CHAPTER 1

INTRODUCTION

1.1 Principles and Rationale

Migraine is a common primary episodic headache disorder characterized by acute attacks. It comprises various combinations of headache and neurological, gastrointestinal and autonomic symptoms [(1)]. Migraine affects the worldwide population by having a significant impact on quality of life, including socio-economic and social aspects of daily living such as family, work and social relationships [(2)]. Migraine was a new condition included in the Global Burden of Disease 2000 study. In the World Health Report of 2002, migraine was the 20th leading cause of Years Lived with Disability (YLDs) at the global level, accounting for 1.4% of total global YLDs. The burden of migraine was high in women at 2% of the total global YLDs, which made it the 9th leading cause of disability in women. In Western countries, it was seen as a very common disorder affecting about 11% of the population, with the highest peak during the productive years between the ages of 25 and 55 years. The prevalence of migraine was lowest in Asia and Africa and increased in Europe, and Central, South and North America. In North America and Europe, the 1-year prevalence of migraine was 6% among men and 15-18% among women [(3, 4, 5, 6)].

In early years, the epidemiology of migraine was lower in Asia than in Western countries, except in findings of a Korean study and the first Hong Kong study, where the range of migraine prevalence was from 8.4% to 12.7% with the sex-specific

migraine prevalence being 11.3% to 14.4% in women and 3.6% to 6.7% in men [7]. During the last decade in Thailand, the prevalence of migraine was also high if compared with other Asian countries. The overall prevalence of migraine in this community was 29.1%, with 10.4% and 35.3% among men and women, respectively. In both sexes, the prevalence declined with increasing age and women were the most affected [8].

Migraine can be aggravated or precipitated by varied stimulators including menstruation, odour, noise, stress, hunger, some food, weather and anxiety [9-21]. Recently, the WHO became concerned about exposure to the radiofrequency (RF) fields from mobile telephones or their base stations, which could affect people's health. Nowadays, there is a rapid growth of mobile telecommunications, which grew to about one billion mobile phone users before 2005. Thus, if there is any impact on health from mobile telephones, it would affect a very large portion of the world's population [22]. A preliminary study reported the symptoms associated with mobile phone use, which consisted of a burning feeling or dull ache mainly occurring in the temporal, occipital or auricular areas. The symptoms usually ceased within an hour after the mobile telephone call, but could last longer [23]. Migraine pathophysiology has shown abnormal excitation of intracranial pain fibers [24]. There has also been increasing central neuronal hyperexcitability as a pivotal physiologic disturbance predisposing to migraine [25]. Some studies have demonstrated the biological effect from radiofrequency (RF) exposure. Salford et al. reported effects of the global system of mobile communication (GSM) on the blood-brain barrier in rats, and found highly significant evidence for neuronal damage in the cortex, hippocampus, and basal ganglia in the brains of the rats exposed. The effect of electromagnetic field

(EMF) exposure also had a positive relationship with dose-response [26]. Cells of the specific central nervous system (CNS) might activate different genes in response to cell phone emissions and there was variable threshold sensitivity depending on cell type. Short-term exposure to cell phone radiofrequency/microwave (RF/MW) radiation emissions could up-regulate specific intermediaries of apoptosis pathways in cells derived from the brain, and neurons appeared to be more sensitive to this effect than astrocytes. Cell phone emissions have the potential to cause dysfunction or death through activation of specific intracellular cell death signaling pathways [27]. Headache is a common symptom reported by mobile phone user's [23, 28, 29]. One study showed a significant increase in the prevalence of headache with increasing duration of mobile phone use by minutes per day. In contrast, the prevalence of headache was reduced by more than 20% among those who used hand-free equipment for their cellular telephone, as compared to those who never used hand-free kits [29]. Bit-Babik et al. reported that the specific absorption rate (SAR) to the user's head was substantially reduced by the use of a wired ''hands free'' earphone-microphone extension [30]. Appropriate tests showed that "hands-free kits" were effective in reducing RF radiation to the head [31], even though a recent study revealed results that there was no association between mobile phone use and headache severity [32, 33]. The facts of these findings were unclear, thus, it was of interest whether mobile phone use might be a trigger factor for migraine. If it could aggravate migraine severity, migraineurs would be able to avoid or decrease the frequency or duration of mobile phone use. Because of the clinical practice of headache management, precipitating factors have been established for patients to avoid [19].

Therefore, this study was conducted as an intervention study at the Outpatient Department of 4 central hospitals in Vientiane municipality, Lao PDR. The objective of this study was to find out the effect of mobile phone use with hands-free equipment on migraine headache.

1.2 The objectives of this study

1.2.1 General objective

- To investigate the effect of mobile phone use with hands-free equipment on migraine headache.

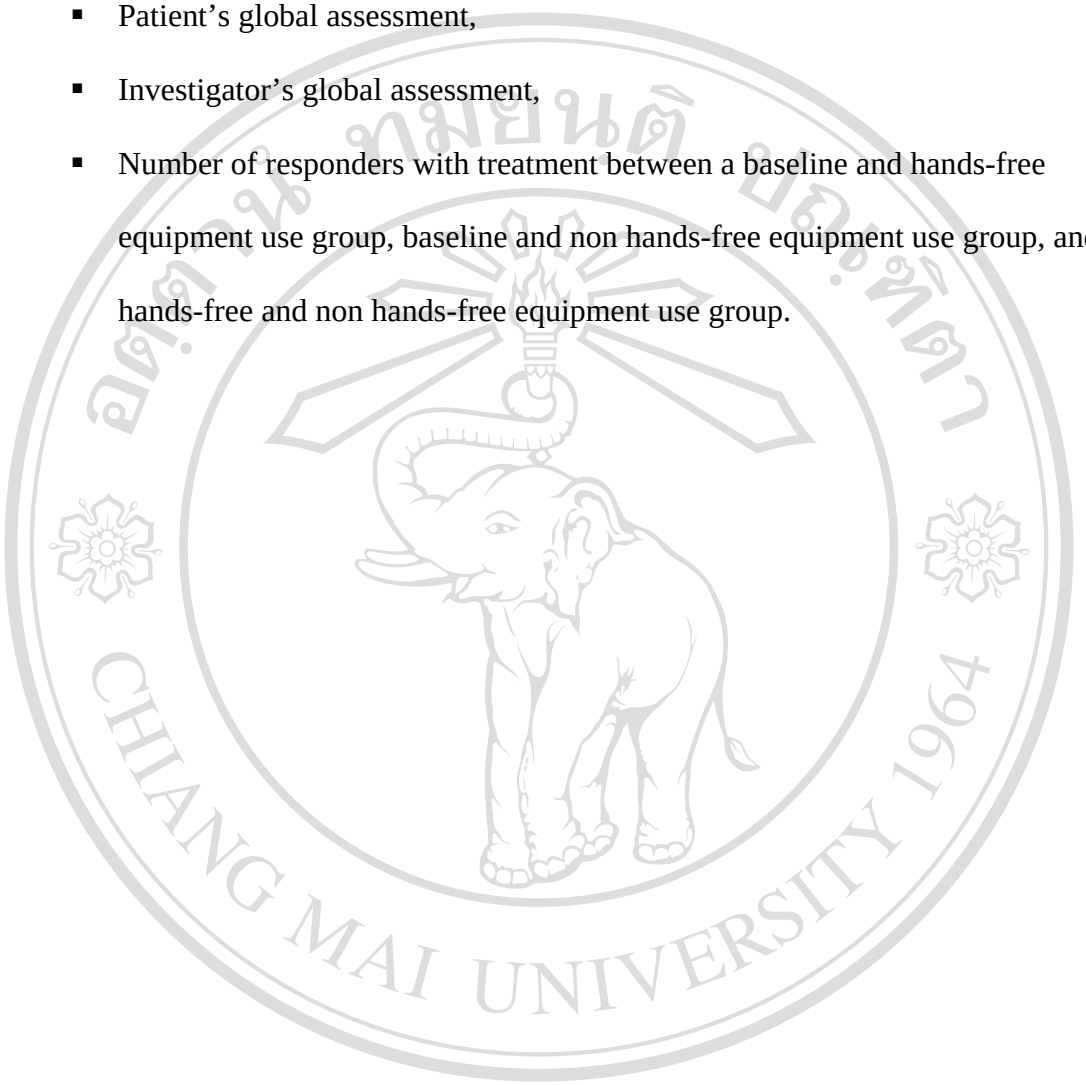
1.2.2 Specific Objectives

- To compare the mean difference of primary outcomes including:

  - Number of migraine attacks,
  - Number of days with migraine attack,
  - Total intensity scores,
  - Total severity scores,
  - Total duration scores,
  - Amount of acute medication, and
  - Number of days with acute medication per month between a baseline and hands-free equipment use group, baseline and non hands-free equipment use group, and hands-free and non hands-free equipment use group.

- To compare the mean difference of secondary outcomes including:

  - Patient's global assessment,
  - Investigator's global assessment,
  - Number of responders with treatment between a baseline and hands-free equipment use group, baseline and non hands-free equipment use group, and hands-free and non hands-free equipment use group.



1.3 Conceptual framework

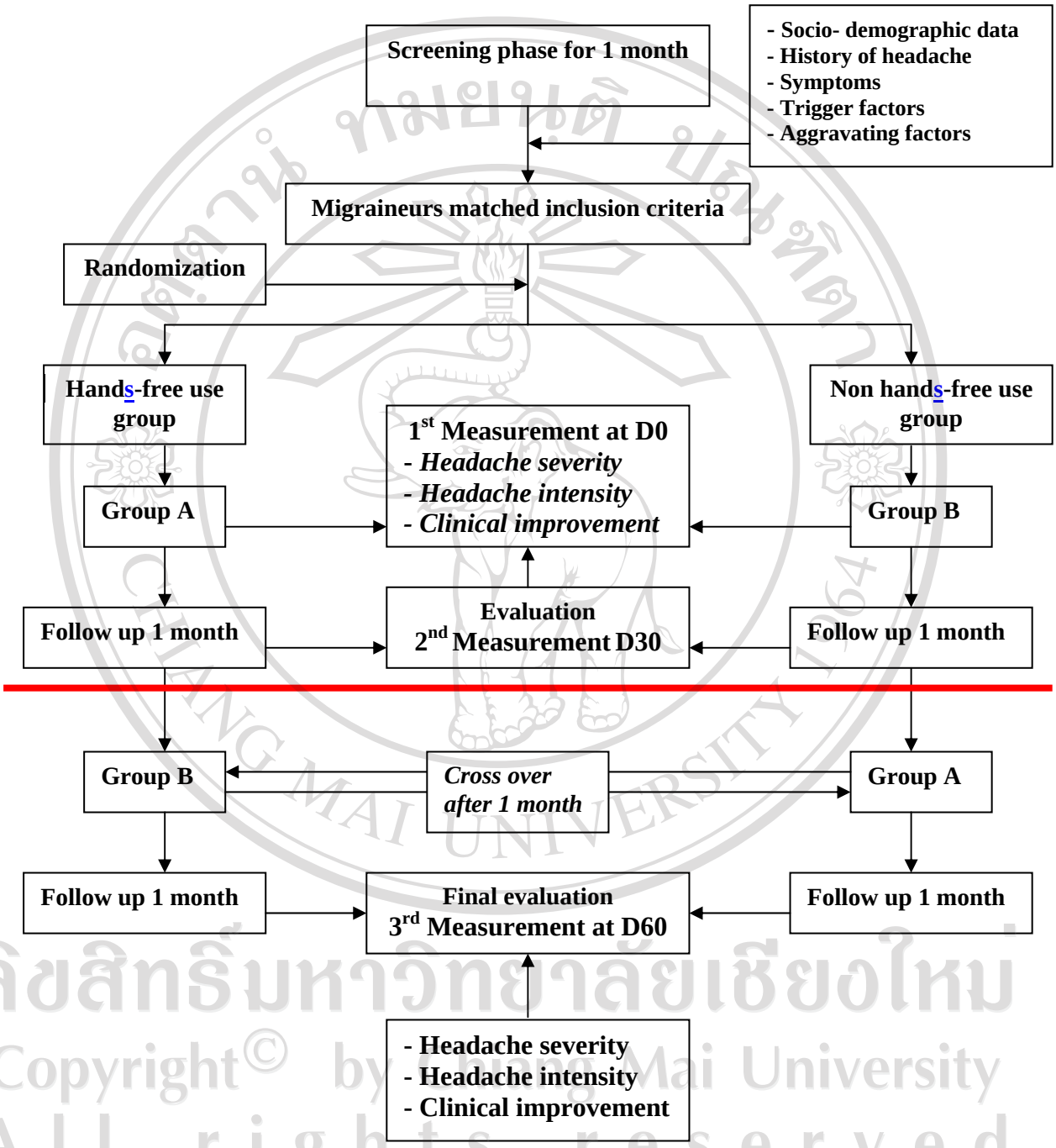


Figure 1.1 Conceptual framework.

1.4 Case definitions

1.4.1 Mobile phone exposure was defined as a person who used a mobile phone near to or directly on their ear without any substituted equipment such as hands-free kits.

1.4.2 Non- mobile phone exposure was defined as a person who used a mobile phone with hands-free equipment; with the mobile phone used far away from their ear.

1.4.3 Migraine headache was defined as any type of migraine with or without aura according to the International Headache Society criteria for migraine.

1.4.4 Risk factor of migraine was defined as the probability of a migraine attack when patients were exposed to a mobile phone for various time periods. The headache severity or frequency of attacks may then be ascertained.

1.4.5 Trigger factor (precipitating factor)

The trigger factor is that which increases the probability of a migraine attack in the short term (usually <48 hours) in persons who suffer with migraine. Although some trigger factors being the causal effect in individual patients may be difficult to prove [34].

1.4.6 Aggravating factor

The aggravating factor is in a person who has already met the criteria for migraine, when particular factors may be associated with relative long-term (usually weeks to months), with increased severity or frequency of attacks [34].

1.4.7 The prevalence of cases referred to old patients who had already been diagnosed with migraine headache and had visited the Headache Clinic many times before.

1.4.8 Incidence referred to new patients who had just been diagnosed with migraine headache on their first visit to the clinic.

1.4.9 Migraine attack was defined as the interval between each headache attack lasting longer than 48 hours.

1.4.10 Intervention was defined as the condition of patients who were assigned to use hands-free equipment with their mobile phone.