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2015

Background

Anxiety, insomnia, mental stress, depression, or headache continues to grow with significant impacts on health and major social, human rights and economic consequences in all countries of the world. Depression is a common mental disorder and one of the main causes of disability worldwide. Current treatments for anxiety, insomnia, mental stress, depression or headache include medications, cognitive behaviour therapy or psychotherapy. However, current treatments may be costly and may be harmful due to side effects. As the number of people with anxiety, insomnia, mental stress, depression, or headache increases, there is an increase interest in traditional and complementary medicine (T&CM). According to the World Health Organization (WHO) Traditional Medicine Strategy 2014-2023, although there are common themes underlying the reasons which motivate people to use T&CM, there are also many differences between individual countries and regions. Some studies have shown that individuals choose T&CM for various reasons, including an increased demand for all health services, a desire for more information leading to an increased awareness of available options, an increasing dissatisfaction with existing health-care services, and a rekindled interest in "whole person care" and disease prevention which are often associated with T&CM.

Shirodhara is a widely practised complementary treatment of Ayurveda in both India and the United States. It is usually indicated to treat stress, anxiety, and insomnia and to relax the nervous system. In Sanskrit, *shiro* means head and *dhara* means dripping; *Shirodhara* is the process of dripping some medium on the forehead for tens of minutes. There are several kinds of *dhara* techniques, depending on the medium for dripping. For example, *takra dhara* uses takra that is prepared with the curd of cow's milk. *Kshira dhara* uses cow's milk mixed with some medicinal herbs such as *Sida cordifolia* or *Asparagus rasemosus*. *Taila dhara* uses medicated oil mixed with cow's milk, water, herbs, and sesame oil. *Shirodhara* is one of the modalities that have been introduced in the Ministry of Health Integrated Hospitals at the T&CM Units. It is offered as a complementary therapy to a patient's existing treatment for the well being of the patient since it is claimed to calm the mind, reduce stress and resolves any emotional imbalances. This technology review was requested by the Director of the Traditional and Complementary Medicine Division, Ministry of Health, Malaysia to look into the evidence on *Shirodhara* practice for patients with anxiety, insomnia, mental stress, depression or headache.

Objective/Aim

The objective of this systematic review was to assess the safety, efficacy / effectiveness, economic and organizational implication of *Shirodhara* as a complement therapy to standard treatment for anxiety, insomnia, mental stress, depression, or headache.

Results and Conclusions

A total of 150 titles were identified through the Ovid interface, AMED database, MANTIS and PubMed. There were seven articles included in this review: two RCTs, two randomised cross over studies, two pre- and post-intervention studies, and one case series. Three studies were conducted in Japan, three in India and one in the United States of America (U.S.A.). Four of the studies were conducted among healthy population. All studies had small sample size.

Efficacy / Effectiveness

There were four articles retrieved on the efficacy / effectiveness of *Shirodhara* for treatment of anxiety, two articles for treatment of insomnia and one article for

mental stress.

There was very limited retrievable evidence to suggest the effectiveness of *Shirodhara* in reducing anxiety, insomnia and mental stress. Three studies reported that as anxiety score decreases, the altered state of consciousness (ASC) scores increases and the skin temperature of the foot increases with increased in ASC scores and decreased in anxiety scores. One study reported an overall significant improvement of mean Insomnia Severity Index (ISI) between baseline and day five (end of treatment); at baseline, the mean ISI score was 19.44, and at day five, the mean ISI score was 13.22, ($P < 0.005$), while the recovery of symptoms for insomnia was found to be significant in another study. One study reported significant improvement in mood scores and level of stress ($P=0.003$). Since the studies retrieved were of short duration, the long term effect of *Shirodhara* on anxiety, insomnia and mental stress could not be determined.

There was no retrievable evidence on the efficacy / effectiveness of *Shirodhara* for the treatment of depression or headache.

Safety

There was very limited retrievable evidence to suggest that *Shirodhara* is safe. However, it should be performed in the most appropriate and safest conditions since in some extreme conditions, some subjects suffered from headache, chill, or other discomfort.

Cost /cost-effectiveness

There was no retrievable evidence on cost-effectiveness.

Organizational

It is pertinent to have a guideline in order to provide safe, quality, and standardised practice of *Shirodhara* especially at all T&CM Units in the Integrative Hospitals. The practitioners need to be trained.

Methods

Electronic databases were searched through the Ovid interface: Ovid MEDLINE® In-process and other Non-indexed citations and Ovid MEDLINE® 1946 to present, EBM Reviews - Cochrane Central Register of Controlled Trials - January 2015, EBM Reviews - Cochrane Database of Systematic Reviews - 2005 to January 2015, EBM Reviews - Health Technology Assessment - 1st Quarter 2015, EBM Reviews – NHS Economic Evaluation Database 1st Quarter 2015, AMED – 1985 to February 2015, MANTIS Database – 1980 to February 2015. Searches were also run in PubMed. Google was used to search for additional web-based materials and information. No limits were applied. Additional articles were identified from reviewing the references of retrieved articles. Last search was conducted on 4 March 2015.