CHAPTER II
METHODOLOGY

This study was conducted with the objective of searching for evidence in order to acquire conclusions for developing an evidence-based practice guideline on posttraumatic headaches management in patients with mild traumatic brain injuries by setting the objectives, scope, and direction for the search for data in order to obtain proper recommendations on the assessment and management of headaches in patients with mild traumatic brain injuries. Steps of the search were as follows:

2.1 Search strategy

2.2 Appraisal method and levels of evidence

2.1 Search Strategy

The search for evidence was systematically conducted by gathering research studies, academic articles, and expert opinions so as to derive at evidence-based practice that matched patients with posttraumatic headaches. After that, the retrieved evidence was analyzed and evaluated to determine its level and credibility and to form conclusions on suggestions for the posttraumatic headache management in mild traumatic brain injury patients in the following steps:

2.1.1 The PICO framework

In this study, in order to acquire evidence concerning guidelines for posttraumatic headache management in patients with mild traumatic brain injuries, the scope for the search for studies and evidence was set using the PICO (Population, Intervention, Comparison, Outcome) framework of Craig and Smyth (2005) and Melnyk and Fineout-Overholt (2005) to set questions for obtaining studies and evidence-based practices that matched the study topic with details as follows:

P (Population): Mild head injury, mild traumatic brain injury, posttraumatic headache

I (Intervention): Cold packs, medication, physical therapy and manipulation, biofeedback, relaxation therapy, transcutaneous nerve stimulators, cognitive and behavioral therapies, thermal biofeedback, progressive muscle relaxation

C (Comparison): None

O (Outcome): Decreased pain, comfort, decreased headache, decrease posttraumatic headache

2.1.2 Scope of the Search

2.1.2.1 The scope of the search was determined as the inclusion criteria for selecting evidence that covered publications and disseminations in 2000-2013 in order to acquire only updated evidence published in either Thai or English with full texts available.

As regards the exclusion criteria, evidence with only abstracts, evidence-based practice conducted with pediatric patients, and evidence conducted with patients with headaches not caused by mild traumatic brain injuries were not selected.

2.1.2.2 The following keywords were used in the search:

- Mild head injury and posttraumatic headache
- Mild traumatic brain injury and posttraumatic headache
- Posttraumatic headache
- Posttraumatic headache and assessment
- Posttraumatic headache and management
- Posttraumatic headache and treatment
- Posttraumatic headache and evaluation
- Posttraumatic headache and intervention
- Posttraumatic headache and therapy
- Posttraumatic headache and cold packs
- Posttraumatic headache and medication
- Posttraumatic headache and physical therapy

- Posttraumatic headache and manipulation
- Posttraumatic headache and biofeedback
- Posttraumatic headache and relaxation therapy
- Posttraumatic headache and transcutaneous nerve stimulators
- Posttraumatic headache and cognitive and behavioral therapies
- Posttraumatic headache and thermal biofeedback
- Posttraumatic headache and progressive muscle relaxation
- Posttraumatic headache and decreased pain
- Posttraumatic headache and comfort
- Posttraumatic headache and decreased headache
- Posttraumatic headache and decreased posttraumatic headache

Settings for key words may change in each search in line with future search results. Boolean operators were used to help combine keywords by using the words “and” and “or” to help in the search.

2.1.2.3 The Following sources were determined for the search:Searches from electronic databases: single research studies were searched from the following electronic databases: Blackwell, BMJ, CINAHL, MDConsult, NursingConsult, OVID, ProQuest, Pubmed, ScienceDirect, SpringerLink. Also, SCOPUS Systematic Reviews were searched from www.joannabriggs.edu.au and The Cochrane Library Guideline from www.guidelines.gov.

- Online searches were also conducted from institutions or organizations that provided services of disseminating associated medical data from reference lists, i.e. www.ThaiLis.or.th.

- Manual searches were conducted to cover health academic journals, theses, and dissertations involved with headache management in patients with mild traumatic brain injuries from Mahidol University Library.

2.2 Appraisal Method and Levels of Evidence

2.2.1 Evaluation of Evidence Quality and Research Quality

Evaluation of the quality of the evidence obtained by the search employed the evidence-based practice assessment framework of DiCenso, Guyatt, and Ciliska (2005) by evaluating the following three issues:

1. Are the results valid?
2. What are the results?
3. How can I apply the results to patient care?

The three issues that were considered in the evaluation of the evidencewere as follows:

1) Are the results valid?

Randomized controlled trials are used increasingly to evaluate the quality, effectiveness, and cost of healthcare services. The power of randomization is that intervention and control groups are likely to be balanced with respect to both known and unknown determinants of outcome. The limitations of randomized controlled trials in health services research related to feasibility, external validity (generalizability), and their limited capacity to address the interaction of context, implementation, and impact of interventions. The strength of these observational designs lies in their potential to accommodate and assess the effects of contextual variation on processes and outcomes in a “natural” environment, thereby enhancing external validity. However, their weak point is their vulnerability to threats to internal validity. In a cohort study, the investigator identifies groups of patients, each a cohort, who are exposed and not exposed to the health services intervention and follows them forward in time to monitor the target outcome. In a case-control study, the starting point is the outcome of interest, such as an adverse event resulting from use or non-use of health services intervention. Those who experience the event are designated cases, and those who do not experience the event are designated controls. Investigators design case control studies to ensure that controls are reasonably similar to case with respect to important determinants of outcome such as age and sex, but who have not experienced the target outcome. Using this case-control design, the investigator then assesses the relative frequency of exposure to the intervention in the cases and

controls, adjusting for differences in known and measured determinants of outcome. As with cohort studies, case-control studies are susceptible to unmeasured confounding variables, particularly when exposure varies over time. Decision makers can draw inferences of only limited strength from the results of case-control studies because they only reveal whether an association exists and cannot determine whether such an association is causal. In systematic reviews, investigators explicitly state inclusion criteria for evidence, conduct a comprehensive search for the evidence, and summarize the results according to explicit rules that include examining how effects may vary in different subgroups. Systematic reviews provide strong evidence when the quality of primary study designs is high and sample sizes are large; they provide weaker evidence when study designs are poor and sample sizes are small. Because judgment is involved in many steps in a systematic review (including specifying inclusion and exclusion criteria, applying these criteria to potentially eligible studies, evaluating the methodological quality of the primary studies, and selection an approach to data analysis), systematic reviews are not immune to biases. Nevertheless, in their rigorous approach to identifying and summarizing data, systematic reviews reduce the likelihood of a bias in estimating causal links between health services intervention options and outcomes.

2) What are the results?

How large is the intervention effect? The same measures that are used to report effect sizes in studies of clinical interventions are also used in studies evaluating health services interventions (e.g., means, medians, odds ratios, relative risks, and absolute risk differences). An analysis of cluster randomized trials involves three approaches: (1) analysis at the cluster level, (2) adjustment of standard tests for the clustering effect, and (3) advanced statistical techniques using data recorded at both individual and cluster levels. How precise is the estimate of the intervention effect? The larger the sample size and the number of outcome events, the narrower the confidence interval. The boundaries of the confidence interval can help us interpret study results.

3) How can I apply the results to patient care?

Were the study setting and context similar to mine ? Health services interventions have effects within, and are influenced by, contexts and the

local and regional health care system within which they operate. Seemingly similar programs can have different effects depending on the local clinical culture and factors such as management structures and level and quality of staff. The time of the research may also affect its relevance. Were all important processes and outcomes considered? Even when investigators report favorable effect of a health services intervention one or more important outcomes, readers should consider whether negative effects on other outcomes may not have been measured or reported. An outcome that is often neglected is the resource implications of alternative health services interventions. The increasing resource constraints facing health care systems mandate careful attention to economic evaluation, particularly of resource-intense intervention.

This part involved consideration of the feasibility of implementation by considering patients, situations and agencies. Implementation of the findings in the care of patients for systematic reviews must consider all significant outcomes and the benefits patients will receive more than expenses and risks with consideration of differences in minor groups, beliefs, values of patients and agency settings. Implementation of the findings in the care of patients by randomized controlled trials requires similarity among the sample groups in studies and interested patient groups while inclusion criteria must match patients in clinics. If the inclusion criteria fails to match the limitations or reasons preventing the intervention from feasible implementation with patients, but the characteristics of the agencies were the same as the research and the interventions can be implemented in agencies with consideration of expenses or dangers, the benefits patients will receive and policy or practice should be changed as a result of these findings. The findings of case-control studies and cohort studies in the care of patients were implemented by considering similarities between the sample group in the studies and interested groups of patients, considering whether or not the characteristics of agencies were the same as in the studies, comparing between risks and benefits to be received from exposure. The findings of this study were consistent with other evidence-based practice. Implementation of the findings in the care of patients of qualitative studies was carried out by considering whether or not the findings had meanings and consistency with practice. The findings prompted greater understanding of environments regarding practice, revealed the effects of the characteristics of participants on research findings

with similarities between agencies and studies. Furthermore, the findings enhanced knowledge and understanding about practice (Grace, 2009).

According to the evaluation of the three issues of validity and reliability, it has been documented that the evidence-based practice could be used to manage posttraumatic headaches in patients with mild traumatic brain injuries.

2.2.2 Evaluating Strength of Evidence

This study used the Therapy Evidence Pyramid of Grace (2009) which divided levels of evidence into the following seven levels:

Levels of reliability of evidence are concluded as shown in Table 2.1 below.

Table 2.1: Levels of Research Evidence

Level	**Sources of Research-based Evidence**
Level 1	Evidence derived from a number of one randomized clinical trials or a systematic review or meta-analysis of randomized clinical trials (RCTs)
Level 2	Evidence derived from a systematic review of randomized trials
Level 3	Evidence derived from a high quality single randomized trial
Level 4	Evidence derived from a systematic review of observational studies addressing patient-important outcomes
Level 5	Evidence derived from single observational study addressing patient-important outcomes
Level 6	Evidence derived from physiologic studies
Level **7**	Evidence derived from unsystematic clinical observations or expert opinions

Summary of M8ethodology

The use of the “PICO” (PICO framework) to determine the scope of the search led to evidence-based practice that matched the topic of management of headaches in patients with mild traumatic brain injury, which was a clinical problem of interest. The data obtained in the search were then analyzed and synthesized.