

Manipal Academy of Higher Education

Impressions@MAHE

Manipal College of Nursing, Manipal Theses
and Dissertations

MAHE Student Work

Winter 11-1-2017

A Randomized controlled trial on effectiveness of a multicomponent intervention on migraine.

Vishnu Renjith

Follow this and additional works at: <https://impressions.manipal.edu/mcon>



Part of the [Nursing Commons](#)

ABSTRACT

Migraine is one of the major primary care issues globally, nationally and regionally. Because of its considerable impact on the quality of life, migraine is considered as one among the prominent causes of chronic suffering and disability, This trial was primarily designed to investigate the effectiveness of a multicomponent intervention in- improving the quality of life, reducing disability, decreasing pain intensity, attack frequency, and duration of migraine attack among migraineurs. The study was a single centre, prospective, randomized, controlled, single-blinded, pragmatic trial with parallel arms. The study was underpinned using the Health Belief Model (HBM). The outcome variables of the study included- the quality of life, level of disability, intensity of migraine attacks, duration of migraine attacks and frequency of migraine attacks. Subjects of the study were recruited from the neurology department of Kasturba Hospital, Manipal, Karnataka.

Ethical committee clearance from Kasturba Hospital Manipal was obtained (IEC50 /2014). The trial was registered prospectively with the Clinical Trial Registry India (CTRI/2015/10/006282). The study involved two arms (1 Intervention & 1 Control). The participants in the intervention arm received the multicomponent intervention + conventional management (routine pharmacological management) whereas the participants in the control arm received only the conventional management. After obtaining written informed consent, eighty eligible participants were randomized to the intervention arm (n=40) or control arm (1-40). To achieve an unbiased comparison group and to have a balanced randomization, permuted block randomization with fixed block size was used for the study. The outcome assessor of the study was blinded to the allocation status of the participants.

Quality of life was the primary outcome variable for this trial. The secondary outcome variables of the trial were; Disability and Pain scores (frequency, duration and Intensity) of patients with migraine. A Socio Demographic & Clinical Data Questionnaire was used to collect the basic demographic & clinical details. Migraine Specific Quality Of Life Questionnaire was used to assess the quality of life. Headache Impact Test (HIT) was used to assess the disability, whereas a Pain Questionnaire (PO) was used to elicit the pain scores.

Intention to Treat was the primary data analytical approach. IBM Statistical Package for Social Sciences (SPSS) software was used for data analysis. The majority of the participants were in the age group of 18-30 years. There was a preponderance of female participants in the study with 82.5% of subjects being females in intervention and control arm. Family history of migraine was present in 80% of subjects in the intervention arm and 70% in control arm. A large proportion of participants (96.3%) reported to experience severe pain intensity (numerical pain score of 7-10).

Clinical outcomes of subjects in the intervention arm and control arm improved significantly over 24 weeks. The subjects in the intervention had a better reduction in disability, frequency, duration and intensity of migraine attacks. The quality of life scores at the post test was significantly higher in the intervention arm than that of the control arm. Repeated

Measures ANOVA showed that there was a significant difference in the mean quality of life scores of migraineurs ($P < 0.001$) in the intervention & control arm. In comparison to the control arm, statistically significant reduction in disability scores were obtained among subjects in the intervention arm ($p < 0,001$). The F ratio and associated significance level of frequency ($p < 0.05$), duration ($p < 0.05$) & intensity scores ($p < 0.05$) denotes statistically significant difference in pain scores among subjects in study arms. Patients who received the multicomponent intervention reported significant; improvement in quality of life scores, reduction in disability scores and pain scores (frequency duration and intensity) than patients who received conventional management. This research concurs with the findings of studies which supported that similar integrative interventions combining both pharmacological and non-pharmacological measures were effective in improving the quality of life and reducing disability,

The intervention was found to have a consistent impact on the clinical outcomes as evidenced by the gradual improvement in all the outcome variables across 4th, 12th and 24th weeks. The study provides 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 generate evidence that informs clinical practice regarding the management of migraine.

Keywords: Migraine, multicomponent intervention, pranayama, behavioural modification, lifestyle modification, quality of life, disability, pain scores