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- Insomnia is an experience of inadequate or poor quality sleep characterized by one or more of the following:
 - difficulty falling asleep
 - difficulty maintaining sleep
 - waking up too early in the morning
 - non-refreshing sleep.
- ♦ It also involves daytime consequences such as tiredness, lack of energy, difficulty concentrating, irritability. (National Heart Lung and Blood Institute, 2007)

PREVALENCE



- The prevalence of insomnia differs according to <u>four</u> <u>definitions</u>:
 - Insomnia Symptoms recognizes that about <u>one-third</u> of a general population presents at least one of them
 - Insomnia Sx w/day time consequences the prevalence is between 9% and 15%
 - Sleep dissatisfaction- represents 8-18% of the general population
 - Insomnia Diagnosis (DSM IV), more precise, prevalence 6%
- Women more affected than men





- Periods of sleep difficulty lasting between one night and a few weeks are referred to as Acute insomnia
- Chronic insomnia refers to sleep difficulty at least three nights per week for one month or more
- Primary Insomnia When other causes of insomnia are ruled out or treated, remaining difficulty with sleep may be classified as primary insomnia



Acute Insomnia

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- emotional or physical discomfort
- significant life stress
- acute illness
- environmental disturbances noise, light, temp.
- jet lag
- Chronic Insomnia <u>many different factors</u> acting singly or in combination, and often occurs in conjunction with <u>other health problems</u>, e.g., psychiatric, medical, and neurological disorders.
- Primary insomnia Chronic stress, hyperarousal, poor sleep hygiene, and behavioral conditioning



Insomnia - Diagnosis

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Table 1. Criteria for the Diagnosis of Insomnia

At least one of the following complaints:

Difficulty initiating and/or maintaining sleep; sleep that is poor in quality; trouble sleeping despite adequate opportunity and circumstances for sleep; waking up too early

At least one of the following types of daytime impairment related to sleep difficulty:

Attention, concentration, or memory impairment; concerns or worries about sleep; daytime sleepiness; errors or accidents at work or while driving; fatigue or malaise; gastrointestinal symptoms; lack of motivation; mood disturbance or irritability; social or vocational dysfunction or poor school performance; tension headaches

International Classification of Sleep Disorders: Diagnostic and Coding Manual. 2nd ed. Westchester, Ill.: American Academy of Sleep Medicine, 2005.



Insomnia – Current Treatments

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Clinical recommendation	Evidence rating	References
Exercise, cognitive behavior therapy, and relaxation therapy are recommended as effective, nonpharmacologic treatments for chronic insomnia.	A	4, 7, 12, 16
Melatonin is effective in patients with circadian rhythm sleep disorders and is safe when used in the short term.	В	20
Benzodiazepines are effective for treating chronic insomnia but have significant adverse effects and the risk of dependency.	В	4, 22, 36
Nonbenzodiazepines (e.g., eszopiclone [Lunesta], zaleplon [Sonata], zolpidem [Ambien]) are effective treatments for chronic insomnia and, based on indirect comparisons, appear to have fewer adverse effects than benzodiazepines.	В	4

A = consistent, good-quality patient-oriented evidence; B = inconsistent or limited-quality patient-oriented evidence; C = consensus, disease-oriented evidence, usual practice, expert opinion, or case series. For information about the SORT evidence rating system, see page 483 or http://www.aafp.org/afpsort.xml.



EVIDENCE FROM CURRENT TX

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- Level A: Consistent, good quality, patient oriented evidence
 - Exercise
 - Cognitive Behavior Therapy
 - Relaxation therapy
- Shirodhara, an ayurvedic oil treatment is a type of relaxation therapy

SHIRODHARA



- Shirodhara is composed of two words shiro + dhara,
- shiro means head and dhara means dripping or flow
- In ayurveda, the warm oil flow on head is known as Shirodhara
- It is one of the most unique oil therapies of Ayurveda





BENEFITS OF SHIRODHARA

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- Helps relieve insomnia, fatigue, tension, anxiety, anger, chronic headaches
- mental relaxation
- Invigorates the body and mind and stimulate cognitive memories
- Helps overcome stress and its ill effects on nervous system
- Is considered as rejuvenating process as it improves vitality



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SHIRODHARA PROCEDURE

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- Step 1: The patient lies supine on a flat surface with head back and a rolled towel or pillow beneath the neck
- Step 2: Sesame or another base oil is blended with a few drops of aromatic essential oil to create the liquid. It is then warmed to a comfortable temperature and the treatment begins
- Step 3: A stream of warm oil is poured very slowly onto the center of the forehead followed by gentle scalp massage (medicated milk or buttermilk, herbal decoction)
- ◆ Typically, the treatment lasts half an hour to an hour. Ideally for a severe illness, the treatment lasts for 14 or 21 days depending on severity the problem.



RESEARCH IN SHIRODHARA

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- Maharishi Ayurveda Shirodhara was tested on the dynamics of brain activity (in patients with neurological and psychological disorders) as measured by EEG was examined
- Results show two contrasting modes of brain activity during the procedure.
 - **♦** First, a low level of activation, is similar to meditative periods of the Transcendental Meditation technique;
 - the second was indicative of brain excitation
- Investigators concluded that Shirodhara creates high coherence in neural systems, and supports more comprehensive states of conscious awareness



UEBABA ET AL STUDY

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Shirodhara

- Bradycardia, lowered tidal volume of CO2 output
- Sympathetic nervous tone was suppressed, while parasympathetic nervous tone remained the same as control
- Changes in EEG indicated restful alertness (frontal lobe, limbic system and medulla oblongata activated)
- Successive Shirodhara treatments reduced anxiety in one month
- Sesame oil better than other mediums such as water, cow's milk and bath salt
- Some patients reported change in lifestyle such as smoking cessation, and improvement in bulimia



HEALING ROBOT FOR SHIRODHARA

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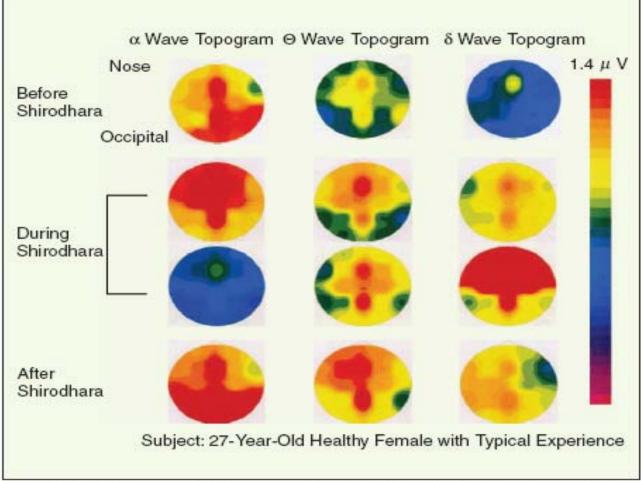


Fig. 8. The EEG mapping for one subject during robotic shirodhara. During shirodhara, α -wave power in the frontal region was dominant, while after shirodhara, occipital α -wave was dominant.



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- Very limited clinical research in the U.S.
- Study the feasibility of studying shirodhara in the U.S.
- Validation of the physiological findings clinically
- A non-invasive procedure/treatment for Insomnia (if efficacy is established)

CASE HISTORY



- ◆ 30 y.o. male, medium built, computer programmer
- Four years of sleeping difficulties, specifically difficulty to fall asleep, disturbed sleep and nonrefreshing sleep, day-time poor concentration and fatigue
- No significant history of past illnesses, hospitalizations, or allergies. Used Tylenol P.M. in the past for sleep, but did not help much
- Mother has insomnia, father healthy and no other positive family history
- No habits except tea once or twice a day
- ◆ Married, one son (?ADHD) cause for mental stress





- On examination, Vitals were normal, no negative general examination findings
- Bladder and bowels are regular
- Healthy diet and good sleeping habits/ hygiene
- Vata and pitta predominant ayurvedic pulse. Prakriti was determined as Vata-pitta type
- A quick review of systems indicated everything normal except a little dry skin



- Based on his history, this patient was diagnosed with Insomnia according to the American Academy of Sleep Medicine diagnostic criteria:
 - difficulty to fall asleep,
 - disturbed sleep and non-refreshing sleep
 - day-time poor concentration and fatigue
- He had almost all of the complaints and day time impairments related to lack of sleep

INTERVENTION



- Shirodhara was advised with Brahmi oil (sesame oil processed with Hydrocotyle asiatica and other herbs) for five days
- Each session lasted 45 minutes (no grading periods adopted)
- Outcomes were measured through
 - Insomnia severity Index
 - HD -16 scale (QOL scale for Insomnia)
 - Both are valid and reliable scales for Insomnia



INSOMNIA SEVERITY INDEX

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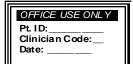
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Figure 2 ollege of Acupuncture & Oriental Medicine **Insomnia Severity Index Test** The Insomnia Severity Index is a self-reported questionnaire that consists of seven items to measure patients' perceptions of their insomnia. Please rate the past week's severity of Very your insomnia problems. None Mild Moderate Severe Severe 1. Difficulty falling asleep: 2. Difficulty staying asleep: 3. Problem waking up too early: Very Very satisfied dissatisfied 4. How satisfied/dissatisfied are you with your current sleep patterns? Not at all Very much 5. To what extent do you consider your sleep problem 3 4 to interfere with your daily functioning (eg, daytime fatigue, mood, memory, etc.)? 6. How noticeable to others do you think your 0 1 3 4 sleeping problem is in terms of impairing the quality of your life? 7. How worried/distressed are you about your current 4 sleep problem? Scoring: 0-7-No clinically significant insomnia; 8-14-Sub-threshold insomnia; 15-21-Moderate clinical insomnia; 22-28-Severe clinical insomnia Source: Adapted from: Morin CM. Insomnia: Psychological assessment and management. Guilford. New York.

1993. Information obtained online at http://eprints.gut.edu.au/archive/00000707/01/Frequency_of_Insomia.pdf

HD-16 scale





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<u>ions:</u> For each item, please choose between the following options and complete the columns by circling the letters:

olutely true; B = R ather true; C = N either true nor false; D = R ather false; E = A b solutely false.

Physical role	Absolutely true	Rather true	Neither true nor false	Rather false	Abs olu tely fal se
rning, I don't even tolerate that	A	В	C	D	Е
talks to me ver during certain parts of the day	A	В	С	D	Е
ne time, I don't have the energy to practice sports activities make me feel tired	A A	B B	C C	D D	E E
Energy, will to do things					
re time, I don't feel like going out of my house ce difficulties finishing something I've started s, I don't even want to call my own friends	A A A	B B B	C C C	D D D	E E E
Concentration, attention, memorization					
oncentrate ne time, my mind is not clear ly break things because of clums iness	A A A	B B B	C C C	D D D	E E E
Relationship with the others			-		
ay I am not full of energy ell me I am not a calm person e irritable easily eed to be left alone	A A A	B B B	C C C	D D D D	E E E E
Psychological role					
nink my nerves are my only drive en worried	A A	B B	C C	D D	E E





End of

- Day 1: Could fall asleep quickly, but had to wake up to attend to his son and could not go back to bed
- Day 2: Could fall asleep quickly and stayed asleep for long although he did wake up a couple of times.
 Did not feel fatigue in the day
- Day 3: Nap for 5 minutes during the Shirodhara treatment and was feeling sleepy when he left. Could fall asleep easily and was good quality sleep according to him



- Day 4: No difficulty in falling asleep at all and most of the time no difficulty staying asleep, but not happy with day time fatigue. Difficulty in waking up too early
- Day 5: No difficulty falling asleep, mild difficulty in staying asleep, severe difficulty in waking up too early (very severe before), but still not satisfied with his sleep pattern
 - We He also felt that the sleep problem interfered with his daily functioning and is still very much worried about his current sleep problem





- Insomnia Severity Index
 - Baseline score: 22 (Severe Insomnia)
 - End of 5 days: 15 (Moderate to sub-threshold insomnia)
- Indicates moderate improvement in Insomnia
- No side effects were reported



HD-16 SCALE

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Dimensions	Baseline	5 days	ge of Acupuncture & Oriental Medicine
Physical role	66.22	80.20	
Energy	31.35	-3.76	
Concentration	53.94	36.20	
Relationship with others	41.12	40.26	
Psychological Role	37.05	22.70	
HD-16 total score	229.70	175.60	





- Single case report
- No follow-up data
- Short duration of treatment and no repeated treatments
- No comparison



ONGOING STUDY

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Inclusion criteria:

- Age 18-75 of either sex
- Duration of insomnia at least one year
- Willing to sign an informed consent
- **♦** A score of minimum 14 on the Insomnia severity index

Exclusion criteria:

- Comorbidities such as Depression or any other psychological conditions that require medications
- Currently on any prescription medication for insomnia
- Serious medical conditions such as uncontrolled hypertension, uncontrolled diabetes, or any other acute condition that disturbs sleep and requires waking up in the middle of the night
- Participants unwilling to comply with the protocol
- Anyone who is in litigation or receiving disability, workers' compensation benefits





- Study was approved by SCU IRB
- Study received private funding



- ◆ Treatment effects are promising and hence Shirodhara may be a beneficial treatment for Insomnia
- Requires further investigation on a larger sample and with a control group and long term follow-up





- This presentation was sponsored by SCU
 FSDC scholarship
- Research Assistants: Julia Wu & Nina La
- The patient for his consent
- Bazaar of India for providing the oil
- OM organization (a non-profit org)







QUESTIONS???