CHAPTER VI
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This chapter presents the summary of major findings and the conclusions drawn from the research.

SUMMARY OF MAJOR FINDINGS OF THE STUDY

The present study evaluated the effectiveness of a multicomponent intervention in clinical outcomes of patients with migraine. The multicomponent intervention included behavioral lifestyle modification program and sessions of pranayama (a form of breathing exercise). Eighty patients diagnosed with migraine were randomized into intervention and control arm. The outcomes were evaluated over a period of 24 weeks. The study participants who received the multicomponent intervention along with routine care demonstrated statistically & clinically significant improvements in outcomes such as, quality of life, disability, frequency of migraine, duration of migraine and intensity of migraine. The key findings of the study are summarized below.

Socio-demographic characteristics of study participants.

- The majority of the study participants were in the age group of 18-30 years (43.8%). There was a preponderance of females in the study with 82.5 % of participants being females in intervention and control arm. Most of the participants had a graduate (35 %) or higher secondary level education (32.5%). Seventy percentage of study participants were residing in rural areas.

- Fifty-six participants (twenty-eight from each arm) were diagnosed to have migraine within a period of 1-10 yrs. There were only 15 (18.8%) participants who were consuming a vegetarian diet. A family history of migraine was present in 80% of participants in the intervention arm and 70% in control arm.

Clinical characteristics of study participants.

- The number of monthly headache episodes ranged from 1-10 in 51.3 % and 11-20 in 48.8% of the study participants. Duration of migraine ranged from 5-11 hrs in 43.8% and 12-24 hrs in 37.5% of participants. A significant proportion
of participants (96.3%) reported experiencing severe pain intensity. Headaches were located predominantly over ‘both the temples’, as reported by 43.8%. ‘Throbbing’ kind of pain was experienced by 95% of participants in intervention and 92.5% of participants in control arm.

- The major symptoms experienced by migraineurs were reported to be, nausea (98.8%), photophobia (87.5), phonophobia (86.3), and vomiting (58.8%). It was interesting to note that 22.5% of the study participants experienced gastritis or diarrhoea during a migraine attack.

- The common pain relieving strategies employed by migraineurs were ‘rest’ (80%), and ‘quiet & darkness’ (70.0%). When asked about how migraine affects their quality of life, participants who responded, “Quite a lot” constituted 61.3% of the study sample.

Quality of Life of Migraineurs

- Migraine Specific Quality of Life Questionnaire (MSQ) was used to evaluate the QOL of patients with migraine. The overall baseline mean (SD), [95 % CI] quality of life score was 61.95 (24.71), [56.45, 67.45] which was against an overall possible score of 300. The domain wise mean (SD) scores were; Role function Restrictive - 18.14 (10.29), Role function Preventive - 23.06 (11.37) and Emotional function - 20.75 (12.09).

- The intervention arm had a slightly better QOL score at baseline than the control [Intervention M(SD) 67.43 (27.56) vs. Control M(SD) 56.47 (20.38)]. The scores indicate that migraine can have incapacitating effects on various domains of an individual’s functioning and can result in poor quality of life of migraineurs.

Disability of Migraineurs

- Disability of the migraineurs was assessed using the Headache Impact Test (HIT). The mean (SD) pre-test scores of intervention and control arms were 70.50 (4.05) and 71.80 (3.03) respectively.
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- The overall mean (SD) scores for HIT was 71.15 (3.62). Among all participants, only one person (1.3%) had a substantial impact of migraine, whereas, 79 (98.8), had a severe impact.

Pain Scores of Migraineurs

- **Frequency of migraine:** The mean (SD) frequency score at baseline was 10.85 (4.01). The mean frequency of 10.85, denotes that, on an average a migraineur experience headache on almost ‘one-third of the days’ in a one month cycle. The control group had a slightly higher mean (SD) frequency than the intervention group [10.15 (4.19) vs. 11.55 (3.76)].

- **Duration of migraine:** The baseline mean duration scores were 19.56 hrs (overall), 20.40 hrs (intervention) and 18.73hrs (control) respectively.

- **Intensity of migraine:** A mean pain intensity score of 8.61 on a 0-10 numerical pain scale, denotes that migraineurs experience severe pain during the attacks. The pain intensity scores of intervention arm and control arm were almost similar (mean score 8.80 vs. 8.43).

Effectiveness of intervention on the ‘quality of life.’

- The baseline mean (SD) QOL scores of intervention and control arm were, 67.43 (27.56) and 56.47 (20.38) respectively. Over a period of 24 weeks, both the intervention and control arm demonstrated considerable improvements in QOL mean scores (67.43- 270.82 and 56.46 – 187.01 respectively).

- Repeated Measures ANOVA showed that there was a significant effect of time (within group) on quality of life scores of migraineurs [ F (2.29, 179.24) = 731.28, P < 0.001]. In comparison to the control arm, statistically significant improvements in QOL scores were obtained among participants in the intervention arm [F (1, 78) = 144.10, p < 0.001].

- The interaction effect (time X group) was also significant [F (2.29, 179.24) = 37.31, p < 0.001], indicating that the groups changed over time, and the change was different across the groups. Significant between group effects were also observed in RR, RP, and EF domains of Quality of life (P<0.05), indicating that
the intervention was not only effective in improving the overall quality of life scores but also in improving the domain-wise quality of life of participants in the intervention arm.

**Effectiveness of intervention on the ‘disability.’**

- During the baseline assessment, mainstream of participants in the intervention arm (n=39) and in control arm (n=40) reported having ‘Severe impact.’ During the first post-test majority of the patients (in both the arms) described that migraine results in substantial or severe impact in their day today functioning. Over a period of 24 weeks, both the intervention and control arm subjects demonstrated considerable reductions in the mean disability scores (70.50 – 42.85 and 71.80 – 56.62 respectively).

- Repeated Measures ANOVA showed that in comparison to the control arm, statistically significant reduction in disability scores was obtained among participants in the intervention arm \( [F (1, 78) = 131.25, p < 0.001] \). A significant interaction effect (time X group) was also observed \( [F (2.36, 184.48) = 50.18, p < 0.001] \). In comparison to the routine care the multicomponent intervention was effective in reducing the disability levels of patients with migraine.

**Effectiveness of the intervention on the frequency of migraine.**

- The mean (SD) frequency scores of the participants in the intervention arm decreased to 1.30 (1.04) after 24 weeks from a baseline value of 10.15 (4.19). In the control arm, the mean scores of frequency decreased to 5.03 (2.64) from a baseline value of 11.15 (3.76).

- RM ANOVA verified that there was a significant time effect, and can be interpreted as participants in both the arms had reduction in migraine frequency scores over time \( [F (1.40, 109.94) = 259.91, P < 0.001] \). The interaction effect (time X group) was significant \( [F (1.40, 109.94) = 7.01, p < 0.001] \), indicating that the multicomponent intervention reduced the frequency of migraine among participants in the intervention arm over 24 weeks.
Effectiveness of the intervention on duration of migraine.

- At the baseline, participants in the intervention and control arms had near similar mean (SD) scores on the duration of migraine (in hours) 20.40 (11.29) vs. 18.73 (10.72). However, during the first (4 weeks), second (12 weeks) and third (24 weeks) post-test evaluations, the mean (SD) duration scores in the intervention arm [ 7.85 (4.26), 4.13 (2.19) and 2.65 (2.13) respectively] were lower than that of the control arm [ 12.53 (7.86), 8.43 (4.31), and 6.43 (3.39) respectively].

- A statistically significant difference could be observed - among the groups (F=6.65, p = 0.012), over time regardless of group (time effect) (F= 121.63, p <0.001), and a significant time × group interaction (F= 6.01, p=0.008).

Effectiveness of the multicomponent intervention on intensity of migraine.

- The mean intensity scores were 8.43 (1.25) and 8.80 (0.96) respectively in the intervention and control arm subjects before the intervention. The mean intensity scores at 4 weeks after the intervention were 5.23 (1.09) and 7.05 (0.81) in the intervention and control arms respectively. After 24 weeks, the mean scores were 2.33 (1.59) and 5.35(0.77) respectively.

- The repeated measures ANOVA indicated a significant between group effect, with the intervention arm experiencing a better reduction in intensity than the control arm [F (1,78) =150.58, p <0.001]. The interaction effect was also significant, denoting statistically significant reduction in pain intensity scores between groups and time points [F (2.13, 166.36) =33.99, p <0.001].

CONFLICT OF INTEREST

- The researcher declare that he had no conflict of interest to disclose.
CONCLUSION

Migraine is a neurological disorder characterized by intense throbbing or pulsating pain and is often associated with symptoms like nausea, vomiting, photophobia and phonophobia. Migraine affects the physical, psychological, vocational and social domains of an individual’s life and is documented to be the seventh highest cause of disability among adults. To the best of the researcher's knowledge, this is the first randomized trial conducted in India, which aimed at evaluating the effectiveness of a nurse led multicomponent intervention for migraine. Whilst components like education, lifestyle modification, and trigger identification were found effective, studies focussing on comprehensive migraine management seems less explored.

The present study evaluated the effectiveness of a multicomponent intervention in clinical outcomes of patients with migraine. The multicomponent intervention included behavioral lifestyle modification program and sessions of pranayama (a form of breathing exercise). Eighty patients diagnosed with migraine were randomized into intervention and control arm. Clinical outcomes of subjects in the intervention arm and control arm improved significantly over 24 weeks. The subjects in the intervention arm had better reductions in disability, frequency, duration and intensity of migraine attacks. The quality of life scores at the post test was significantly higher than that of the control arm. The intervention was found to have a consistent impact on the clinical outcomes as evidenced by the gradual improvement across 4th, 12th and 24th weeks after the intervention.

The study provide evidence to support the multicomponent intervention as an appropriate and effective one to bring about positive changes in clinical outcomes of migraineurs. The outcomes of the study reinforce the importance of a comprehensive management of migraine headaches and generate evidence that inform clinical practice regarding the management of migraine.

EPILOGUE

This chapter dealt with major findings, study conclusions and its implications. Plagiarism check of the work was done using Turnitin, an internet based plagiarism detection service and the report is enclosed (Appendix 6 A). The trial was closed as on 13.01.2017, the closure report is enclosed (Appendix 6 B)