowed to contact the physiotherapist or neurologist with questions (telephone or visit). No restriction was made on the use of concomitant acute medication.</p>			

Abbreviations: NR=not reported, M/F=male/female, N= number of patients, SD=Standard deviation, SE=Standard error, ITT=Intention to treat analysis, CI=confidence interval, IQR=Interquartile range, MSQoL=Migraine specific quality of life questionnaire, VAS=visual analogue scale, ICHD=International Classification of Headache Disorders