SHIRODHARA
FOR
ANXIETY, INSOMNIA, MENTAL STRESS, DEPRESSION OR HEADACHE

HEALTH TECHNOLOGY ASSESSMENT SECTION
MEDICAL DEVELOPMENT DIVISION
MINISTRY OF HEALTH MALAYSIA
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DISCLAIMER

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DISCLOSURE

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EXECUTIVE SUMMARY

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.

SHIRODHARA FOR ANXIETY, INSOMNIA, MENTAL STRESS, DEPRESSION, OR HEADACHE

1. 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. Globally, about 400 million people of all ages suffer from depression.[1] The adjusted global prevalence of anxiety disorders was 7.3% (4.8 to 10.9%) and ranged from 5.3% (3.5 to 8.1%) in African cultures to 10.4% (7.0 to 15.5%) in Euro/Anglo cultures.[2] It has been estimated that 47% of adult population have headache at least once within last year in general.[3]

In Malaysia, a study by Sidik SM, Arroll B, Goodyear-Smith F among 895 women attending a primary care clinic reported an anxiety prevalence of 7.8%.[4] Zailinawati et al. reported the prevalence of insomnia symptom in Malaysian adults based on a community survey in four urban areas involving 1,611 subjects as 33.8%, whereby 12.2% of the subjects were found to have chronic insomnia.[5] In another cross sectional study involving 2,049 adults patients attending seven primary care clinics in Peninsular Malaysia it was found that 60% reported insomnia symptoms, 38.9% had frequent insomnia symptoms (> 3 times per week), 30.7% had chronic insomnia without daytime consequences and 28.6% had chronic insomnia with daytime dysfunction.[6]

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. In the last decade, across all types of utilization patterns, there has been an increase in self-health care as consumers choose to be more proactive about their own health. Many consumers turn to T&CM

products and practices on the assumption that “natural means safe”, which is not necessarily true.[7]

Shirodhara is a widely practised complementary treatment of Ayurveda in both India and the United States.[8] It is usually indicated to treat stress, anxiety, and insomnia and to relax the nervous system.[8] *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.[9] 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.

2. 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.

3. TECHNICAL FEATURES

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 t*akra* 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.[10]

3.1. Indications and contraindications of *Shirodhara* at the T&CM Units[9]

Indications:[9]

- Insomnia
- Headaches
- Stress or mental fatigue
- Anxiety
- Depression – only patients with mild depression

Contraindications:[9]

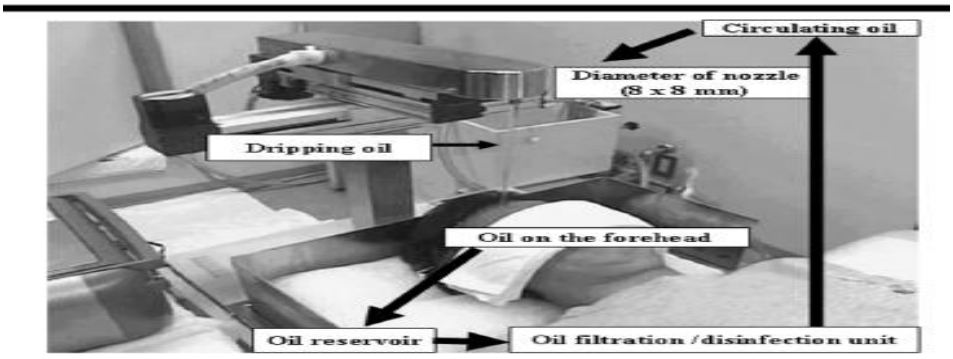
- Low blood pressure
- Alcoholism
- Drug dependency or addiction
- Pregnancy

- Brain tumour
- Central or peripheral neuropathy
- Peripheral arterial disease
- Conditions of the head and neck region; recent neck injury, presence of an open wound, presence of inflammation, loss of sensation, acute sinusitis

3.2. Treatment procedure

In the original method of *Shirodhara,* various kinds of vessels are used for reservoirs of dripping oil or other mediums. The dripping technique cannot be regulated in a reproducible manner. [10]

Shirodhara can be performed by a machine with a pumping and heating system (*Shirodhara* healing robot) where treatment can be regulated automatically by the computerised system as shown in below.[10]



- *Shirodhara* is performed with the patient lying in supine position with the head and neck supported with a roll of towel or pillow[9]
- A towel is placed over the eyes to protect them from the oil during the procedure[9]
- A stream of warm oil is poured onto the centre of the forehead, between the eyes. This point is said to be the centre of perception.
- Most appropriate and safest conditions in performing the procedure is; oil temperature kept at 39 °C ± 0.2 °C, oil flow rate of 2.0 to 2.3

L/min, diameter of the dripping oil nozzle of 8 x 8 mm to 10 x 10 mm, distance between nozzle and forehead at 20 cm.[9,10]

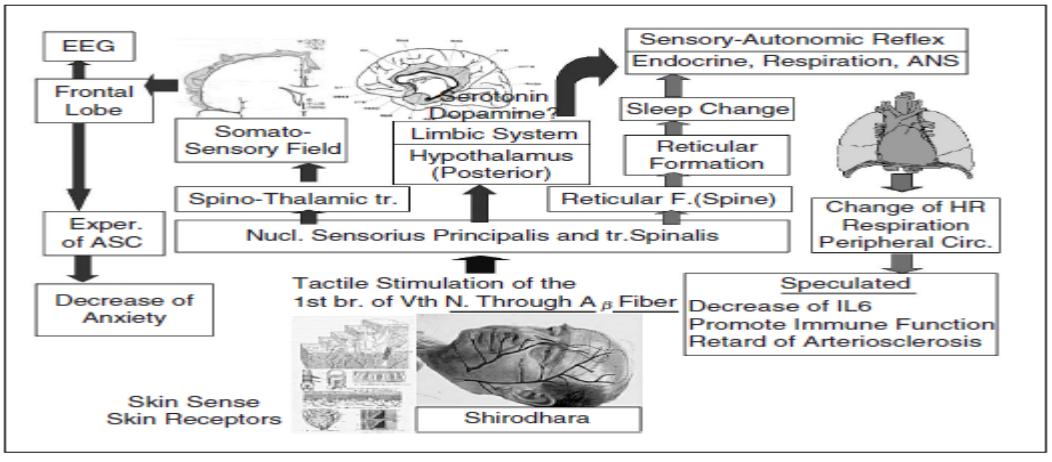
- The oil dripping procedure is followed by a gentle scalp or head and neck massage[9]
- Patients are required to rest at the treatment table for 10 to 15 minutes after completion of the procedure.[9]

3.3. Treatment Regime[5]

- Each treatment session should last between 45 to 60 minutes:
  - ✓ Massage of the above shoulder region – 15 minutes
  - ✓ *Shirodhara* – 30 minutes
  - ✓ Rest after *Shirodhara* – 10 to 15 minutes
- Treatment sessions will be done, based on the practitioner's assessment of the patient's condition:
  - ✓ Daily for 3 to 4 days, or
  - ✓ Once a week, or
  - ✓ Once a month

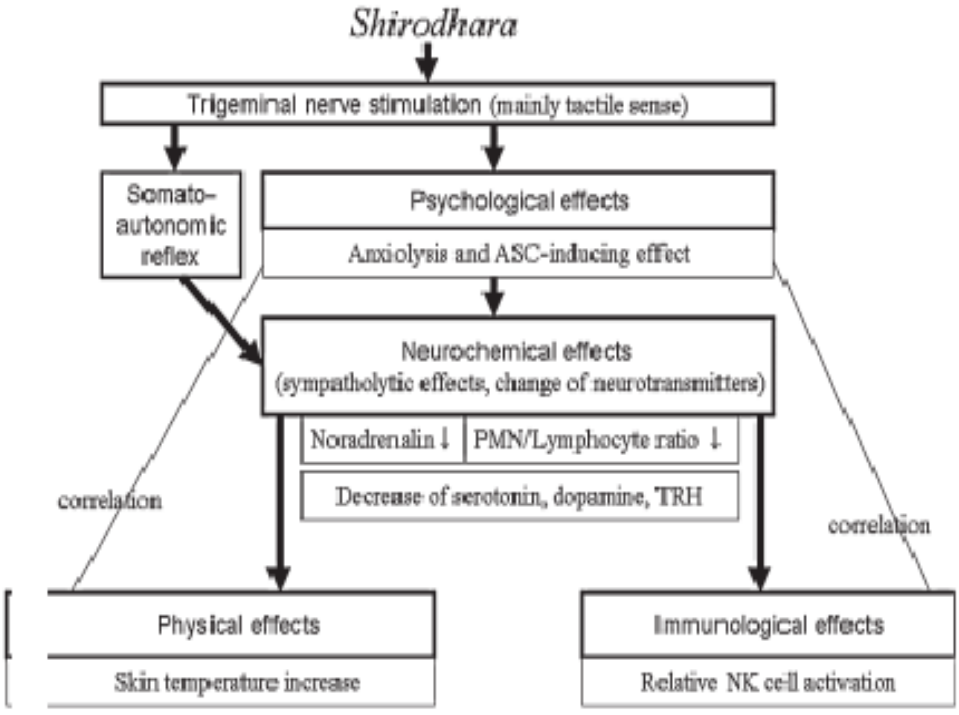
3.4. Hypothesised neurophysiological mechanism of *Shirodhara*[10]

The neurophysiological mechanism of the effects of *Shirodhara* on the psycho-physiological changes may be related to the tactile stimulation of the skin or hair follicles innervated by the first branch of the trigeminal nerves (ophthalmic nerve). The impulses would be transmitted to the thalamus through the principal nucleus and forward to the cerebral cortex (somato-sensory field) or limbic system. The routes would provide the subjects with altered states of consciousness (ASC) experience and a relief from anxiety. Other routes from the principal nucleus to the reticular formation and posterior region of the thalamus, which is the centre of autonomic nervous system, would be possible. The latter routes would provide a rationale for changes in sleep and changes of autonomic nervous balance, as reflected bt the R-R variability and the skin temperature of the foot. This hypothesis is outlined below.



3.5. Hypothesised psychoneuroimmunologic mechanism of *Shirodhara*[11]

Uebaba et al. postulated that warm, plain sesame oil starts the action from the tactile stimulation of the skin innervated by the first branch of the trigeminal nerve. It is possible that the impulses are transmitted to the thalamus through the principal nucleus and forwarded to the cerebral cortex. The impulses from the forehead cause a somato-autonomic reflex, and changes in levels of various neurotransmitters including, serotonin, TRH, and catecholamine, resulting in sympathetic suppression and physioimmunologic changes of peripheral circulation and NK cell activity as shown below.



4. METHODS

4.1. Searching

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.

Appendix 1 showed the detailed search strategies.

4.2. Selection

A reviewer screened the titles and abstracts against the inclusion and exclusion criteria and then evaluated the selected full text articles for final article selection.

The inclusion and exclusion criteria were:

Inclusion criteria

Population	Patient / people with anxiety, insomnia, mental stress, depression, or headaches
Interventions	*Shirodhara*
Comparators	No comparator or standard treatment
Outcomes	i. Safety: - Adverse events, complications associated with *Shirodhara* ii. Efficacy: - Reduction in anxiety, reduction in insomnia, reduction in mental stress, reduction in depression or reduction in headaches - Quality of life - Days lost from work, school or other daily activities iii. Economic implication (cost, cost-effectiveness) iv. Organizational issues: practitioner, training, guidelines
Study design	Health Technology Assessment (HTA), Systematic Review, Randomised Controlled Trial (RCT), Non randomised controlled trial, Cohort study, pre- and post-intervention study, cross sectional study, case series
	English full text articles

Exclusion criteria

Study design	Studies conducted in animals, narrative reviews, or case report
	Non English full text articles

Relevant articles were critically appraised using Critical Appraisal Skills Programme (CASP) and graded according to US/Canadian preventive services task force (Appendix 2). Data were extracted and summarised in evidence table as in Appendix 3.

5. RESULTS AND DISCUSSION

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.).

5.1. 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 no article retrieved on the efficacy / effectiveness of *Shirodhara* for treatment of depression or headache.

5.1.1. Anxiety

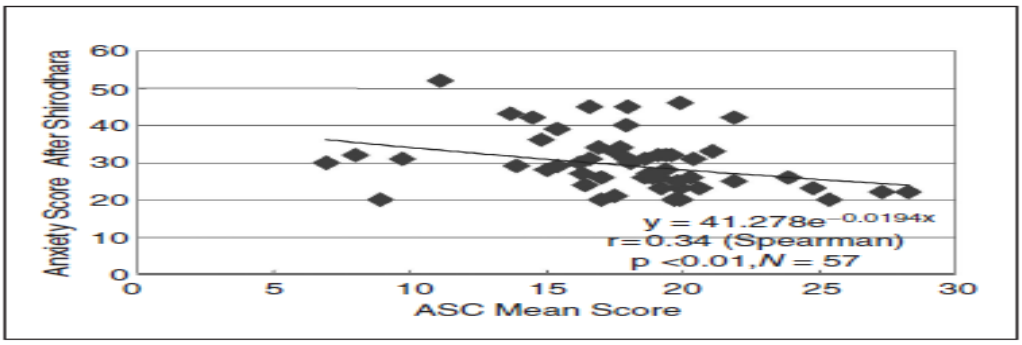
Uebaba et al. conducted pre- and post- intervention studies to assess the impact of *Shirodhara* on the patient's state of well being and to assess factors in the therapy that altered the patient's state. Fifty seven healthy volunteers participated in this study (ages: 22 to 46 years). Treatment was regulated automatically by the computerised system using the healing robot. The oil used was plain cold-pressed preheated sesame oil (Kadoya oil Co., Ltd.). The pretreatment control period was set at 10 min and the *Shirodhara* treatment session was fixed for 25 min. The mode of dripping sesame oil was as follows; oil temperature (39 ± 0.2°C), oil flow (2.3 ± 0.2 L/min), dripping pattern (five minutes each for eight knot, horizontal, and vertical, then another four minutes for each). The nozzle of oil moved at the slowest speed (1.5 cm/s). The subjects skin temperature of the right neck, right hand, and right foot was monitored throughout *Shirodhara.* The psychological changes were assessed by psychometric studies using the State-Trait-Anxiety Inventory (STAI) before and after *Shirodhara* and altered state of consciousness (ASC) questionnaire developed by Saito just after *Shirodhara*. In order to assess the anxiolytic effect of the robotic therapy, 10 of the 57 subjects with abnormally high STAI scores from the above study participated. An STAI score of more than 40 was considered as high. Ten females received *Shirodhara* for 25 minutes once each week, four times a month. Profile of Mood States (POMS) scores were assessed before and after *Shirodhara.* POMS have five assessment domains: tension and anxiety, depression, anger and hostility, vitality, exhaustion and confusion.[10, level II-2]

The studies found that, 46 of 57 subjects (81%) who were treated with *Shirodhara* experienced some kind of ASC. The highest ASC scores were obtained in the domains of trance, passiveness, timeless sensation, wordless sensation, and concentration. In the 10 subjects with the high

state of anxiety, the changes in the POMS score indicated significant decrease of tension and anxiety (Wilcoxon signed rank test, P < 0.005) and tendency towards a decrease in exhaustion. The other domains (depression, anger and hostility, vitality, confusion) the average level showed improvement with *Shirodhara* but none of these differences were statistically significant.[10, level II-2]

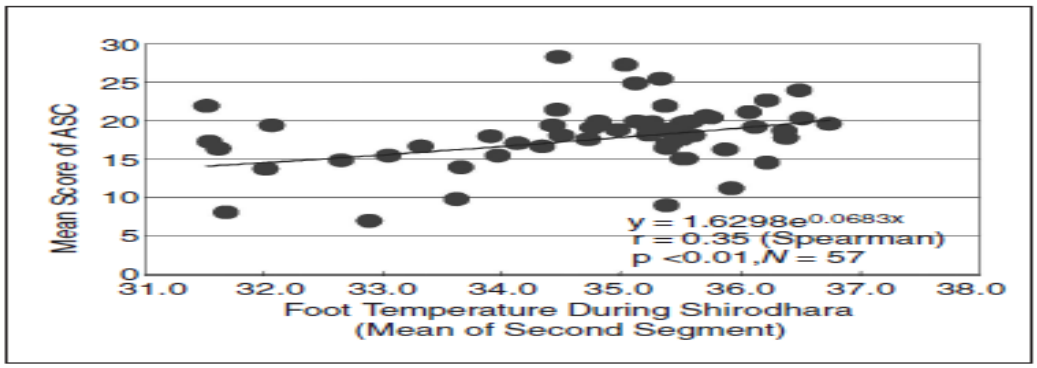
The correlation between the mean ASC score and anxiolytic effects was not very high, but a significant correlation was obtained (Figure 1, r = 0.34, P < 0.01, Spearman's correlation coefficient). The trend line shows that anxiety decreases with increasing ASC score. [10, level II-2]

Figure 1. The Correlation between mean ASC score and anxiety after *Shirodhara.*



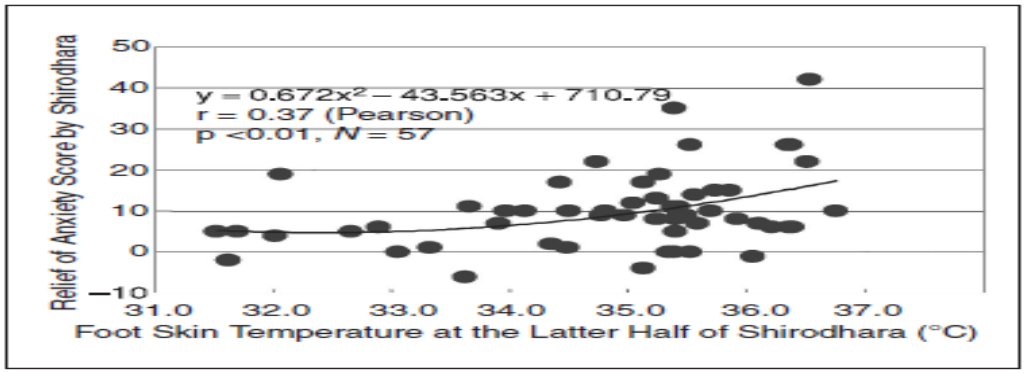
A similar degree of correlation was obtained between the means ASC score and the mean skin temperature of the foot during the later half of the *Shirodhara* (Figure 2, r = 0.35, P < 0.01, Spearman's correlation coefficient). The trend line indicates that as foot temperature increases, so does AFC.[10 level II-2]

Figure 2. The correlation between mean ASC score and foot skin temperature during *Shirodhara.*



The mean skin temperature of the foot in the latter half of *Shirodhara* is also correlated with a decrease in the state of anxiety (Figure 3, r = 0.37, P < 0.01, Spearman's correlation coefficient). The trend line shows that foot skin temperature increases with decreasing levels of anxiety.[10, level II-2]

Figure 3. The correlation between anxiety score and foot skin temperature during *Shirodhara.*

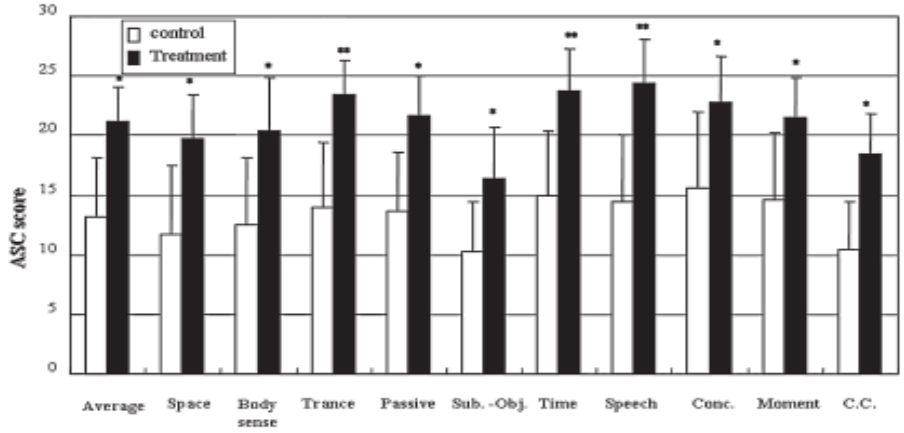


The skin temperature of the right hand or the right neck had nothing to do with ASC or anxiety. The authors concluded that the subjects feeling during *Shirodhara* showed deep restfulness with less anxiety–as if the subject were between the sleep and awake states.[10, level II-2]

Uebaba et al. conducted another study (randomised cross over study) involving 16 healthy females to assess the psychoneuroimmunologic changes achieved by *Shirodhara.* The 16 females were assigned to either the plain sesame oil *Shirodhara* treatment or control supine position for 30 minutes in a random sequence. Anxiety was assessed using STAI and anxiolysis was calculated as the percent change between pre-and post-treatment assessments. The psychometric instrument for ASC was used. Skin temperature of the dorsal side of the right hand and foot was monitored with thermocouple sensors. Skin temperature was measured every 10 seconds and recorded. Serum thyrotropin-releasing hormone (TRH) was measured using radioimmunoassay (RIA), natural killer (NK) cell activity measured using chromium uptake method, plasma catecholamine (adrenaline, noradrenaline, and dopamine by high-performance liquid chromatography), and urinary serotonin were examined with Mitsubishi Chemical Co. Ltd. [11, level II-2]

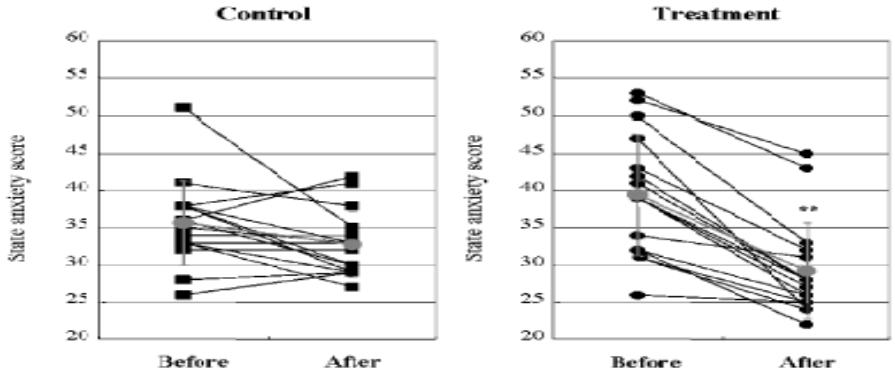
They reported that subjects receiving *Shirodhara* treatment showed decreased levels of state anxiety, and higher levels of ASC scores than those in the control supine position. ASC scores in the treatment are higher than that of the control supine position in all the domains ($P < 0.05$ or $P < 0.01$) – Figure 4. *Shirodhara* treatment induced significant anxiolysis ($P < 0.01$), without any change in the control supine position (Figure 5).[11, level II-2]

Figure 4. Comparison of altered state of consciousness (ASC) by *Shirodhara* and control supine position.



Footnote: * P < 0.05, ** P < 0.01

Figure 5. Anxiolytic effect of *Shirodhara* in treatment and control groups.



Footnote: ** P < 0.01

The skin temperature of the dorsal aspects of the right foot, but not the right hand, increased more in the *Shirodhara* treatment than in the control condition (P < 0.1). The found that plasma noradrenaline levels in the *Shirodhara* treatment decreased significantly more than that in the control (P<0.05). Neither plasma adrenaline nor plasma dopamine levels showed a significant difference. Urinary serotonin excretion just after and one hour after finishing *Shirodhara* was decreased significantly more than in the control condition (P<0.05).[11, level II-2]

The correlation between ASC scores of all 10 domains and the anxiolytic effect were significantly higher in the Trance experience of *Shirodhara* (r = 0.52, P < 0.05), while there was no significant correlation in the control condition (r = 0.13, P = 0.64). The increase in foot skin temperature after S*hirodhara* showed a significant correlation with anxiolysis and the depth depth of Trance of ASC (r = 0.58, P < 0.01, r = 0.43, P < 0.01,

respectively).NK cell activity after S*hirodhara* treatment showed significant correlation with anxiolysis and the depth of Trance of ASC ($r = 0.33$, $P < 0.05$, $r = 0.56$, $P < 0.01$, respectively).[11, level II-2]

The pharmaco-physio-psychologic effect of *Shirodhara* with medicated sesame oil including an essential oil from *Lavendula angustifolia* (lavender) were studied by Xu et al. Sixteen healthy females (38 ± 8 years old) were assigned at random to three treatment applied by a robotic oil-dripping system. Each subject had all of the three kinds of treatments. The first treatment was *Shirodhara* using medicated sesame oil with 0.3 volume % of lavender essential oil (lavender *Shirodhara*), the second treatment was *Shirodhara* using plain sesame oil (plain *Shirodhara)* and the third treatment was the control supine position. Psychophysiologic parameters including the heart rate, skin temperature of the dorsum of hands and feet, as well as anxiety and ASC were monitored and the rates of change of these items were calculated.[12, level II-2]

They found that after two types of *Shirodhara* treatment, the subjects showed significant decreased levels of state anxiety ($P < 0.05$), while the control condition revealed no such change. There was no significant difference between anxiolytic effects induced by lavender *Shirodhra* and plain *Shirodhara*. Lavender *Shirodhara* led to higher scores than control in eight domains in the ASC, while plain *Shirodhara* led to higher scores than the control in only three domains according to Dunnet's t-test. However, there was no significant difference between lavender and plain *Shirodhara* treatment. Average ASC score was not correlated with anxiolysis in the control study, while plain and lavender *Shirodhara* showed a correlation ($r = 0.44$, $r = 0.50$) respectively. In terms of correlation between anxiolysis and each ASC domains; lavender *Shirodhara* revealed the most significant correlations: five of the 10 ASC domains were correlated with anxiolysis.[12, level II-2]

The study also found that during the 10 minutes after starting *Shirodhara*, control and *Shirodhara* treatments led to similar increases in the skin temperature: 0.4-0.6ºC (hands), and 0.2-0.3ºC (feet). However, from 15 to 30 minutes, the differences between lavender *Shirodhara* and control treatments became clear, with maximal difference 0.2ºC (hands) and 0.6ºC (feet). The foot skin temperature showed a significantly greater elevation even in the plain *Shirodhara* treatment compared to control. The foot skin temperature elevation showed strongest correlation with anxiolysis and the average ASC score in lavender *Shirodhara,* and weakest correlation with the control treatment. The plain and lavender *Shirodhara* showed a significant increase in RR mean compared with the control during the first five minutes of the 30-minute *Shirodhara* treatment. [12, level II-2]

The authors speculated that the psycho-physiologic effects of lavender *Shirodhara* would be brought about by three mechanisms: (1) the well-known relaxing action of essential oils from L. *angustifolia* mediated by olfactory nerves, (2) pharmacologic action of substances absorbed through the skin or mucosa in the sesame oil or lavender essential oil, and (3) the physiologic effect of sesame oil dripped on the forehead induced by the somato-autonomic reflex through the sensors or pressure sensors in the skin or hair follicles via the trigeminal nerves.[12, level II-2]

The use of *Shirodhara* in combination with *Manasamitra Vataka* (an Ayurveda medication) for the treatment of patients with Generalized Anxiety Disorder (GAD) with comorbid generalised social phobia was evaluated by Tubaki et al. in an RCT. Seventy two patients were randomly divided using blocked randomisation into one of the three groups: Group I (n=24) received *Manasamitra Vataka* tablets (100 mg twice daily for 30 days), Group II (n=24) in addition to *Manasamitra Vataka*, underwent *Shirodhara* (therapy involving dripping of medicated oil [Brahmi tail] over the forehead) treatment for the first 7 days, Group III (n=24) received clonazepam 0.75 mg daily in divided dose for 30 days. The assessment of the study was done using Hamilton Anxiety Rating Scale (HARS), Beck Anxiety Inventory (BAI), Beck Depression Inventory (BDI), Epworth Sleepiness Scale (ESS), World Health Organization Quality of Life BREF (WHOQOL BREF), and Clinical Global Impression scales (CGI) (Improvement and efficacy). All patients were subjected to clinical evaluation on the 15^{th} and 30^{th} day of the treatment. Response to treatment was defined as reduction of 50% or more in the HARS and BAI scales. Symptom remission was defined as HARS < 8, BAI score < 7, and CGI-I (very much and much improved) of one or two scores. Comparison of groups across different time points was carried out by repeated-measure analysis of variance (ANOVA) with Tukey post-hoc test.[13, level II-2]

They reported significant improvement on both the 15^{th} and 30^{th} day of interventions in HARS ($P<0.001$), BAI ($P<0.001$, and CGI-I ($P < 0.001$).
There were no significant differences observed in any of these parameters between groups. The effect size of Groups II and Group I showed moderate to large effect compared to Group III. However, the response and remissions were comparable between groups. They found that all interventions produced significant linear improvement in BDI ($P<0.001$). However, improvement in ESS was observed only in Group II. The authors concluded that this is the first study conducted on the efficacy of *Manasamitra Vataka* in anxiety disorders. The results suggest that *Manasamitra Vataka* is effective in the management GAD with comorbid generalized social phobia. Add-on effect of *Shirodhara* reduced the daytime sleepiness. Further studies on *Manasamitra Vataka* need to be carried out to judge its potential as a first-line treatment modality.[13, level II-2]

5.1.2. Insomnia

Vinjamury et al. conducted a study (case series) to determine the feasibility of recruiting and retaining participants in a clinical trial on *Shirodhara* for insomnia in the U.S.A. Ten consecutive volunteers who responded to community wide recruitment efforts were enrolled in the study between September 2009 and August 2010. Participants between ages 18 and 75 years of either sex with a duration of insomnia of at least one year who were willing to sign an informed consent and who had a minimum score of 14 on the Insomnia Severity Index (ISI) were included in the study. The study excluded people with comorbidities such as depression or any other psychological conditions that require medications and those who were on prescription medication for insomnia. *Shirodhara* with Brahmi oil (coconut oil processed with *Hydrocotyle asiatica* primarily and less than 20% of *Triphala*) was done for 45 minutes on each participant for five consecutive days. Insomnia Severity Index was used to evaluate the severity of insomnia as well as to determine the response of *Shirodhara* therapy. Data were collected at baseline, end of treatment (day five), and one week after treatment ended.[8, level II-3]

One participant dropped out after one treatment because she did not want to wash her hair every day after the oil treatment. They found that comparing baseline to day five (end of treatment), all nine participants experienced improvement; for six participants, the percentage of improvement ranged from 25.93% to 69.57%. For the other three participants, there was slight improvement with a ranged of 3.85% to 8.33%. When comparing baseline to one week post treatment, the percentage of improvement ranged from 8.33% to 86.96% with one exception (one study participant's insomnia worsened by -66.67%). Comparisons of means between baseline and day five (end of treatment) indicated an overall significant improvement; at baseline the mean ISI score was 19.44, and at day five the mean ISI score was 13.22, ($P < 0.005$), but in comparison of baseline versus one week post treatment, the improvement was not significant ($P < 0.089$). The authors concluded that Shirodhara with Brahmi oil may be beneficial for moderate to severe insomnia. It is feasible to recruit and retain participants for such therapies in the United States. It is important to validate these findings and investigate the mechanism of action using a larger sample and rigorous research design.[8, level II-3]

Pokharel S and Sharma AK conducted an RCT in 30 clinically diagnosed patients with *Anidra* (insomnia) to evaluate the clinical efficacy of *Shirodhara* and *Tab. Insomrid* (proposed herbal formulation) for the management of insomnia. The patients were randomly divided into the following three groups of 10 patients each: Group I, (n=10) were recommended Tab. *Insomrid* for 30 days, Group II, (n=10) were

administered *Shirodhara* with luke warm milk for 15 days and Group III, (n=10), were recommended both Tab. *Insomrid* and *Shirodhara* simultaneously. Patients were followed up after 15 days and 30 days and changes, improvements, deterioration and any other effects produced after therapy were noted down. Following symptoms of insomnia were assessed before and after therapy: Yawning, drowsiness, malaise, fatigue & alertness, headache, lack of concentration, loss of memory, poor sensory perception, indigestion, constipation, weight loss, loss of lustre. A sleep diary was provided and it contained the following points: time into bed, time of lights out, time to fall asleep, number of awakenings, time out of bed, naps-day time, rate how you felt today, irritability, total time of sleep, sleep quality.[14, level II-2]

The study reported that the clinical recovery of symptoms for insomnia were found to be highly significant ($P < 0.001$ or $P < 0.01$), or significant ($P < 0.05$) for 11 insomnia symptoms in Group I, Group II and Group III. Only one symptom (poor sensory perception) did not improve significantly ($P < 0.10$). Recovery in sleep diary assessment for time to fall asleep, number of awakenings, naps-day time, rate how you felt today, irritability, total time of sleep and sleep quality was found to be highly significant ($P < 0.001$ or $P < 0.01$) in all the three groups. The authors concluded that Tab. *Insomrid* (herbal formulation) and *Shirodhara* with milk are very safe and effective treatment modalities and can be used effectively in the management of *Anidra* (insomnia).[14, level II-2]

5.1.3. Stress

Dhuri KD, Bodhe PV, Vaidya AB conducted a pre- and post-intervention study to evaluate the psychological and physiological effects of *Shirodhara* in healthy volunteers by monitoring the rating of mood and levels of stress, electrocardiogram (ECG), electroencephalogram (EEG), and selected biochemical markers of stress. The study was conducted in the human pharmacology laboratory. The study was open labelled, comparing the baseline variables with values after *Shirodhara. Shirodhara* was preceded by Abhyanga –whole body massage. The *Shirodhara* method was standardised for rate of dripping with peristaltic pump and temperature was controlled with a thermostat. The stress and mood were assessed with the use of validated rating scales; V.A.S. (Visual Analogue Scale) and M.A.S (Mood Assessment Scale), basally, immediately after *Shirodhara* and three days later. The salivary cortisol and urinary catecholamines were assessed by standard ELISA method and fluorometry, respectively. [15, level II-2]

They found that there was a significant improvement in mood scores and the level of stress ($P = 0.003$). These changes were accompanied by significant decrease in rate of breathing ($P = 0.02$) and in reduction in diastolic blood pressure ($P = 0.027$) along with reduction in heart rate ($P =$

0.0015). The relaxed alert state, after Shirodhara, was co-related with an increase in alfa (α) rhythm in EEG. [15, level II-2]

5.2. SAFETY

Uebaba et al. conducted a cross sectional study among 16 healthy females to determine the most appropriate conditions in operating the robotic system of oil dripping. They found that the most appropriate and safest conditions of operating the robotics of oil dripping were 30-minute duration at 39°C at an oil flow rate of 2.3 L/min. The diameter of the dripping oil nozzle was 8 x 8 mm. Other fixed conditions were the moving speed of the dripping nozzle, set at 1.5 cm/sec, and the height of the nozzle, being set at 20 cm above the forehead. The pattern of dripping comprised temple, horizontal, and vertical movements, two times each 5-minute movement. The safety of the methods should be taken into account, because, in some extreme conditions, some subjects suffered from headache, chill, slight chill, or other discomfort.[11]

In another study, Uebaba et al. reported that there were no cases of headache or skin eruption which was directly related to *Shirodhara*. However, some subjects complained of compression discomfort of the occipital region or numbness of the extremities or lower back, which were not directly attributed to *Shirodhara.*[10, level II-2] Vinjamury et al. reported that there was no adverse events or side effects experienced by participants during the entire study period.[8, level II-3] Similarly, Pokarel S and Sharma AK reported no adverse effects were noted in any of the patients during the trial period.[14, level II-2]

5.3. COST / COST-EFFECTIVENESS

There was no cost-effectiveness analysis retrieved. *Shirodhara* treatment is free in the T&CM Units in MOH hospitals. The estimated charge per session in the private ranged from [redacted]

5.4. ORGANIZATIONAL

5.4.1 Guideline

The Traditional & Complementary Medicine Division, Ministry of Health Malaysia had develop the Traditional and Complementary Medicine Practice Guidelines on *Shirodhara* in 2011.[9]

5.4.2. Training

Vinjamury et al. reported that *Shirodhara* was performed by two research assistants who were trained by an Ayurvedic practitioner trained in India.[8, level II-3]

5.5. LIMITATIONS

This technology review has several limitations. The selection of studies was done by one reviewer. Although there was no restriction in language during the search but only English full text articles were included in this review.

There were only seven studies retrieved. All the studies have small sample size, and there was no blinding mentioned in the RCTs. Four of the seven studies were conducted among healthy population. All the studies were of short duration.

6. CONCLUSION

6.1. Efficacy / effectiveness

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 scores decreases, the ASC scores increases and the skin temperature of the foot increases with increased in ASC scores and decreased in anxiety scores. 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.

6.2. 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.

6.3. Cost /cost-effectiveness

There was no retrievable evidence on cost-effectiveness.

6.4. 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.

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14. Pokharel S, Sharma AK. Evaluation of Insomrid Tablet and *Shirodhara* in the management of *Anidra* (insomnia). Ayu.2010;31(1):40-47

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8. APPENDIX

8.1. Appendix 1: LITERATURE SEARCH STRATEGY

Ovid MEDLINE® In-process & other Non-Indexed citations and OvidMEDLINE® 1946 to present

1. "Sleep Initiation and Maintenance Disorders"/
2. (insomnia adj1 (chronic or secondary or primary or rebound or nonorganic or transient or psychological)).tw.
3. dysfunction*adj1 sleep initiation.tw.
4. (awakening adj1 early).tw.
5. insomnia.tw.
6. Headache/
7. (headach* adj1 (retro-ocular or retro ocular or periorbital or sharp or generalized or orthostatic or ocular or unilateral or bilateral or vertex or throbbing)).tw.
8. (pain* adj1 (cranial or head)).tw.
9. cephal*.tw.
10. hemicrania.tw.
11. headach*.tw.
12. Depression/
13. (depress* adj1 (symptom* or emotional)).tw.
14. depression.tw.
15. Anxiety/
16. anxiet*.tw.
17. nervousness.tw.
18. hypervigilance.tw.
19. Stress, Psychological/
20. (stress* adj1 (psychologic* or life or emotional)).tw.
21. (mental adj1 suffering).tw.
22. anguish.tw.
23. suffering.tw.
24. mental stress.tw.
25. 1 or 2 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24
26. Medicine, Ayurvedic/

27. shirodhara.tw.

28. (medicine adj1 (siddha or ayurvedic or hindu)).tw.

29. 26 or 27 or 28

30. 25 and 29

OTHER DATABASES	
EBM Reviews - Cochrane Central Register of Controlled Trials	Same MeSH, keywords, limits used as per MEDLINE search
EBM Reviews - Cochrane database of systematic reviews	
EBM Reviews - Health Technology Assessment	
EBM Reviews – NHS Economic Evaluation Database	
AMED	
MANTIS database	

PubMeD

(((((("sleep initiation and maintenance disorders"[MeSH Terms] OR ("sleep"[All Fields] AND "initiation"[All Fields] AND "maintenance"[All Fields] AND "disorders"[All Fields]) OR "sleep initiation and maintenance disorders"[All Fields] OR "insomnia"[All Fields]) OR ("headache"[MeSH Terms] OR "headache"[All Fields])) OR ("depressive disorder"[MeSH Terms] OR ("depressive"[All Fields] AND "disorder"[All Fields]) OR "depressive disorder"[All Fields] OR "depression"[All Fields] OR "depression"[MeSH Terms])) OR ("anxiety"[MeSH Terms] OR "anxiety"[All Fields])) OR ("stress, psychological"[MeSH Terms] OR ("stress"[All Fields] AND "psychological"[All Fields]) OR "psychological stress"[All Fields] OR ("mental"[All Fields] AND "stress"[All Fields]) OR "mental stress"[All Fields])) AND shirodhara[Text Word]

8.2. Appendix 2

DESIGNATION OF LEVELS OF EVIDENCE

I Evidence obtained from at least one properly designed randomized controlled trial.

II-I Evidence obtained from well-designed controlled trials without randomization.

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one centre or research group.

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.

III Opinions or respected authorities, based on clinical experience; descriptive studies and case reports; or reports of expert committees.

SOURCE: US/CANADIAN PREVENTIVE SERVICES TASK FORCE (Harris 2001)

Appendix 3

Evidence Table: Efficacy / effectiveness
Question: How effective is *Shirodhara* for treatment of anxiety?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
1. Uebaba K, Xu FH, Taqawa M, Asakura R, Itou T, Tatsuse T, Taguchi Y, Ogawa H, Shimabayashi M, Hisajima T. Using a healing robot for the scientific study of Shirodhara . IEEE Eng Med Biol Mag.2005;March/April:69-78	Pre-and-post intervention studies (2 studies) Objective of the study was to assess the impact of *Shirodhara* on the patient's state of well being and to assess factors in the therapy that altered the patient's state. **Physio-Psychological Changes during *Shirodhara* by the healing robot in relation to anxiety and altered states of consciousness (ASC)** Fifty seven healthy volunteers participated in this study. Treatment was regulated automatically by the computerised system using the healing robot. The oil used was plain cold-pressed preheated sesame oil	II-2	57 healthy volunteers (ages 22 to 46, 33 ± 8 years).	*Shirodhara* using computerised system (healing robot) Oil used; plain sesame oil	-		**Altered state of consciousness (ASC) experiences during *Shirodhara*:** • 46 of 57 subjects (81%) experienced some kind of ASC. • The highest ASC scores were obtained in the domains of trance, passiveness, timeless sensation, wordless sensation, and concentration. **Anxiolytic Effects of *Shirodhara* in subjects with high anxiety, N=10** **Changes in the POMS score:** • Significant decrease of tension and anxiety (P < 0.005) and tendency towards a decrease in exhaustion. • Other domains (depression, anger and hostility, vitality, confusion) the average level showed improvement with *Shirodhara* but none of these differences were statistically significant. **Correlation between ASC or Anxiolysis and skin temperature of foot and hand:** • The correlation between the mean ASC score and anxiolytic effects was not very high, but a significant correlation was	

Evidence Table: Efficacy / effectiveness
Question: How effective is *Shirodhara* for treatment of anxiety?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
	(Kadoya oil Co., Ltd.). The pretreatment control period was set at 10 min and the *Shirodhara* treatment session was fixed for 25 min. The mode of dripping sesame oil was as follows: ✓ oil temperature; 39 ± 0.2°C ✓ oil flow: 2.3 ± 0.2 L/min ✓ dripping pattern: 5 min each for eight knot, horizontal, and vertical, then another 4 min for each. The nozzle of oil moved at the slowest speed (1.5 cm/s). The subjects skin temperature of the right neck, right hand, and right foot was monitored throughout *Shirodhara.* The psychological changes were assessed by psychometric studies using the State-Trait-Anxiety Inventory (STAI) before and after *Shirodhara* and ASC questionnaire developed by Saito just after *Shirodhara*.						obtained (r = -0.34, P < 0.01, Spearman's correlation coefficient). Anxiety decreases with increasing ASC score. • A similar degree of correlation was obtained between the means ASC score and the mean skin temperature of the foot during the later half of the *Shirodhara* (r= 0.35, P < 0.01, Spearman's correlation coefficient). As foot temperature increases, so does AFC. • The mean skin temperature of the foot in the latter half of *Shirodhara* is also correlated with a decrease in the state of anxiety (r = - 0.37, P , 0.01, Spearman's correlation coefficient). Foot skin temperature increases with decreasing levels of anxiety. • The skin temperature of the right hand or the right neck had nothing to do with ASC or anxiety. **Authors conclusion:** The subjects feelings during *Shirodhara* showed deep restfulness with less anxiety–as if the subject were between the sleep and awake states. *Shirodhara* induced bradycardia and relative suppression of LF/HF power spectrum density,	

Evidence Table: Efficacy / effectiveness
Question: How effective is *Shirodhara* for treatment of anxiety?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
	The questionnaire asked about the ASC experiences in 10 domains. The average scores of these 10 domains were calculated from 60 questions. **Anxiolytic effect of the robotic therapy** In this study, 10 of the 57 subjects with abnormally high STAI scores from the above study participated. An STAI score of more than 40 was considered as high. Ten females received *Shirodhara* for 25 minutes once each week , four times a month. Profile of Mood States (POMS) scores were assessed before and after *Shirodhara.* POMS have five assessment domains: tension and anxiety, depression, anger and hostility, vitality, exhaustion and confusion.		10 females of the 57 subjects (ages 23 to 35, 30 ± 6 years)	*Shirodhara* using computerised system (healing robot) Oil used; plain sesame oil		1 month	which indicated lowered sympathetic tone. Expired gas analysis showed a decreased tidal volume and CO_2 excretion. The EEG showed the slowing of the α wave, an increase in α and θ activity, and an increase in right-left coherence. These metabolic, ECG, and EEG findings support the reported experiences of relaxed and low metabolic states during *Shirodhara.*	

Evidence Table: Efficacy / effectiveness
Question: How effective is *Shirodhara* for treatment of anxiety?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
2. Uebaba K, Xu FH, Ogawa H, Tatsuse T, Wang BH, Hisajima T, Venkatraman S. Psychoneuroimmunologic effects of Ayurvedic oil-dripping treatment. The Journal of Alternative and complementary medicine.2008; 14(10):1189-1198	1st study, cross sectional study. Objective of the study to determine the most appropriate conditions of operating robotic system. In order to compare the comfort levels during shirodhara, the robotic oildrip system was used to regulate the conditions. 2nd study, Randomised cross over study. Objective of the study was to assess the psychoneuroimmunologic changes achieved by *Shirodhara.* 16 healthy females were assigned to either the *Shirodhara* treatment or control supine position for 30 minutes, with monitoring of physiologic, biochemical, immunologic, and psychometric parameters including anxiety and altered states of consciousness (ASC). The sequence of the study with the plain	II-2	16 females (21-56 years old; 33 ± 9 years old) who were physically and psychologically healthy 16 females (21-60 years old; 39 ± 9 years old) who were physically and psychologically healthy	*Shirodhara* using computerised system (healing robot) Oil used; plain sesame oil *Shirodhara* using computerised system (healing robot) Oil used; plain sesame oil	- No *Shirodhara* treatment (control - supine position)		**Comparison between *Shirodhara* and control:** • Subjects receiving *Shirodhara* treatment showed lowered levels of state anxiety score and higher levels of ASC than those in the control position. • *Shirodhara* treatment induced significant anxiolysis (P < 0.01), without any change in the control supine position. • ASC scores in the treatment are higher than that of the control supine position in all the domains (P < 0.05 or P < 0.01). • The skin temperature of the dorsal aspects of the right foot, but not the right hand, increased more in the *Shirodhara* treatment than in the control condition (P < 0.1) • Plasma noradrenaline levels in the *Shirodhara* treatment group decreased significantly more than in the control (P<0.05). • Neither plasma adrenaline nor plasma dopamine levels showed a significant difference. • Urinary serotonin excretion just after and 1 hour after finishing *Shirodhara* was decreased significantly more than in the control condition (P<0.05).	Small sample size, no blinding

Evidence Table: Efficacy / effectiveness
Question: How effective is *Shirodhara* for treatment of anxiety?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
	sesame oil and the control supine position was assigned in a random sequence. **Examinations for the assessment of psychoneuroimmunologic changes:** Evaluation of comfort; an original visual analogue scale (VAS) for comfort 100 mm long was used. Subjects checked the initial zero point of the VAS scale when they felt neither comfort, and the 100-mm point when they felt the most comfortable. **Psychologic examinations:** Anxiety was assessed using State-Trait Anxiety Inventory. Anxiolysis was calculated as the percent change between pre-and post-treatment assessments. The psychometric instrument for ASC was used.						**Comparison of correlation between parameters in *Shirodhara* and control:** • The correlation between ASC scores of all 10 domains and the anxiolytic effect were significantly higher in the Trance experience of *Shirodhara* ($r = 0.52$, $P < 0.05$), while there was no significant correlation in the control condition ($r = 0.13$, $P = 0.64$). • The increase in foot skin temperature after S*hirodhara* showed a significant correlation with anxiolysis and the depth depth of Trance of ASC ($r = 0.58$, $P < 0.01$, $r = 0.43$, $P < 0.01$, respectively). • NK cell activity after S*hirodhara* treatment showed significant correlation with anxiolysis and the depth of Trance of ASC ($r = 0.33$, $P < 0.05$, $r = 0.56$, $P < 0.01$, respectively).	

Evidence Table: Efficacy / effectiveness
Question: How effective is *Shirodhara* for treatment of anxiety?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
	Physical examinations: Skin temperature of the dorsal side of the Right hand and foot was monitored with thermocouple sensors. Skin temperature was measured every 10 seconds and recorded. **Neuroimmunologic examinations:** Serum thyrotropin-releasing hormone (TRH) by radioimmunoassay (RIA), natural killer (NK) cell activity (chromium uptake method, %), plasma catecholamine (adrenaline, noradrenaline, and dopamine by high-performance liquid chromatography), and urinary serotonin were examined with Mitsubishi Chemical Co. Ltd.							

Evidence Table: Efficacy / effectiveness
Question: How effective is *Shirodhara* for treatment of anxiety?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
3. Xu F, Uebaba K, Ogawa H, Tatsube T, Wang BH, Hisajima T, Venkatraman S. Pharmaco-Pysio-Psychlogic effect of Ayurvedic oil dripping treatment using an essential oil from *Lavendula angustifolia.* The Journal of Alternative and Complementary Medicine. 2008;14(8):947-956	Randomised cross over study. Objective of the study was to elucidate the pharmaco-physio-psychologic effect of *Shirodhara* with medicated sesame oil including an essential oil from *Lavendula angustifolia* (lavender). 16 healthy females (38 ± 8 years old) were assigned at random to three treatment applied by a robotic oil-dripping system. Each subject had all of the three kinds of treatments. **Psychophysiologic parameters** including the heart rate, skin temperature of the dorsum of hands and feet, as well as anxiety and ASC were monitored and the rates of change of these items were calculated. **Psychometric examinations:** Anxiety was measured using The State-Strait Anxiety	II-2	16 healthy females (38 ± 8 years old)	*Shirodhara* using robotic oil dripping system. Oil used; medicated sesame oil with a 0.3 volume% of lavender essential oil (lavender *Shirodhara*)	*Shirodhara* using robotic oil dripping system. Oil used; plain sesame oil (plain *shirodhara*) No *Shirodhara* treatment (control - supine position)		**Changes in state anxiety and ASC:** • After two types of *Shirodhara* treatment, the subjects showed significant decreased levels of state anxiety ($P < 0.05$), while the control group revealed no such change. • There was no significant difference between anxiolytic effects induced by lavender *Shirodhra* and plain *Shirodhara*. • Lavender *Shirodhara* led to higher scores than control in eight domains in the ASC, while plain *Shirodhara* led to higher scores than the control in only three domains according to Dunnet's t-test. • There was no significant difference between lavender and plain *Shirodhara* treatment. **Correlation between anxiolysis and ASC:** • Average ASC score was not correlated with anxiolysis in the control study, while plain and lavender Shirodhara showed a correlation ($r = 0.44$, $r = 0.50$) respectively. • Correlation between anxiolysis and each ASC domains; lavender	Small sample size, no blinding

Evidence Table: Efficacy / effectiveness
Question: How effective is *Shirodhara* for treatment of anxiety?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
	Inventory (STAI), which is considered the "gold standard" for the evaluation of anxiety. Anxiolysis was calculated as the percent change between pre- and post-treatment assessments. ASC standardised scores were calculated according to Saito's method. **Physiologic examinations**: Heart rate variability (HRV) estimated by ECG. Mean R to R wave (R-R) intervals every 5 minutes were obtained and the HR fluctuation was subjected to Fourier analysis to calculate the power spectrum density of lower frequency (LF), higher frequency (HF), and total frequency (TF) to obtain HF/LF (an indicator of sympathetic tonus). Skin temperature of the centre of the dorsum of the right hand and foot was monitored with two thermocouple sensors.						*Shirodhara* revealed the most significant correlations: 5 of the 10 ASC domains were correlated with anxiolysis. **Changes in skin temperature:** • During the 10 minutes after starting *Shirodhara*, control and *Shirodhara* treatments led to similar increases in the skin temperature: 0.4-0.6ºC (hands), 0.2-0.3ºC (feet). However, from 15 to 30 minutes, the differences between lavender *Shirodhara* and control treatments became clear, with maximal difference 0.2ºC (hands) and 0.6ºC (feet). The foot skin temperature showed a significantly greater elevation even in the plain *Shirodhara* treatment compared to control. **Correlation between psychologic effects and skin temperature elevation:** • Foot skin temperature elevation showed strongest correlation with anxiolysis and the average ASC score in lavender *Shirodhara,* and weakest correlation with the control treatment.	

Evidence Table: Efficacy / effectiveness
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							Changes in HR and HRV: • The plain and lavender *Shirodhara* showed a significant increase in RR mean compared with the control during the first 5 minutes of the 30-minute *Shirodhara* treatment. It was speculated that the psycho-physiologic effects of lavender *Shirodhara* would be brought about by three mechanisms: (1) the well-known relaxing action of essential oils from L. *angustifolia* mediated by olfactory nerves, (2) pharmacologic action of substances absorbed through the skin or mucosa in the sesame oil or lavender essential oil, and (3) the physiologic effect of sesame oil dripped on the forehead induced by the somato-autonomic reflex through the sensors or pressure sensors in the skin or hair follicles via the trigeminal nerves.	

Evidence Table: Efficacy / effectiveness
Question: How effective is *Shirodhara* for treatment of anxiety?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
4 Tubaki BR, Chandrashekar CR, Sudhakar D, Sathya P Prabha TN, Lavekar GS, Kutty BM. Clinical efficacy of Manasamitra Vataka (an Ayurveda Medication) on generalized anxiety disorder with comorbid generalized social phobia: A randomized controlled study. The Journal of Alternative and Complementary Medicine. 2012;18(6): 612-621	Randomised controlled trial. Objective of the study was to evaluate the effect of *Manasamitra Vataka* on GAD with comorbid generalized social phobia. 72 patients were randomly divided using blocked randomisation into one of the three groups: Group I (n=24) received *Manasamitra Vataka* tablets (100 mg twice daily for 30 days), Group II (n=24) in addition to *Manasamitra Vataka,* underwent *Shirodhara* (therapy involving dripping of medicated oil [Brahmi tail] over the forehead) treatment for the first 7 days, Group III (n=24) received clonazepam 0.75 mg daily in divided dose for 30 days. The assessment of the study was done using Hamilton Anxiety Rating Scale (HARS), Beck Anxiety Inventory (BAI),	II-2	72 patients age 20 and 55 years, diagnosed as having generalised anxiety disorder (GAD) with comorbid social phobia per DSM IV TR criteria. Group I = N (24) Group II = N (24) Group III = N (24)	*Manasamitra Vataka* tablets (100 mg twice daily for 30 days),	*Shirodhara* for first 7 days in addition to *Manasamitra Vataka* Clonazepam (0.25 mg in morning and 0.50 mg at night) for 30 days	30 days	**Changes in both 15th and 30th day of interventions:** • Significant improvement on both the 15th and 30th day of interventions in HARS [F (2,124)=698.82,P<0.001, BAI [F(2,124)=361.92, P<0.001], and CGI-I[F(1,62)=96.623, P<0.001]. • No significant differences were observed in any of these parameters between groups. • Effect size of Groups II and I showed moderate to large effect compared to Group III. However, the response and remissions were comparable between groups. • All interventions produced significant linear improvement in BDI [F(2,124)=117,880 P<0.001]. • Improvement in ESS was observed only in Group II. Authors conclusion: This is the first study conducted on the efficacy of *Manasamitra Vataka* in anxiety disorders. The results suggest that *Manasamitra Vataka* is effective in the management GAD with comorbid generalized social phobia. Add-on effect of *Shirodhara* reduced	Small sample size, no blinding.

Evidence Table: Efficacy / effectiveness
Question: How effective is *Shirodhara* for treatment of anxiety?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
	Beck Depression Inventory (BDI), Epworth Sleepiness Scale (ESS), World Health Organization Quality of Life BREF (WHOQOL BREF), and Clinical Global Impression scales (CGI) (Improvement and efficacy). All patients were subjected to clinical evaluation on the 15th and 30th day of the treatment. Response to treatment was defined as reduction of 50% or more in the HARS and BAI scales. Symptom remission was defined as HARS < 8, BAI score < 7, and CGI-I (very much and much improved) of 1 or 2 scores. Comparison of groups across different time points was carried out by repeated-measure analysis of variance (ANOVA) with Tukey post-hoc test.						the daytime sleepiness. Further studies on *Manasamitra Vataka* need to be carried out to judge its potential as a first-line treatment modality.	

Evidence Table: Efficacy / effectiveness
Question: How effective is *Shirodhara* for treatment of insomnia?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
5. Vinjamury SP, Vinjamury M, Martirosian Cd, Miller J.Ayurvedic therapy (*Shirodhara*) for Insomnia: A case series. Global Advances in Health and Medicine.2014;3(1):75-80	Case series Objective of the study was to determine the feasibility of recruiting and retaining participants in a clinical trial on *Shirodhara* for insomnia in the United States and also to investigate the therapeutic usefulness of *Shirodhara* for insomnia using standardised outcome measure. Ten consecutive volunteers who responded to community wide recruitment efforts were enrolled in the study between September 2009 and August 2010. *Shirodhara* with Brahmi oil was done for 45 minutes on each participant for 5 consecutive days. Insomnia Severity Index (ISI) was used to evaluate the severity of insomnia as well as to determine the response of *Shirodhara* therapy. Data were collected at baseline, end of treatment (day 5), and 1 week after treatment ended.	II-3	10 participants between ages 18 and 75 years of either sex with a duration of insomnia of 1 year and who have a minimum score of 14 on the Insomnia Severity Index (ISI). Nine completed the study: 2 males and seven females with a mean age of 40 years. Exclusion: People with comorbidities such as depression or any other psychological conditions that require medications and serious medical conditions such as uncontrolled hypertension, uncontrolled diabetes and other acute conditions that disturbed sleep.	*Shirodhara* – Brahmi oil (coconut oil processed with *Hydrocotyle asiatica* primarily and less than 20% of *Triphala*) manufactured by Bazaar of India Imports. Equipment manufactured by ShiroPlus that automatically warms and pumps the oil was used.	-	12 days	**Changes in ISI scale** **Percentage of improvement:** • Comparing baseline to day 5 (end of treatment): - All nine participants experienced improvement; for six participants, the percentage of improvement ranged from 25.93% to 69.57%. For the other three participants, there was slight improvement with a ranged of 3.85% to 8.33%. • Comparing baseline to 1 week post treatment: - The percentage of improvement ranged from 8.33% to 86.96% with one exception: one study participant's insomnia worsened by -66.67%. **ISI Mean scores:** • At baseline the mean ISI score was 19.44, which decreased over time; at day 5, the mean ISI score was 13.22, and at 1 week post treatment the mean ISI score was 14.33. • For the baseline and day	

Evidence Table: Efficacy / effectiveness
Question: How effective is *Shirodhara* for treatment of insomnia?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
							5 comparison, there was an overall improvement (P < 0.005), and for baseline versus 1 week post treatment comparison, the comparison was not significant (P < 0.089). Authors conclusion: *Shirodhara* with Brahmi oil may be beneficial for moderate to severe insomnia. It is feasible to recruit and retain participants for such therapies in the United States. It is important to validate these findings and investigate the mechanism of action using a larger sample and rigorous research design.	

Evidence Table: Efficacy / effectiveness
Question: How effective is *Shirodhara* for treatment of insomnia?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
6. Pokharel S, Sharma AK. Evaluation of Insomrid Tablet and *Shirodhara* in the management of Anidra (insomnia). AYU.2010;31 (1):40-47	Randomised controlled trial. Objective of the study was to clinically evaluate the efficacy of *Shirodhara* and Tab. *Insomrid* (proposed herbal formulation) in the management of *Anidra* (insomnia). 30 clinically diagnosed patients with *Anidra* selected from OPD / IPD unit of PG. Department of Kayachikitsa were randomly divided into the following three groups of 10 patients each: Group I (n=10) were recommended Tab. *Insomrid* for 30 days, Group II, (n=10) were administered *Shirodhara* with luke warm milk for 15 days and Group III (n=10), were recommended both Tab. *Insomrid* and *Shirodhara* simultaneously. Patients were followed up after 15 days and 30 days and changes, improvements, deterioration and any other effects produced after therapy were noted down.	II-2	30 patients, majority age between 31-40 years and 51-60 years. Out of the 30 patients, 16 (53.33%) were having chronic insomnia with more than 18 months duration.	Tab. Insomrid which contains 5 drugs (Ashwagandha, Sarpagandha, Jatamansi, Tagara, Parasika Yavani), 2 gms per day for 30 days (Group I).	*Shirodhara* with luke warm milk (the temperature of the milk was 38°C to 40°C for a period of 15 days (Group II). Tab. *Insomrid* and *Shirodhara* simultaneously (Group III).	15 days and 30 days	**Subjective improvement:** • After the completion of therapeutic trial there was marked improvement in feeling of wellbeing, physical and mental fitness in the three groups. • The incidence of improvement was highest in Group III (mixed therapy). • Significant improvement was observed in Group II and Group I also. **Clinical improvement in symptoms of insomnia:** • Clinical recovery of symptoms were found to be highly significant ($P < 0.001$ or $P < 0.01$), or significant ($P < 0.05$) for 11 insomnia symptoms in Group I, Group II and Group III except for one symptom [poor sensory perception ($P < 0.10$)]. **Sleep diary assessment:** • Recovery in sleep diary assessment for time to fall asleep, no. of awakenings, naps-day time, rate how you felt	Small sample size, allocation concealme-nt and blinding not mentioned.

Evidence Table: Efficacy / effectiveness
Question: How effective is *Shirodhara* for treatment of insomnia?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
	Both the subjective and clinical improvements were employed for assessment of the impact of the therapy. Subjective criteria of evaluation included the observations of both patients and assessment of the physician. Clinical improvement using symptom rating scale developed by Prof. A.K. Sharma et al. Following 12 symptoms of insomnia were assessed before and after therapy: Yawning, drowsiness, malaise, fatigue & alertness, headache, lack of concentration, loss of memory, poor sensory perception, indigestion, constipation, weight loss, loss of lustre. A sleep diary was provided and it contained the following points: time into bed, time of lights out, time to fall asleep, number of awakenings, time out of bed, naps-day time, rate how you felt today, irritability, total time of sleep, sleep quality.						today, irritability, total time of sleep and sleep quality was found to be highly significant ($P < 0.001$ or $P < 0.01$) in all the three groups. **Authors conclusion:** Tab. *Insomrid* (herbal formulation) and *Shirodhara* with milk are very safe and effective treatment modalities and can be used effectively in the management of *Anidra* (insomnia).	

Evidence Table: Efficacy / effectiveness
Question: How effective is *Shirodhara* for treatment of stress?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
7. Dhuri KD, Bodhe PV, Vaidya AB. Shirodhara: A psycho-physiological profile in healthy volunteers. Journal of Ayurveda and Integrative Medicine. 2013;4(1): 40-44	Pre and post-intervention study. Objective of the study was to evaluate the psychological and physiological effects of *Shirodhara* in healthy volunteers by monitoring the rating of mood and levels of stress, electrocardiogram (ECG), electroencephalogram (EEG), and selected biochemical markers of stress. The study was conducted in the human pharmacology laboratory. The study was open labelled, comparing the baseline variables with values after *Shirodhara. Shirodhara* was preceded by Abhyanga –whole body massage. The *Shirodhara* method was standardised for rate of dripping with peristaltic pump and temperature was controlled with a thermostat. The stress and mood were assessed with the use of validated rating scales; V.A.S. (Visual Analogue Scale) and M.A.S	II-2	16 healthy volunteers (10 males and 6 females). Age group 30-60 years, weighing 45 to 90 kg with normal blood pressure and no illness within the last 3 months. No history of allergy to oils, heavy tobacco, or alcohol consumption in any of the patients.	*Shirodhara* method standardised for rate of dripping with peristaltic pump and temperature was controlled with a thermostat. *Shirodhara* dripping oil was standardised as per Ayurvedic pharmacopoeia containing *Centella asiatica (Brahmi), Nardostachys jatamansi (Jatamansi), and Withania somnifera (Ashwagandha)* in a proportion of 10 mg of aqueous extract of each/ 100 mL of til oil.	-	3 days	**Changes after *Shirodhara*:** • After Shirodhara, volunteers showed a significant reduction in the respiratory rate (P = 0.02) • The mean diastolic blood pressure also reduced significantly (P = 0.027), with a significant drop in mean pulse rate (P = 0.0015) • In all 16 subjects, EEG showed an increase in the alfa rhythm, and a decreased of beta activity was observed in two subjects. The EEG changes are similar to those observed after deep meditation and alert relaxation. • The V.A.S. score and M.A.S. score for stress and mood changed significantly (P = 0.003) • No significant difference in the mean value of salivary cortisol (P = 0.58) • No significant difference in the pre-and post-*Shirodhara* urinary creatinine levels (P = 0.46), urinary epinephrine levels (P = 0.62), urinary norepinephrine levels (P = 0.39)	.

Evidence Table: Efficacy / effectiveness
Question: How effective is *Shirodhara* for treatment of stress?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
	(Mood Assessment Scale), basally, immediately after *Shirodhara* and 3 days later. Adverse events, if any were recorded. The pre-and post-*Shirodhara* ECG and EEG records were evaluated. The salivary cortisol and urinary catecholamines were assessed by standard ELISA method and fluorometry, respectively.						**Authors conclusion:** A standardized *Shirodhara* leads to a state of alert calmness similar to the relaxation response observed in meditation. The clinical benefits observed with *Shirodhara* in anxiety neurosis, hypertension, and stress aggravation due to chronic degenerative diseases could be mediated through adaptive physiological effects.	

Evidence Table: Safety
Question: How safe is *Shirodhara* for treatment of anxiety?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
1. Uebaba K, Xu FH, Taqawa M, Asakura R, Itou T, Tatsuse T, Taguchi Y, Ogawa H, Shimabayashi M, Hisajima T. Using a healing robot for the scientific study of Shirodhara . IEEE Eng Med Biol Mag.2005;March/April:69-78	Pre-and-post intervention studies (2 studies) Objective of the study was to assess the impact of *Shirodhara* on the patient's state of well being and to assess factors in the therapy that altered the patient's state. **Physio-Psychological Changes during *Shirodhara* by the healing robot in relation to anxiety and altered states of consciousness (ASC)** Fifty seven healthy volunteers participated in this study. Treatment was regulated automatically by the computerised system using the healing robot. The oil used was plain cold-pressed preheated sesame oil	II-2	57 healthy volunteers (ages 22 to 46, 33 ± 8 years).	*Shirodhara* using computerised system (healing robot) Oil used; plain sesame oil	-		There were no cases of headache or skin eruption which was directly related to *Shirodhara*. However, some subjects complained of a compression discomfort of the occipital region or the numbness of the extremities or lower back, which were not directly attributed to *Shirodhara.*	

Evidence Table: Safety
Question: How safe is *Shirodhara* for treatment of anxiety?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
	(Kadoya oil Co., Ltd.). The pretreatment control period was set at 10 min and the shirodhara treatment session was fixed for 25 min. The mode of dripping sesame oil was as follows: ✓ oil temperature; 39 ± 0.2°C ✓ oil flow: 2.3 ± 0.2 L/min ✓ dripping pattern: 5 min each for eight knot, horizontal, and vertical, then another 4 min for each. The nozzle of oil moved at the slowest speed (1.5 cm/s). The subjects skin temperature of the right neck, right hand, and right foot was monitored throughout *shirodhara.* The psychological changes were assessed by psychometric studies using the State-Trait-Anxiety Inventory (STAI) before and after *Shirodhara* and ASC questionnaire developed by Saito just after *shirodhara*.							

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Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
	The questionnaire asked about the ASC experiences in 10 domains. The average scores of these 10 domains were calculated from 60 questions. **Anxiolytic effect of the robotic therapy** In this study, 10 of the 57 subjects with abnormally high STAI scores from the above study participated. An STAI score of more than 40 was considered as high. Ten females received *Shirodhara* for 25 minutes once each week , four times a month. Profile of Mood States (POMS) scores were assessed before and after *Shirodhara.* POMS have five assessment domains: tension and anxiety, depression, anger and hostility, vitality, exhaustion and confusion.		10 females of the 57 subjects (ages 23 to 35, 30 ± 6 years)	*Shirodhara* using computerised system (healing robot) Oil used; plain sesame oil		1 month		

Evidence Table: Safety
Question: How safe is *Shirodhara* for treatment of anxiety?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
2. Uebaba K, Xu FH, Ogawa H, Tatsuse T, Wang BH, Hisajima T, Venkatraman S. Psychoneuroimmunologic effects of Ayurvedic oil-dripping treatment. The Journal of Alternative and complementary medicine.2008; 14(10):1189-1198	1st study, cross sectional study (screening test). Objective of the study to determine the most appropriate conditions of operating robotic system. In order to compare the comfort levels during *Shirodhara*, the robotic oildrip system was used to regulate the conditions. 2nd study, Randomised cross over study. Objective of the study was to assess the psychoneuroimmunologic changes achieved by *Shirodhara.* 16 healthy females were assigned to either the *Shirodhara* treatment or control supine position for 30 minutes, with monitoring of physiologic, biochemical, immunologic, and psychometric parameters including anxiety and altered states of consciousness (ASC). The sequence of the study with the plain	II-2	16 females (21-56 years old; 33 ± 9 years old) who were physically and psychologically healthy 16 females (21-60 years old; 39 ± 9 years old) who were physically and psychologically healthy	*Shirodhara* using computerised system (healing robot) Oil used; plain sesame oil *Shirodhara* using computerised system (healing robot) Oil used; plain sesame oil	- No *Shirodhara* treatment (control - supine position)		**Most appropriate and safest conditions of operating the robotics of oil dripping:** • The safety of the methods should be taken into account, because, in some extreme conditions, some subjects suffered from headache, chill, slight chill, or other discomfort. • The screening tests showed that the most comfortable and safest conditions were 30-minute duration at 39°C at an oil flow rate of 2.3 L/min. The diameter of the dripping oil nozzle was 8 x 8 mm. Other fixed conditions were the moving speed of the dripping nozzle, set at 1.5 cm/sec, and the height of the nozzle, being set at 20 cm above the forehead. The pattern of dripping comprised temple, horizontal, and vertical movements, two times each 5-minute movement.	

Evidence Table: Safety
Question: How safe is *Shirodhara* for treatment of anxiety?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
	sesame oil and the control supine position was assigned in a random sequence. **Examinations for the assessment of psychoneuroimmunologic changes:** Evaluation of comfort; an original visual analogue scale (VAS) for comfort 100 mm long was used. Subjects checked the initial zero point of the VAS scale when they felt neither comfort, and the 100-mm point when they felt the most comfortable. **Psychologic examinations:** Anxiety was assessed using State-Trait Anxiety Inventory. Anxiolysis was calculated as the percent change between pre-and post-treatment assessments. The psychometric instrument for ASC was used.							

Evidence Table: Safety
Question: How safe is *Shirodhara* for treatment of anxiety?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
	Physical examinations: Skin temperature of the dorsal side of the Right hand and foot was monitored with thermocouple sensors. Skin temperature was measured every 10 seconds and recorded. Neuroimmunologic examinations; Serum thyrotropin-releasing hormone (TRH) by radioimmunoassay (RIA), natural killer (NK) cell activity (chromium uptake method, %), plasma catecholamine (adrenaline, noradrenaline, and dopamine by high-performance liquid chromatography), and urinary serotonin were examined with Mitsubishi Chemical Co. Ltd.							

Evidence Table: Safety
Question: How safe is Shirodhara for treatment of insomnia?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
3. Vinjamury SP, Vinjamury M, Martirosian Cd, Miller J.Ayurvedic therapy (Shirodhara) for Insomnia: A case series. Global Advances in Health and Medicine.2014;3(1):75-80	Case series Objective of the study was to determine the feasibility of recruiting and retaining participants in a clinical trial on *Shirodhara* for insomnia in the United States and also to investigate the therapeutic usefulness of *Shirodhara* for insomnia using standardised outcome measure. Ten consecutive volunteers who responded to community wide recruitment efforts were enrolled in the study between September 2009 and August 2010. *Shirodhara* with Brahmi oil was done for 45 minutes on each participant for 5 consecutive days. Insomnia Severity Index (ISI) was used to evaluate the severity of insomnia as well as to determine the response of *Shirodhara* therapy. Data were collected at baseline, end of treatment (day 5), and 1 week after treatment ended.	II-3	10 participants between ages 18 and 75 years of either sex with a duration of insomnia of 1 year and who have a minimum score of 14 on the Insomnia Severity Index (ISI). Nine completed the study: 2 males and seven females with a mean age of 40 years. Exclusion: People with comorbidities such as depression or any other psychological conditions that require medications and serious medical conditions such as uncontrolled hypertension, uncontrolled diabetes and other acute conditions that disturbed sleep.	Shirodhara – Brahmi oil (coconut oil processed with *Hydrocotyle asiatica* primarily and less than 20% of *Triphala*) manufactured by Bazaar of India Imports. Equipment manufactured by ShiroPlus that automatically warms and pumps the oil was used.	-	12 days	**Adverse events:** • No adverse events or side effects were reported by participants during the entire study period. • One participant dropped out after one treatment because she did not want to wash her hair every day after the oil treatment.	

Evidence Table: Safety
Question: How safe is *Shirodhara* for treatment of insomnia?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
4. Pokharel S, Sharma AK. Evaluation of Insomrid Tablet and *Shirodhara* in the management of Anidra (insomnia). AYU.2010;31 (1):40-47	Randomised controlled trial. Objective of the study was to clinically evaluate the efficacy of *Shirodhara* and Tab. *Insomrid* (proposed herbal formulation) in the management of *Anidra* (insomnia). 30 clinically diagnosed patients with *Anidra* selected from OPD / IPD unit of PG. Department of Kayachikitsa were randomly divided into the following three groups of 10 patients each: Group I (n=10) were recommended Tab. *Insomrid* for 30 days, Group II, (n=10) were administered *Shirodhara* with luke warm for 15 days and Group III (n=10), were recommended both Tab. *Insomrid* and *Shirodhara* simultaneously. Patients were followed up after 15 days and 30 days and changes, improvements, deterioration and any other effects produced after therapy were noted down.	II-2	30 patients, majority age between 31-40 years and 51-60 years. Out of the 30 patients, 16 (53.33%) were having chronic insomnia with more than 18 months duration.	Tab. Insomrid which contains 5 drugs (Ashwagandha, Sarpagandha, Jatamansi, Tagara, Parasika Yavani), 2 gms per day for 30 days (Group I).	Shirodhara with luke warm milk (the temperature of the milk was 38°C to 40°C for a period of 15 days (Group II). Tab. *Insomrid* and *Shirodhara* simultaneously (Group III).	15 days and 30 days	**Adverse events:** No adverse effects were noted in any of the patients during the trial period.	Small sample size, allocation concealme-nt and blinding not mentioned.

Evidence Table: Safety
Question: How safe is *Shirodhara* for treatment of insomnia?

Bibliographic citation	Study Type / Methodology	LE	Number of patients and patient characteristics	Intervention	Comparison	Length of follow up (if applicable)	Outcome measures/ Effect size	General comments
	Both the subjective and clinical improvements were employed for assessment of the impact of the therapy. Subjective criteria of evaluation included the observations of both patients and assessment of the physician. Clinical improvement using symptom rating scale developed by Prof. A.K. Sharma et al. Following 12 symptoms of insomnia were assessed before and after therapy: yawning, drowsiness, malaise, fatigue & alertness, headache, lack of concentration, loss of memory, poor sensory perception, indigestion, constipation, weight loss, loss of lustre. A sleep diary was provided and it contained the following points: time into bed, time of lights out, time to fall asleep, number of awakenings, time out of bed, naps-day time, rate how you felt today, irritability, total time of sleep, sleep quality.							