CHAPTER I
INTRODUCTION
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INTRODUCTION

BACKGROUND OF THE STUDY

Headache is considered as one of the most common symptoms in medicine and is often the primary complaint with which people consult a neurologist or a general physician (Netter et al., 2012; Longo et al., 2012). It is a universal experience with one-year prevalence of about 90% and life time prevalence of about 99% (Renjith, Pai, Castelino, Pai, & George, 2016a). According to the world health organization headache remain as the most common disorder affecting the nervous system. Almost half of the adult population experience an attack of headache every year (Headache disorders, 2016).

- **Headache**

  Headache refers to pain in any region of head. The nine pain sensitive areas of head are - cranium, muscles, nerves, arteries & veins, subcutaneous tissues, eyes, ears, sinuses, and mucous membranes. Headache can be a presenting symptom for various systemic and neurologic conditions. Management of headache disorders are based on careful clinical history, associated symptoms, and other diagnostic measures.

  Recurrent headaches cause a considerable burden on the individual as well as the society. “Atlas of headache disorders and resources in the world”, a collaborative project of World Health Organization and Lifting the Burden reports that headache disorders, including migraine and tension-type headaches are among the most prevalent disorders of mankind. The prevalence studies estimate that more than half of the adults in the world have had an episode of headache in the previous year (WHO, 2011).

  Figure 1.1 presents the response of neurologists and primary-care physicians regarding the percentage of individuals seeking consultation with complaints of headache. From this graph, it is evident that in a primary care setting, tension type headaches, followed by migraines accounted as the most prevalent kind of headache disorders. Migraines were ranked high in estimated percentages of all headache cases seen by a neurologist (WHO, 2011).
### Classification of Headaches

The first comprehensive system of classification of headache disorders was developed by the International Headache Society (IHS) in the year 1988. The IHS classification, termed as the ‘International Classification of Headache Disorders’ (ICHD) is the widely-accepted system of classification of headache disorders. According to the IHS (2004), headaches are broadly classified as primary and secondary headaches.

Primary headaches are those headaches in which the primary problem of concern is just headache without any underlying neurological pathology (Drislane, Acosta, Caplan, Chang, & Tarulli, 2013; Netter et al., 2012). The most common type of primary headaches are tension type headaches, migraine headaches, and cluster...
headaches. Primary headaches tend to impact immensely on the functioning of the individuals and is associated with varying levels of disability and poor quality of life (Renjith, Pai, Castelino, Pai, & George, 2016b).

The secondary headaches occur due to underlying pathological, infectious, and inflammatory disease processes (Drislane et al., 2013; Netter et al. 2012). Secondary headaches include a spectrum of diseases from mild ones to life threatening entities. The most common secondary headaches are due to systemic infections, brain tumors and other vascular disorders (Daroff et al. 2015; Netter et al., 2012; Longo et al., 2012).

- **Migraine**

Globally, the second most common cause of a headache is migraine (Menon & Kinnera 2013; Renjith et al. 2016a) Migraine is a primary headache disorder characterized by repeated attacks of throbbing or pulsating pain, usually on only one side of the head. These headaches are often associated with nausea, vomiting, photophobia, and phonophobia and usually last about 4 to 72 hours (IHS, 2004).

The term ‘Migraine’ is derived from the Greek word “hemikranios” which means half headed as initial descriptions of migraine defined it as a purely unilateral headache. Migraine is described as a benign, recurring headache disorder associated with a number of neurological symptoms in varying admixtures (Longo et al., 2012). The period of onset of migraine is during puberty or in early 20’s. Generally, they decrease in frequency and intensity with advancing years. Women are found more susceptible than men. Migraine headaches usually occur at irregular intervals and the frequency varies from several times in a week to only a few times in a year. The two major subtypes of migraine are the- Migraine With Aura (MWA) and the Migraine With Out Aura (MWOA).

Migraine with aura is also referred as classic or typical migraine. The experience of transient neurological disturbances will precede the headache attack, referred to as ‘Aura’. Visual auras are most common. This include photopsia (unformed flashes of light), fortification spectra or teichopsia (dazzling zigzag lines), scotoma, hemianopia or central blindness. Some individuals experience vertigo, dizziness, mild aphasia, uncertainty in gait or drowsiness (Ropper, 2005).
Migraine without aura is also referred as common or atypical migraine. It is defined as recurrent disorder manifesting in attacks of reversible focal neurological symptoms that develop gradually over 5-20 minutes and last for less than 60 minutes (HIS, 2004). The headache begins with prodromal symptoms but there will not be any experience of auras. MWOA is more common than MWA.

Migraine headaches are often initiated by certain factors referred to as triggers. A trigger is any event, change, external stimulus, or physical act which seems to result in migraine. It precedes the attack by a short interval which could be as much as up to 6 to 8. ‘Anything under the sun’, including the sun may trigger a migraine attack in a person predisposed to this condition. The common migraine triggers include bright light, sound, physical exertion, stress, hormonal changes, certain foods like chocolate, cheese, vine, lack of sleep and strong odors.

- **Migraine: Pathogenesis**

The precise mechanism of migraine pathophysiology is unclear. Various hypotheses explain the pathophysiological mechanisms of Migraine headaches, the most acceptable one being the hypothesis of “The Cortical Spreading Depression” (CSD). CSD refers to a wave of hyperpolarization followed by a wave of depolarization that spread across the cortex at a rate of 2 to 3 mm/min. It is hypothesized that CSD leads to release of chemical substances that activate trigeminal nerve and subsequent release of vasoactive neuropeptides and pro inflammatory substances resulting in migraine (Netter et al., 2012; Drislane, 2013). There is a growing evidence that supports the role of brain serotogenic system in the development of migraine headaches (Opacka-Juffry, 2008; Hamel, 2007). Migraine is believed to result from the activation of trigeminal nociceptors in the meninges and intracranial blood vessels. Serotonin, also called as 5-hydroxy tryptamine (5HT) is a neuro transmitter found in the central and peripheral nervous system. Serotonin play a major role in regulating the tone of blood vessels. When serotonin level drops down, the blood vessels dilate leading to migraine headache. The ‘triptan’ class of drugs stimulate the 5HT causing vasoconstriction and promote the migraine relief. Serotonin is responsible for balancing the mood as low levels of serotonin lead to depressive symptoms. Hence patients with migraine often experience depression symptoms. Improving and maintaining an optimum serotonin level may help to decrease the number of migraine headaches.
Before the advancement of the plausible explanation by the CSD, Vascular theory was the widely accepted. According to the Vascular Theory (VT), the early neurological symptoms (warning signs) are due to the constriction of intracranial vessels. The later intense, throbbing headache is due to the dilatation of extracranial and intracranial branches of the external carotid artery (Polaski, Tatro, & Luckmann, 1996)

- **Migraine: Diagnosis and clinical features**

The diagnosis of migraine is mainly clinical and is purely based on the patients’ signs, symptoms and the headache patterns. A detailed headache history is a key for proper diagnosis and hence collecting a history focusing on onset, duration, frequency, intensity, and triggering factors is vital. Other investigations such as a computerized tomography (CT) or Magnetic Resonance Imaging (MRI) may be necessary to rule out the secondary causes of headache. The ICHD II (IHS, 2004) diagnostic criteria for migraine without aura is given in figure 1.2.

<table>
<thead>
<tr>
<th>Clinical features of migraine</th>
<th>Patients affected, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Photophobia</td>
<td>93.3</td>
</tr>
<tr>
<td>Throbbing pain</td>
<td>90</td>
</tr>
<tr>
<td>Difficulty in performing ADL</td>
<td>88.3</td>
</tr>
<tr>
<td>Phonophobia</td>
<td>85</td>
</tr>
<tr>
<td>Sleep disturbances</td>
<td>83.3</td>
</tr>
<tr>
<td>Fatigue</td>
<td>81.7</td>
</tr>
<tr>
<td>Nausea</td>
<td>76.7</td>
</tr>
<tr>
<td>Vomiting</td>
<td>41.7</td>
</tr>
<tr>
<td>Blurring of vision</td>
<td>38.3</td>
</tr>
</tbody>
</table>

Migraine is associated with the clinical features such as throbbing pain, photophobia, phonophobia, nausea, vomiting, scalp tenderness, light headedness, paraesthesia and visual disturbances. The clinical features of migraine are summarized in Table 1.1 (Renjith et al. 2016b).
The International Classification of Headache Disorders (ICHD):
DIAGNOSTIC CRITERIA FOR MIGRAINE WITHOUT AURA

**Description:** Recurrent headache disorder manifesting in attacks lasting 4-72 hours. Typical characteristics of the headache are unilateral location, pulsating quality, moderate or severe intensity, aggravation by routine physical activity and association with nausea and/or photophobia and phonophobia.

**DIAGNOSTIC CRITERIA FOR MIGRAINE WITHOUT AURA**

A. At least 5 attacks fulfilling criteria B-D.

B. Headache attacks lasting 4-72 hours (untreated or unsuccessfully treated).

C. Headache has at least two of the following characteristics:
   1. unilateral location.
   2. pulsating quality.
   3. moderate or severe pain intensity.
   4. aggravation by or causing avoidance of routine physical activity (eg, walking, climbing stairs).

D. During headache, at least one of the following:
   1. nausea and/or vomiting.
   2. photophobia and phonophobia.

E. Not attributed to another disorder.

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**Figure 1.2:** The ICHD II diagnostic criteria for migraine without aura.

Source: Adapted from the International Headache Society (IHS) The International Classification of Headache Disorders: 2nd edition.
**Burden of migraine**

The one-year prevalence of headache disorders among adults is around 50% and among those individuals approximately 30% suffer from migraine (WHO, 2016). Migraine is commonly seen in females than in males (3:1). Seventy percent of the patients with migraine have a first degree relative with the history of migraine headache. The prevalence of migraine is highest among the individuals aged 22-55 years, the most productive years of one’s life (Netter et al., 2012).

According to the Global Burden of Disease (GBD) study, tension type headaches and the migraine headaches are ranked as the second and third highly prevalent disorders worldwide (Vos et al., 2013). The global prevalence of migraine is 14.7% with 10.68% among males and 18.79% among females (Vos et al. 2013; Steiner et al. 2013). Global prevalence of 14.7% means that one in seven people suffer from migraine (Steiner et al. 2013). In the United States, 6% of men and 15-17% of women suffer from migraine (Netter et al. 2012). The one-year prevalence of migraine among adults in Europe is about 14% with 7.6% of males and 18.3% of females experiencing migraine (Stovner, Zwart, Hagen, Terwindt, & Pascual, 2006). The mean one-year prevalence of migraine across various regions as reported by the WHO is reproduced in table 1.2 (WHO, 2011). As per the report, the prevalence of migraine in the Africa is 4.0%, in America it is 10.6%, Eastern Mediterranean is 6.8%, Europe is 14.9%, South-East Asia is 10.9% and in Western Pacific is 10.4%. South East Asian region ranks second as the most migraine prevalent area across the globe.

### Table 1.2
Mean 1-year prevalence (%) of all headache & migraine among adults

<table>
<thead>
<tr>
<th></th>
<th>Africa</th>
<th>Americas</th>
<th>Eastern Mediterranean</th>
<th>Europe</th>
<th>South-East Asia</th>
<th>Western Pacific</th>
</tr>
</thead>
<tbody>
<tr>
<td>All headache</td>
<td>21.6</td>
<td>46.5</td>
<td>78.8</td>
<td>56.1</td>
<td>63.9</td>
<td>52.8</td>
</tr>
<tr>
<td></td>
<td>(n=2)</td>
<td>(n=1)</td>
<td>(n=2)</td>
<td>(n=8)</td>
<td>(n=1)</td>
<td>(n=4)</td>
</tr>
<tr>
<td>Migraine</td>
<td>4.0</td>
<td>10.6</td>
<td>6.8</td>
<td>14.9</td>
<td>10.9</td>
<td>10.4</td>
</tr>
<tr>
<td></td>
<td>(n=2)</td>
<td>(n=1)</td>
<td>(n=2)</td>
<td>(n=9)</td>
<td>(n=1)</td>
<td>(n=6)</td>
</tr>
</tbody>
</table>

n= number of studies in the WHO region contributing to the reported mean.

Source: Prepared based on the data from the WHO Atlas of headache disorders (2011)
• Extrapolation statistics on the prevalence rate of migraine to countries and regions (2012) reports that approximately 109 million Indians are suffering from migraine. A survey among the medical students of South India reported that 68% of medical students suffer from headache disorders and the prevalence of migraine is about 28% (Menon & Kinnera 2013).

Kulkarni et al. (2015) reported the crude 1-year prevalence of migraine in the state of Karnataka as 25.6%. Females are reported to have a higher prevalence of migraine (32.4%) than males (18.6%). The overall prevalence of migraine was found to be higher in rural (29.7%) than urban (21.9%) habitation.

- Impact of migraine.

Migraine headaches are ranked the seventh highest cause of disability (Steiner et al. 2013) and thus contributing to 2.9% of all years of life lost due to disability (YLDs). Freitag (2007) and Renjith et al. (2016b) reported that migraine is accompanied by throbbing pain, photophobia, phonophobia, nausea, and vomiting.

Migraine results in reduced productivity at work as well as at home and it disrupts the social and family relationships. The study conducted by Smitherman et al. (2011) found that the subjects with migraine had reduced quality of life and impaired functioning, in comparison with the subjects without migraine. Symptoms of both depression and anxiety were found to be high among the subjects with migraine. In a longitudinal descriptive study by Raggi et al. (2011), it was found that women with migraine demonstrated a pervasive deterioration in disability and Health Related Quality of life (HRQoL). Renjith et al (2014) reported that majority of migraineurs (60%) experience poor biopsychosocial well-being.

Vuillaume De Diego and Lanteri-Minet, (2005) evaluated the headache-related disability among migraineurs. The study found that around 50% of the migraineurs presented a very severe impact score as measured by the Headache Impact Test (HIT). The American Migraine Prevalence and Prevention (AMPP) study reported that 22.1% of the migraineurs had severe levels of disability (Lipton et al. 2007). Renjith et al (2016b) reported that around 73% of the migraineurs belonged to moderate to severe levels of functional disability, when assessed using the MIDAS (Migraine Induced Disability ASsessment) questionnaire.
Numerous works report that the migraineurs experience a lower quality of life than other patients who suffer from chronic problems like depression, hypertension, and diabetes (Brown et al. 2008 & Renjith et al. 2014). Migraine pain can be intense and unremitting that can interfere with the daily routine and reduce the ability to think and function normally. Various reports affirm that migraine is associated with substantial impairment in quality of life and disability (Lipton et al., 2000; Diego & Minet 2005; Freitag, 2007; Lipton et al., 2007; Smitherman et al., 2011). Being a chronic primary headache disorder, migraine is one of the prominent reasons for chronic suffering and disability.

- **Non-pharmacological & integrated interventions for migraine**

Various non-pharmacological and integrated interventions have been evaluated for its effectiveness in improving the outcomes of patients with migraine.

An RCT (John et al. 2007) was carried out to evaluate the efficacy of yoga for the treatment of migraine. The analysis showed a noteworthy decrease in frequency of migraine and related clinical parameters, among the subjects treated with yoga. Dindo et al. (2012) conducted a study to assess the effectiveness of One-Day Behavioural Intervention in Migraine Patients. Participants assigned to the intervention group exhibited a significant reduction in depressive symptoms and disability.

Cady et al. (2008) did a study on nurse based education for the migraineurs. The analysis showed that the education program was readily accepted by the migraineurs and they were successful in assimilating the information that increased their confidence in self-management of migraine attacks. Harpole et al. (2003) evaluated the outcomes of patients referred to a headache management program. A significant improvement in headache related disability and functional status were observed among the subjects. The participants reported a greater satisfaction with care.

A pilot study was undertaken (Main et al. 2002) to evaluate the effect of nurse led health education program in the management of primary headache disorders. The study concluded that the health education was an effective means in reducing the severity and disability among the individuals with primary headaches.
Several studies (Main et al. 2002, Harpole et al. 2003, Cady et al. 2008, John et al. 2007, Dindo et al. 2013) suggest that non-pharmacological therapies and integrative therapies play a major role in the management of migraine headaches.

Migraine is one of the major primary care issues both globally and regionally. Because of its considerable impact on the quality of life, migraine is considered one among the prominent causes of chronic suffering and disability. Despite of its high prevalence and the burden it poses on the sufferers, migraine remain as the less focused area of primary care research. For successful and optimal management of migraine the accurate diagnostic and holistic management are necessary. Improving the management of migraine also will reduce the progression towards chronic state of this disorder (Singh, 2014).

RESEARCH GAPS IDENTIFIED

Headache disorders are a worldwide problem and it affects people of all age groups, socioeconomic backgrounds, races, and geographic locations. Despite of its public health importance, headache disorders remain underestimated, underrecognized and under-treated across the globe (Headache disorders, 2016).

Migraine affects the physical, emotional, social, and vocational domains of an individual’s life. However, the routine treatment focuses on the physical aspect of management. The holistic nature of management is often neglected in general practice. The conventional management of migraine headache is suboptimal, and overuse of episodic medication will lead to the development of chronic daily headache. Thus, the studies focusing on non-pharmacological or integrative therapies for prevention of migraine are justified.

A variety of behavioral, educational, complementary/alternative, as well as the non-pharmacological modalities, are found to be effective in managing headaches (Main et al. 2002, Harpole et al. 2003, Cady et al. 2008, John et al. 2007, Dindo et al. 2013). A recent trend is observed in management of headaches, where these therapies are integrated with the pharmacologic care. However, very few studies have been reported from India / South East Asia, which have been conducted to analyze the effectiveness of integrative non-pharmacological therapy for migraine.
People suffering from migraine can do a lot to help themselves prevent migraines or reduce the intensity of pain during a migraine attack (Renjith & George, 2015). People can lower their risk of a migraine by simply avoiding stress, getting enough sleep, eating regularly, and by avoiding triggers. A lacuna is identified in the literature regarding the efficacy of a multicomponent nonpharmacological noninvasive intervention for the management of migraine. Hence, the researcher conceptualized a study evaluating the effectiveness of a multicomponent intervention in managing migraine headaches. The multicomponent intervention includes behavioral lifestyle modification program and sessions of pranayama (a form of breathing exercise). To the best of the researcher’s knowledge, this is the first attempt from the country, to explore the effectiveness of a multicomponent intervention (with components of behavioral lifestyle modification program and breathing exercises) on the outcomes of patients with migraine.

**TITLE OF THE STUDY**

Effect of multicomponent intervention on migraine.

**STATEMENT OF THE PROBLEM**

A randomized controlled trial on the effectiveness of a multicomponent intervention on quality of life; disability and pain among migraineurs.

**RESEARCH QUESTION**

The ‘PICOS’ acronym is the widely used structured approach to frame the question for an evidence based research. In the acronym P stands for Population, I stand for Intervention, C represents comparator, and O represents outcomes (Aromataris & Pearson 2014). The question and PICOS components of the study are;

**Among adults with migraine, how effective is multicomponent intervention in comparison to routine care in improving the quality of life, reducing disability and pain scores?**

- **Population:** Migraineurs  
- **Intervention:** Multicomponent intervention  
- **Comparison:** Routine care  
- **Outcomes:** Quality of life, disability, and pain  
- **Study design:** Randomized Controlled Trial (RCT)
INTRODUCTION

PURPOSE

The trial is 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. Addition of multicomponent intervention to routine medical management would improve clinical outcomes of migraineurs. The findings of the study will help to widen the scientific base regarding the care of patients with migraine.

With increasing importance to holistic care, the current study will help to generate evidences which nurses and other health care providers can utilize in their day-to-day practice. The findings of the study are expected to open up new horizons in health care arena emphasizing the use of non-pharmacological non-invasive integrated therapies for less focused area of primary care health problem of migraine.

OBJECTIVES

To achieve the overall purpose of the study, following objectives are formulated:

1. Assess the quality of life of the migraineurs using Migraine Specific Quality of Life Questionnaire (MSQ).

2. Determine the disability of the migraineurs using the Headache Impact Test (HIT).

3. Elicit the pain scores (intensity, frequency, and duration) of the migraine attacks using a Pain Questionnaire (PQ).

4. Explore the effectiveness of the multicomponent intervention on the quality of life of patients with migraine.

5. Find the effectiveness of the multicomponent intervention on the disability levels of patients with migraine.

6. Determine the effectiveness of the multicomponent intervention on the pain scores (intensity, frequency, and duration) of patients with migraine.
INTRODUCTION

HYPOTHESES
The trial is designed to test the hypotheses at 0.05 level of significance. To achieve the objectives of the study, following two tailed hypotheses were formulated:

H1: Posttest Quality of Life (QOL) scores among the migraineurs in the intervention arm will be significantly different from that of the control arm.

H2: Posttest disability scores among the migraineurs in the intervention arm will be significantly different from that of the control arm.

H3: Posttest pain scores (intensity, frequency, and duration) among the migraineurs in the intervention arm will be significantly different from that of the control arm.

ASSUMPTIONS
The assumptions underlying the study are
• Quality of life is multidimensional and can be empirically measured.
• Migraineurs experience low level of quality of life.
• Migraine headaches can cause varying levels of disability.
• Migraine headaches are of moderate to severe in pain intensity.

VARIABLES

• Independent Variable
  • Multicomponent intervention for the management of migraine

• Dependent (Outcome) Variables
  • Primary outcome variable:
    • Quality of life of migraineurs
  • Secondary outcome variables:
    • Disability of migraineurs
    • Pain intensity of migraine attacks
    • Frequency of migraine attacks
    • Duration of migraine attacks

• Demographic Variables
  • Age, Gender, Education, Place of residence, Type of family, Occupation, Food habits and Family history
DEFINITION OF TERMS

For the purpose of the study, the following concepts have been operationally defined.

**Migraine:** In this study migraine refers to Migraine With Out Aura (MWOA). The ICHD II definition of migraine was used in this work. MWOA also known as common migraine is defined as “Recurrent headache disorder manifesting in attacks lasting 4-72 hours. Typical characteristics of the headache are unilateral location, pulsating quality, moderate or severe intensity, aggravation by routine physical activity and association with nausea and/or photophobia and phonophobia” (ICHD-II, 2004).

**Migraineur:** In this study migraineur refers to an adult who is diagnosed to have migraine without aura using International Classification of Headache Disorders Criteria (ICHD II) by a registered medical practitioner.

**Effectiveness:** It refers to the extent to which the multicomponent intervention implemented has achieved the desired results as expressed by improvement in quality of life scores, decreased disability scores, reduced pain intensity, decreased duration of attacks, and reduced attack frequency of migraine among migraineurs under study.

**Multicomponent intervention:** It refers to the complex nursing intervention designed to improve the clinical outcomes of patients with migraine disorders. The multicomponent intervention program includes behavioral - lifestyle modification program and the sessions on pranayama.

**Quality of life (QOL):** Quality of life refers to the effects of migraine on various facets of life of a migraineur and is measured by the Migraine-Specific Quality-of-Life Questionnaire (MSQ). MSQ evaluates migraineurs’ health related quality of life for the past four weeks.

**Disability:** In this study disability refers to the impact of migraine on the patient’s ability to function at work, at school, at home and in social situation as measured by the Headache Impact Test (HIT). HIT evaluates the impact the migraine had on the functioning of the individual for the past four weeks.

**Pain scores:** Pain scores in the study refers to pain intensity, duration of migraine attacks and frequency of attacks as measured by the pain questionnaire. The pain scores are measured as an average score of the past four weeks.
**Pain Intensity:** Pain intensity refers to the severity of pain and is measured using the Pain Questionnaire (PQ). Pain intensity is referred as the average intensity of migraine attacks for the past one month.

**Duration:** Duration refers to the time-period of a migraine attack as expressed in hours and is measured using Pain Questionnaire (PQ). Duration is referred as the average duration of migraine attacks for the past one month.

**Frequency of migraine:** Refers to the number of migraine attacks per day and is measured using Pain Questionnaire (PQ). Frequency is referred as the average number of migraine attacks for the past one month.

**CONCEPTUAL FRAMEWORK**

A theoretical / conceptual framework can be defined as an abstract representation of a presumed relationship among key concepts or variables of a study (Miles & Huberman, 1994). Exploring, selecting, and utilizing an appropriate conceptual framework is a vital step in development of research work.

Health science researchers, especially nurse researchers traditionally embed their research work in well-established conceptual frameworks or theories. Conceptual frameworks provide an organized structure for the research design, act as a frame of reference, guide intervention development, provide rationale for testing of hypothesis, and help to interpret them in a scientific context.

The identification, application and testing of the framework was based on the process of incorporating a conceptual model into the research report as outlined by Fawcett, J. (1996). A three-step process was used to incorporate the conceptual framework to the study.

- **Step I:** Identification of an appropriate conceptual model.
- **Step II:** Overview of the selected conceptual model.
- **Step III:** Concepts of the conceptual model and study variables.
**Step I: Identification of an appropriate conceptual model.**

The primary objective of the study was to assess the effectiveness of multicomponent intervention for patients with migraine headache. The multicomponent intervention comprises of behavioral lifestyle modification program and sessions of pranayama. Behavioural / lifestyle modification program and pranayama are conceptualized as health promotional activities. Health Belief Model (HBM) is based on the assumption that peoples’ decisions about health-related behaviour to a given disease are guided by five main factors such as perceived susceptibility of the individual to the disease, perceived seriousness of the disease, the perceived benefits and barriers of taking action against the disease and the cues that motivates the action process in the individual. Since the objective of the study was to predict the outcome of migraineurs undertaking the multicomponent intervention, it was found appropriate to conceptualize the study using the health belief model (Rosenstock et al. 1988).

**Step II: Overview of the selected conceptual model.**

The health belief model has been developed in the 1950’s and 1960’s by a group of public health researchers who were interested in exploring the health behaviors of individuals (Davidhizar, 1983). The model utilized in the present study is based on the classic description by Rosenstock (1974a, 1974b). The model proposes that when an individual consider oneself as susceptible to a risk condition and believe that a particular course of action would be beneficial to reduce the risk, he or she is more likely to follow the actions to reduce those risks (Glanz et al. 2008).

The five major constructs as per the HBM are perceived susceptibility, perceived severity, perceived benefits, perceived barriers, and cues to action (Rosenstock, 1974a; Rosenstock, 1974b; Davidhizar, 1983; Baranowski, 2003; & Daddario, 2007). The first four constructs accounts for an individual’s “readiness to act.” The fifth construct, cues to action, would activate that readiness and stimulate overt behavior.

- **Perceived Susceptibility:** Refers to the level of personal susceptibility of getting an illness. It is an individual’s perceived risk of contracting the particular illness or a condition.
• **Perceived Severity**: Denotes to one’s opinion on how serious a condition is and what are the consequences (biological and/or social) that result from contracting the particular illness or a condition. It is an individual’s perception regarding the clinical or psychosocial impact of contracting the illness.

• **Perceived Benefits**: One’s belief regarding the potential benefits of health actions or its efficacy in preventing or reducing the susceptibility and severity of illness. It is an individual’s perception regarding the good things that probably could happen from undertaking the prescribed health behaviors, especially regarding the reduction of the threat of contracting a disease.

• **Perceived Barriers**: One’s opinion of the physical, social, psychological, financial, and other barriers or costs, that result from initiating and continuing the advocated actions. It is an individual’s perception regarding the difficulties in undertaking the prescribed course of action.

• **Cues to Action**: Cues to action consists of those strategies to activate “readiness”. It includes both internal and external stimulus that trigger or prompt appropriate health behaviors in an individual. Cues to action serve as catalysts for health behaviors.

• **Modifying factors**: A group of three factors such as demographic, socio-psychological, and structural variables that can modify the course or the outcome of illness. It is conceptualized that the modifying factors condition the individual perceptions of susceptibility, severity, and perceived benefits of preventive actions.

**Step III: Concepts of the conceptual model and the study variables.**

It is conceptualized on the grounds of HBM that when an individual perceives, oneself susceptible to migraine attacks (perceived susceptibility) and believes that recommended course of action (multicomponent intervention) is beneficial in improving the health (perceived benefits- improved quality of life, reduced disability, reduction in frequency, duration and intensity of migraine attacks), he/she is likely to undergo those actions (likelihood of taking action). Major constructs of HBM & its application in present study are explained below.
• **Perceived Susceptibility:** In this study, perceived susceptibility is the vulnerability of an individual to migraine attacks. Poor knowledge, poor trigger control, poor headache hygiene, poor sleep hygiene, lack of health promotional activities and noncompliance to treatment make an individual susceptible to migraine attacks.

• **Perceived Severity:** In this study the perceived severity refers to factors such as poor quality of life, high levels of disability, high pain intensity, increased frequency of attacks, and increased duration of attacks.

• **Perceived Benefits:** One’s belief in the efficacy of the advised action (multicomponent intervention) to reduce risk or seriousness of impact. In this study, perceived benefits are positive effects expected by migraineurs, which include - improved quality of life, reduced disability, reduced pain intensity, reduced attack frequency and decreased duration of migraine attacks.

• **Perceived Barriers:** The perceived barriers in undertaking the prescribed therapeutic regimen (multicomponent intervention) are personal barriers, environmental barriers and cultural barriers.

• **Cues to Action:** Cues to action consists of those strategies to activate "readiness". Internal cues to action include experience with headaches and trigger avoidance strategies. Whereas the external cues to action include - advice from family and peers, education from health professionals, exposure to mass media / internet, illness of family member or friend, and book, newspaper, or magazine article.

• **Proposed Action:** A construct on ‘proposed action’ is included in the study to represent the multicomponent intervention. It is conceptualized that the multicomponent intervention will enhance the perceived susceptibility, strengthen the perceived seriousness, fortify the cues to action as an external catalyst, reinforce the perceived benefits and minimize the perceived threats. Thus, the intervention enhances the likelihood of taking action, which results in positive outcomes such as improved quality of life, reduced disability, reduced pain intensity, reduced attack frequency and decreased duration of migraine attacks.
A Randomized Controlled Trial on Effectiveness of a Multicomponent Intervention on Migraine

Figure 1.3 Conceptual framework on 'Effectiveness of a multicomponent intervention on migraine' based on Rosenstock's (1974a, 1974b) Health Belief Model (HBM)
**DELIMITATIONS OF THE STUDY**

The study is delimited in its scope by the following aspects

- Adult migraineurs who attended the neurology Out Patient Department (OPD) of a single tertiary care hospital were only included.
- Migraineurs who were residents of Udupi district of Karnataka.
- Migraineurs who could read, write & understand Kannada (local language) or English.
- Migraineurs who were willing to participate in the study.

**EPILOGUE**

This chapter dealt with the background of the study, statement of the problem, purpose of the study, objectives of the study, hypotheses, assumptions, variables, definition of terms, conceptual framework, and delimitations of the study.

**OUTLINE OF THE REPORT**

The report of the study is further organized in subsequent chapters as follows

- **Chapter II: Review of Literature** – Presents an overview of the related research and non-research literature

- **Chapter III: Methodology** - Deals with the detailed methodological aspects of the trial and describe the plan for analysis.

- **Chapter IV: Analysis and Interpretation** - Presents the statistical analysis of the study and its interpretation.

- **Chapter V: Discussion, Implications, Rigor, Limitations, and recommendations.** – Critically discusses the study findings with other research, briefs the implications of the study, enumerate the methods used to ensure rigor, acknowledges the limitations and present recommendations for future research.

- **Chapter VI: Summary and Conclusion:** The chapter summarize the cardinal findings and conclude the study.