

# Feasibility and Pilot Efficacy Testing of Integrated Yoga and *Shirodhara* (Ayurvedic Oil-Dripping) Intervention on Clinical Symptoms, Cognitive Functions and Sleep Quality of Adults with Anxiety Disorder

## Abstract

**Background:** Beneficial effects of yoga therapy in anxiety disorders (ADs) are known. Traditional texts describe usefulness of Ayurvedic oil-dripping, *Shirodhara* technique, in relieving anxiety. Thus, present study was planned to assess the feasibility and synergistic value of *Shirodhara* as an add-on to yoga therapy in adults with AD. **Materials and Methods:** Thirty adults (males = 14, females = 16) admitted in a residential holistic health care center with an age range of  $29.66 \pm 6.63$  years and diagnosis of one of the ADs (generalized AD,  $n = 18$ ; social phobia,  $n = 8$ ; and panic AD,  $n = 4$ ) as per mini-international neuropsychiatric interview (M. I. N. I. English version 5.0) by a psychiatrist were randomly divided into two groups: (1) integrated yoga-based lifestyle program (YT;  $n = 15$ ) and (2) YT + Ayurveda (YA;  $n = 15$ ). Both groups continued to receive conventional treatment and were on stable medications throughout the study period except in cases of emergency. Assessments were done by an independent assessor at baseline and after 2 weeks of intervention for clinical symptoms (HAM-A, State and Trait Anxiety Inventory, and Brief Psychiatric Rating Scale), sleep quality (sleep rating questionnaire), and cognition (Stroop test and digit letter substitution test) using standard validated tools. Parametric tests were applied using SPSS 10.0 to analyze the data. **Results:** Twelve subjects in yoga group and thirteen subjects in YA group completed the trial. No side effects were reported in any of the groups. Within-group comparisons showed a significant improvement in clinical symptoms, cognition and sleep quality in both the groups. Between-group comparisons showed significantly better scores in Stroop word task for YA group as compared to YT group. Furthermore, there was a trend toward better improvement in sleep quality for YA group. **Conclusion:** Adding of *Shirodhara* technique to YT was feasible and may be useful in improving executive memory and sleep quality in adults with ADs.

**Keywords:** Adults, anxiety disorders, Ayurveda-based oil-dripping, integrated yoga, *Shirodhara*

## Introduction

Anxiety disorders (ADs) are a group of mental disorders characterized by feelings of anxiety and fear.<sup>[1]</sup> As per the Diagnostic and Statistical Manual-5 (DSM-5), the following psychiatric diagnoses are included under ADs: (a) separation AD, (b) selective mutism, (c) specific phobia, (d) social phobia (SP), (e) panic disorder (PD), (f) agoraphobia, (g) generalized AD (GAD), (f) substance/medication-induced AD, (g) ADs due to other medical conditions, and (h) other specified or unspecified ADs. Lifetime prevalence of any psychiatric disorder is 46.4%, among which ADs are the most common psychiatric disorders with lifetime prevalence of 28.8%.<sup>[2]</sup> Females are affected twice more than males, usually

beginning before the age of 25 years.<sup>[3]</sup> ADs are known to cause substantial distress and impairment often complicated with comorbidities, both psychiatric and medical.<sup>[4,5]</sup>

ADs manifest with a wide range of physical and affective symptoms with changes in behavior and cognition.<sup>[6]</sup> Several studies have found cognitive impairment in people suffering from ADs. The impairments are reported in following cognitive domains: executive functions, short-term memory, long-term memory, visuospatial or perceptual ability, and working memory.<sup>[7,8]</sup> Another study revealed that antidepressant intake worsened the executive and

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non-verbal memory task performance in patients suffering from GAD compared to those who did not take.<sup>[9]</sup> Sleep disturbances are common in people suffering from GAD, SP, PD, and post-traumatic stress disorder (PTSD).<sup>[10]</sup> Disturbed sleep further enhances severity of anxiety symptoms and worsens the disability related to ADs.<sup>[11,12]</sup>

Yoga has emerged as a useful adjuvant in the management of various psychiatric disorders.<sup>[13]</sup> A study on patients with GAD and panic ADs reported that a group intervention using meditation-based stress reduction program for 12 weeks was useful in decreasing panic and anxiety symptoms.<sup>[14]</sup> Another study observed that 5 weeks of meditation therapy was as effective as pharmacotherapy (imipramine and chlordiazepoxide) in patients suffering from GAD. In addition, the study reported that meditation intervention was free from side effects which are usually observed with medications such as habit formation, withdrawal reaction, and concerns of overdose.<sup>[15]</sup> Recent meta-analysis assessed effect of yoga therapy for anxiety. Six randomized control trials were included in the study, and it was observed that there was evidence for small short-term effects of yoga on anxiety compared to no treatment and large effects compared to active comparators. Though, results were inconclusive for ADs diagnosed with DSM criteria.<sup>[16]</sup> A bi-directional relationship has been observed between breathing and emotion/cognition<sup>[17]</sup> and voluntarily changing the pattern of breath may account for at least 40% of the variance in feelings of anger, fear, joy, and sadness.<sup>[18]</sup> A study on 41 subjects suffering from GAD found that Sudarshan Kriya Yoga, a predominantly breathing-based yoga program, given for 8 weeks duration as an add-on to standard treatment, was effective in reducing HAM-A (Hamilton Anxiety Rating Scale) total scores and psychic subscale. It was also observed that the response rate was 73% and the remission rate was 41% at the end of the intervention.<sup>[19]</sup> Another self-as control study reported improvement in state anxiety and psycho-motor performance immediately after yoga-based Mind Sound Resonance Technique (MSRT) in patients with GAD.<sup>[20]</sup> Similarly, a number of research studies have demonstrated usefulness of yoga in improving cognitive functions<sup>[21,22]</sup> as well as sleep quality<sup>[23,24]</sup> in health and disease.

As per Ayurveda, psychiatric disorders are described under *Unmada* (abnormal mental state). *Chittodvega* (agitated state of mind) is a group of symptoms mentioned in Ayurvedic scriptures which closely correlates with ADs.<sup>[25,26]</sup> Ayurveda-based oil-dripping or *Shirodhara* has been described as a useful procedure for the management of *Chittodvega*.<sup>[27,28]</sup> *Shiro* means head and *Dhara* means flow. It involves the dripping of continuous flow of medicated or nonmedicated liquids such as oil, decoctions, milk, and medicated buttermilk on the forehead of a person from a vessel at a stipulated height.<sup>[29]</sup> *Shirodhara* is also one of the procedures done under panchakarma therapies and is indicated mainly in *Urdhwa Jatrugata Vikaras* (disorders

pertaining to areas above collar bone).<sup>[29]</sup> This results in improved circulation, giving relaxation to the body and helps in stress relief, thus relaxing the mind.<sup>[30]</sup> *Takradhara* is one among the types of *Shirodhara* where the liquid used for the procedure is medicated buttermilk. Previous scientific studies have found *Shirodhara* to be effective in reducing sympathetic activity by reducing heart rate, mean diastolic blood pressure and stress levels in healthy volunteers,<sup>[29]</sup> and reducing systolic as well as diastolic blood pressure in patients suffering from essential hypertension.<sup>[30]</sup> Another study observed beneficial effects of *Shirodhara* in reducing anxiety, depression, irritability, fatigue and sleep disturbances in peri-menopausal women in comparison to hormonal therapy.<sup>[31]</sup> Another open-label trial assessed effect of 1-week *Shirodhara* intervention plus an Ayurvedic herbal combination (Manas Mitra Vatakam) on sleep architecture of GAD patients using polysomnography and compared the effects with those taking clonazepam. It was observed that Ayurvedic treatments were more effective in promoting and preserving slow wave sleep thus maintaining the normal sleep architecture, whereas clonazepam treatment grossly altered the sleep architecture in GAD patients.<sup>[32]</sup> Preliminary studies have also reported improvement in cognition after *Shirodhara* intervention.<sup>[33,34]</sup> The above mentioned studies did not report any side effects due to *Shirodhara* technique.

Thus, both yoga as well as *Shirodhara* have the potential to help reduce anxiety symptoms, enhance sleep quality, and improve cognitive performance in ADs.

Present study was planned to assess the feasibility of combining *Shirodhara* with yoga-based lifestyle regimen in patients suffering from ADs and assess the efficacy of the same through a randomized pilot study.

## Materials and Methods

### Subjects

Subjects were recruited from in-patient population getting admitted in the psychiatry unit of a holistic health-care center in Bengaluru, India. Thirty adults (male = 14; female = 16) within the age range of  $29.66 \pm 6.63$  years, diagnosed with one of the ADs (GAD,  $n = 18$ ; SP,  $n = 8$ ; and panic AD,  $n = 4$ ) by a psychiatrist using Mini-International Neuropsychiatric Interview (M. I. N. I. English version 5.0) and following the DSM V criteria were randomly divided into two groups: (1) integrated yoga-based lifestyle program (YT) and (2) YT + Ayurveda (YA) using an online randomization software ([www.randomizer.org](http://www.randomizer.org)). Randomization was done using a random number table (<https://www.randomizer.org/>). Selection bias was prevented through allocation concealment. Demographic details were comparable in both the groups at the baseline with no significant between-group differences [Table 1].

**Table 1: Demographic details of the subjects**

Variable	YT group		YA group	
	n/range	Mean±SD	n/range	Mean±SD
Number of subjects	15		15	
Gender				
Male	7		8	
Female	8		7	
Age (years)	21-40	28.93±6.00	19-40	30.4±7.34
Education (years)	10-22	15.53±2.85	12-22	15.83±2.38
Duration of anxiety disorder (years)	1-9	3.76±2.33	1-25	6±6.14
Type of anxiety disorder	GAD - 8 SP - 4 PD - 3		GAD - 10 SP - 4 PD - 1	
Medications (number of subjects)	Sertraline (2) Paroxetine (2) Escitalopram (1) Clonazepam (10) Fluoxetine (2) Lonazepam (1) Alprazolam (1) Duloxetine (1) Mirtazapine (1) Venlafaxine (1)		Escitalopram (3) Fluoxetine (3) Clonazepam (8) Venlafaxine (1) Mirtazapine (1) Alprazolam (1)	
Comorbid illnesses (number of subjects)	Hypertension (1) Gastrintestinal Reflux disorder (2) Migraine (2)		Migraine (1) Irritable Bowel syndrome (2) Gastrintestinal reflux disorder (1)	

GAD=Generalized anxiety disorder, SP=Social Phobia, PD=Panic disorder, SD=Standard deviation

### Design and selection criteria

A two-group, pre–post design was followed in this study.

Inclusion criteria were: (1) both gender within the age range of 18–50 years; (2) patients who were diagnosed with one of the following ADs: GAD, SP, panic AD (PAD), PTSD and separation AD as per the DSM-5 criteria with HAMA scores  $\geq 18$ ; (3) patients on stable medications since last 1 month (except use of benzodiazepine during episodic acute exacerbations; drugs should not be changed across the pharmacological categories); (4) patients having common co-morbidities such as depression, diabetes, hypertension, irritable bowel syndrome, gastroesophageal reflux disorder, and obesity etc; and (5) patients who could read and write in English language.

Exclusion criteria were: (1) patients with obsessive–compulsive disorder or substance/medication-induced ADs or ADs due to other medical conditions; (2) patients undergoing structured psychotherapy programs such as cognitive behavioral therapy and rational emotive behavior therapy; (3) subjects with a history of substance abuse and/or dependence; (4) patients on antipsychotic medications; (5) patients with mania, schizophrenia or other psychotic comorbidities or dementias; (6) patients with suicidal or homicidal tendencies; (7)

patients with organic brain disease; (8) patients with medical conditions which would hamper practice of yoga such as malignancies, arthritis, low back pain, severe obesity, heart disease and stroke; and (9) conditions where *Shirodhara* was contraindicated such as during menstruation or third trimester of pregnancy; fever, chills, upper respiratory tract infections; neck pain, abrasions or cuts on the head and acute conditions such as nausea, vomiting, severe weakness, and exhaustion.

### Ethical consideration

Signed informed consent was obtained from all the subjects who participated in the study. Approval from the institutional review board was obtained.

### Assessments

Assessments were performed by a trained psychologist (who was blind to the group status of the subjects) at the baseline and after 2 weeks of intervention. The following assessments were done.

#### *The Hamilton Anxiety Rating Scale (HAM-A)*

The Hamilton Anxiety rating scale (HAM-A) is used to detect the severity of the anxiety symptoms in people already diagnosed with ADs.<sup>[35]</sup> It is valid and reliable.<sup>[35]</sup>

The questionnaire has 14 items, each item having a number of symptoms, with grades ranging from 0 to 4 in terms of severity. At the end, the total of all the scores is calculated from 0 to 56 to understand the severity of anxiety. A score of 17 or less indicates mild anxiety severity. A score from 18 to 24 indicates mild-to-moderate anxiety severity. Finally, a score of 25–30 indicates a moderate-to-severe anxiety severity.

#### *State and Trait Anxiety Inventory-X*

State and Trait Anxiety Inventory (STAI) form X is valid and reliable tool<sup>[36]</sup> containing 20 self-rating questions pertaining state anxiety (X-1) and 20 pertaining trait anxiety (X-2).<sup>[36]</sup> Each question in form X-1 can be scored from 0 (Not at all) to 4 (Very much so). The final score may range from 20 to 80 for each scale.

#### *Brief Psychiatric Rating Scale*

The Brief Psychiatric Rating Scale (BPRS) is a methodological instrument frequently used to evaluate symptoms such as depression, anxiety, hallucinations, and unusual behavior.<sup>[37]</sup> It consists of 18 symptom constructs and takes 20–30 min for the interview and scoring. The rater should enter a number ranging from 1 (not present) to 7 (extremely severe). 0 is entered if the item is not assessed. In a large number of studies, BPRS showed good reliability coefficients, both for total score and for individual. Validity tests of this instrument performed by an experienced rater yielded good interrater reliability coefficients items.<sup>[37]</sup>

#### *Stroop Color and Word Test*

The Stroop color and word test is a valid and reliable test<sup>[38]</sup> which assesses a person's cognitive processing, executive functions, resistance to disturbance from external stimuli, creativity and psychopathology.

The Stroop color and word test yields three basic scores: (1) raw word scores, (2) raw color scores and (3) raw color and word scores. The raw word score is the number of items completed on the word page, the raw color score is the number of items completed on the color page, and the raw color and word score is the number of items completed on the color and word page. The pure interference score is calculated by subtracting the raw color score from the raw color and word score.<sup>[38]</sup>

#### *The Digit Letter Substitution Test*

The digit letter substitution test (DLST) is a valid and reliable test<sup>[38]</sup> for psychomotor performance. It consists of a worksheet having 8 rows and 12 columns with randomly arranged digits. The task is to substitute as many target digits as possible in the specified time of 90 s. The total number of substitutions and wrong substitutions are scored. The net score is obtained by deducting wrong substitutions from the total substitutions attempted.<sup>[39,40]</sup>

#### *Quality of sleep – sleep rating questionnaire*

The sleep rating questionnaire is a commonly used brief tool for assessing sleep quality. It consists of seven self-rating questions, of which five questions are open ended and two are dichotomous, i.e., two options: yes/no. The other responses are in either the number of times or number minutes.<sup>[41]</sup>

### **Intervention**

#### *Integrated Yoga-Based Lifestyle Program (YT)*

The program involved following a regulated lifestyle based on principles of yoga in a residential setup. The day started with practice of meditation on the sound AUM, followed by practice of specially designed 60 min yoga module which included loosening exercises, breathing practices, *Suryanamaskāra*, *Asanas* along with *Prāṇāyāma* and relaxation techniques [Table 2].<sup>[42]</sup> This yoga practice module is being used as an add-on at the National Institute of Mental Health and Neurosciences, Bengaluru, India, for clinical management of patients suffering from ADs. The program also included yoga-based wholesome *sattwic* diet<sup>[43]</sup> and lectures on promoting healthy lifestyle and managing stress through yoga.<sup>[44]</sup> The details of YT program and its philosophical basis has been described elsewhere.<sup>[44,45]</sup> Subjects followed this program for 2 weeks duration in this study.

#### *Shirodhara intervention*

Along with the daily schedule of YT program, subjects in the YA group also underwent *Shirodhara* intervention in the morning for 40 min every day for 7 days between 8 am to 10 am. The intervention was started from the 3<sup>rd</sup> day of admission till the 10<sup>th</sup> day. *Shirodhara* procedure comprised three phases: *Purvakarma* (pre-treatment procedure) which involved *shiro-abhyanga* (the head massage with lukewarm sesame seed oil), *Pradhanakarma* (Main *Shirodhara* procedure), and *Paschatkarma* (post-treatment procedure). Table 3 provides details pertaining to contents used in *Shirodhara* liquid. Table 4 describes the three phases of *Shirodhara* procedure followed in the study in detail.

### **Data analysis**

Data were found normally distributed using Shapiro–Wilk test ( $P < 0.05$ ). Paired and independent samples *t*-tests were applied using SPSS version 10.0 (IBM India Private Limited) for within- and between-group comparisons, respectively. Cut off value for significance was set at  $\alpha = 0.05$ .

### **Results**

Twelve subjects in the YT group and 13 subjects in the YA group completed the study. The main reason for dropouts were: (1) subjects got discharged early due to personal reasons (2 in the YT group and 1 in the YA group); (2) subjects developed upper respiratory tract infection (1 in the YA group) and (3) subjects unwilling to undergo post assessments (1 in the YT group). No subject reported any side effects due

**Table 2: Yoga module for anxiety disorder**

Practice (Sanskrit)	Practice (English)	Rounds/counts	Time (in min)
<b>Preparatory practices</b>			
<i>Shvasa Kriya</i>	Hands stretch breathing	10 Counts	1
<i>Shvasa Kriya</i>	Hands in and out breathing	10 Counts	1
<i>Vyaghrasana Shvasa Kriya</i>	Tiger breathing	10 Counts	1
<i>Shashankasana Shvasa Kriya</i>	Rabbit pose breathing	10 Counts	1
<i>Setubandasana Shvasa Kriya</i>	Bridge pose breathing	10 Counts	1
<b>Relaxation after breathing practice</b>			
In <i>Shavasana</i>	Quick relaxation technique	1 round	3
<b>Standing asanas</b>			
<i>Tadasana</i>	Palm tree pose	2 Rounds	2
<i>Ardha Kati Cakrasana</i>	Lateral arc pose		
	Right side	1	1
	Left side	1	1
<i>Ardhachakrasana</i>	Half wheel pose	2 Rounds	2
<b>Sitting asanas</b>			
<i>Shashakasana</i>	Rabbit pose	2 Rounds	2
<i>Vajrasana</i>	Thunderbolt pose	2 Rounds	2
<i>Vakrasana</i>	Half spinal twist pose		
	Right side	1	1
	Left side	1	1
<b>Prone Asanas</b>			
<i>Bhujangasana</i>	Cobra pose	2 Rounds	2
<i>Shalabhasana</i>	Locust pose	2 Rounds	2
<b>Relaxation after yogasanas</b>			
<i>Yoga Nidra</i>		1 round	5
<b>Pranayama Practices</b>			
<i>Vibhagiya Pranayama</i>	Sectional breathing	9 Rounds	4
<i>Nadi Shuddi</i>	Alternate nostril Breathing	9 Rounds	4
<i>Chandra Anuloma Viloma</i>	Left nostril breathing	9 Rounds	2
<i>Sheetali Pranayam</i>	Cooling breath	9 Rounds	2
<b>Meditative chanting</b>			
<i>Nadanusandhana</i>	Sound resonance technique		
	<i>AA kara</i>	5 rounds	5
	<i>UU kara</i>	5 rounds	
	<i>MM kara</i>	5 rounds	
	<i>AUM kara</i>	5 rounds	

**Table 3: Medicines used in Shirodhara Liquid**

Medicine	Scientific name	English name	Hindi name	Kannada name
<i>Musta*</i>	<i>Cyperusrotundus</i>	Nut grass	<i>Motha/Nagarmotha</i>	<i>TungeGadde</i>
<i>Amalaki*</i>	<i>Emblicaofficinales</i>	Indian Gooseberry	<i>Amla</i>	<i>NelliKayi</i>

\*Above medicines were mixed in equal proportion in buttermilk (*Takram*) at room temperature

to yoga or Ayurveda intervention in either of the groups, respectively. Thus, it was feasible to combine *Shirodhara* technique with a yoga-based lifestyle program.

Within-group comparisons revealed significant improvements in clinical symptoms (HAM-A, STAI-X1 and BPRS), Stroop performance, DLST scores, and various sleep parameters in both YT [Table 5] and YA [Table 6] groups. Between-group comparisons [Table 7] showed significantly

better performance in the Stroop neutral word task in the YA group as compared to the YT group. Furthermore, there was a trend toward higher sleep quality scores in the YA group as compared to the YT group. It was found that YA group had 10% reduction in sleep latency, 11% improvement in sleep hours, 11% reduction in sleep disturbances, and 40% reduction in incidences of daytime sleep. Though these findings were not statistically significant.

**Table 4: Three phases of Shirodhara procedure in detail**

<b>Purvakarma (pretreatment procedure and preparations)</b>	<b>Pradhanakarma (main treatment procedure)</b>	<b>Paschatkarma (posttreatment procedure)</b>
<p>Procurement of <i>Shirodhara</i> apparatus</p> <ol style="list-style-type: none"> <li><i>Dhara droni</i> (<i>Shirodhara</i> table) - a special table designed to carry out this procedure generally made of oil proof wood having 8×3×3 feet dimensions on which patient was made to lie down</li> <li>Dhara stand: It was made of wood placed exactly behind the head end of table with a hook at the top whose height could be adjusted to varying lengths. It was 7 feet in height with tripod base</li> <li>Dhara pot: A copper vessel suspended from the hook of the stand, filled with medicated buttermilk and having a standardized hole at the bottom. A sterile cloth was passed through that hole such that a portion of it lies inside the vessel and few inches outside, so that the liquid drops down slowly through the cloth instead of falling in a big stream</li> </ol> <p>Preparation of medicated buttermilk: Equal quantities of <i>Musta</i> and <i>Amalaki</i> powder was boiled with 14 times water on a moderate flame until 1/3<sup>rd</sup> of the total quantity was left. To this mixture, equal quantity of buttermilk was added to get the required liquid</p> <p>Preparation of patient</p> <p>The patient was asked to come fasting or not having anything in last 1 h before initiating procedure</p> <p>Also, they were asked to clear their bowels and bladder before coming</p> <p>Before starting the main procedure, they were given head massage with lukewarm sesame oil</p>	<ol style="list-style-type: none"> <li>After the head massage patient was asked to lie comfortably in supine position on the <i>dhara</i> table with head on the extra projection of the table</li> <li>Eyes were covered with cotton gauze piece to protect them from any spillage of medicated liquid</li> <li>After this the <i>dhara</i> pot filled with medicated liquid, suspended from <i>dhara</i> stand was so adjusted so that it was at a height of 2 feet above the midpoint of the center of the patient's forehead</li> <li>Now the medicated buttermilk kept at room temperature was made to flow out of the vessel slowly and uniformly over the forehead of the patient, by swinging of the vessel by attendant uniformly</li> <li>This <i>Takradhara</i> was continuously given for 40 min with intermittent head massage in between during the flow itself, for better effect</li> </ol>	<p>After the procedure the patient's head was wiped off using a sterile cloth and following instructions were given to the patient to be followed</p> <ol style="list-style-type: none"> <li>Prevent direct exposure to air or sun</li> <li>Take hot water bath after an h</li> <li>Consume light, hot, fresh and digestible food that day and avoid heavy, oily, refrigerated or fast foods</li> <li>Abstaining from traveling, sex, smoking, alcohol consumption or taking stress</li> </ol>

**Table 5: Comparison of baseline scores with Post-intervention scores within the yoga therapy group**

Variables	Mean±SD		P <sup>a</sup>	CI		Percentage change
	Prescores	Postscores		Lower	Upper	
HAM-A	31.00±6.24	18.80±4.28	0.01**	9.87	14.52	-39.35
BPRS	30.20±10.44	16.87±8.97	0.01**	11.08	15.58	-44.13
SR1	62.00±40.21	32.67±19.89	0.01**	15.45	43.21	-47.30
SR2	6.16±1.33	6.43±1.96	0.54	-1.18	0.65	+4.38
SR3	2.33±1.50	1.20±1.01	0.01**	0.63	1.62	-48.49
SR5	0.07±0.25	0.93±0.25	0.01**	-1.06	-0.67	+12.28
SR6	0.27±0.45	0.20±0.41	0.58	-0.18	0.32	-25.92
SR7	15.00±25.98	6.00±16.81	0.09	-1.78	19.78	-60.00
STAI	63.00±7.50	38.13±3.70	0.01**	19.85	29.87	-39.47
STROOP W	147.80±16.60	163.67±18.93	0.01**	-20.75	-10.98	+10.73
STROOP C	114.87±17.41	128.87±17.22	0.01**	-17.82	-10.18	+12.78
STROOP CW	37.80±10.51	48.60±9.68	0.01**	-13.44	-8.15	+28.57
DLST T	44.53±11.35	53.60±13.93	0.01**	-11.31	-6.81	+20.36
DLST C	44.53±11.35	53.60±13.93	0.01**	-11.31	-6.81	+20.36

<sup>a</sup>Paired samples *t*-test, *P*<0.05, \*\**P*<0.01. HAM-A=Hamilton Anxiety Rating Scale, BPRS=Brief Psychiatric Rating Scale, SR1=Approximately how long (minutes) does it take you to fall asleep?, SR2=How many hours do you sleep each night?, SR3=How many times (if any) do you wake up during the night?, SR5=Do you feel rested in the morning? ("yes" or "no"), SR6=Do you sleep in the day time? ("yes" or "no"), SR7=If your answer to question 6 was "yes" for how long do your daytime naps last? (minutes), STAI=State Trait Anxiety Inventory, STROOP W=Stroop word test, STROOP C=Stroop color test, STROOP CW=Stroop color word test, DLST T=Digit letter substitution test total score, DLST C=Digit letter substitution test correct score, SD=Standard deviation, CI=Confidence interval

**Table 6: Comparison of baseline scores with postintervention scores within the yoga therapy + Ayurveda group**

Variables	Mean±SD		P <sup>a</sup>	CI		Percentage change
	Prescores	Postscores		Lower	Upper	
HA	31.47±5.20	19.33±3.79	0.01**	9.89	14.37	-38.57
BPRS	32.33±9.80	17.93±7.53	0.01**	12.17	16.62	-44.54
SR1	66.00±31.64	30.67±17.20	0.01**	24.94	45.71	-53.5
SR2	5.83±1.31	6.73±0.62	0.01**	-1.33	-0.46	+15.43
SR3	3.13±1.84	1.27±1.03	0.01**	1.28	2.45	-59.42
SR5	0.13±0.35	0.87±0.35	0.01**	-0.98	-0.48	+5.69
SR6	0.40±0.50	0.13±0.35	0.10	-0.06	0.59	-67.5
SR7	30.00±43.54	7.00±18.68	0.09	-4.16	50.16	-76.66
STAI	65.67±6.30	40.40±5.69	0.01**	22.39	28.14	-38.48
STROOP W	142.47±131.67	146.80±13.60	0.01*	-8.27	-0.39	+30.39
STROOP C	110.20±12.16	123.00±11.63	0.01**	-14.56	-11.03	+11.61
STROOP CW	37.47±9.28	46.80±9.46	0.01**	-10.83	-7.82	+24.89
DLST T	43.40±10.39	52.40±8.53	0.01**	-11.09	-6.90	+20.73
DLST C	43.40±10.39	52.40±8.53	0.01**	-11.09	-6.90	+20.73

<sup>a</sup>Paired samples *t*-test, \**P*<0.05, \*\**P*<0.01. HAM-A=Hamilton Anxiety Rating Scale, BPRS=Brief Psychiatric Rating Scale, SR1=Approximately how long (minutes) does it take you to fall asleep?, SR2=How many hours do you sleep each night?, SR3=How many times (if any) do you wake up during the night?, SR5=Do you feel rested in the morning? (“yes” or “no”), SR6=Do you sleep in the day time? (“yes” or “no”), SR7=If your answer to question 6 was “yes” for how long do your daytime naps last? (minutes), STAI=State Trait Anxiety Inventory, STROOP W=Stroop word test, STROOP C=Stroop colour test, STROOP CW=Stroop colour word test, DLST T=Digit letter substitution test total score, DLST C=Digit letter substitution test correct score, SD=Standard deviation, CI=Confidence interval

## Discussion

The current study is the first attempt to assess the add-on effect of *Shirodhara* technique to integrated yoga intervention on clinical symptoms, cognitive functions and sleep quality in patients suffering from ADs. We found that it was feasible to combine yoga and *Shirodhara* together in patients suffering from ADs. Both YT and YA groups showed significant clinical improvements. Furthermore, it was observed that addition of *Shirodhara* to residential integrated yoga-based lifestyle program led to better improvements in executive functions (as demonstrated by higher scores on Stroop Word Task) as compared to YT group. A trend toward higher improvements in sleep latency, sleep duration, lesser sleep disturbances, and reduced daytime sleep was also observed in the YA group.

Previously, in a study Vikhnan *et al.* compared the effect of two types of *Shirodhara* – *Takradhara* (using buttermilk with herbs as the liquid for *Shirodhara*) and *Jaladhara* (using water as the liquid for *Shirodhara*) on healthy volunteers. They found that there was a significant reduction in HR and root mean squared standard deviation with *Takradhara*. Whereas scores on sleep quality, perceived stress scale, and WHO well-being scales were significantly better after *Takradhara* as well as *Jaladhara*. The study also observed that Depression Anxiety Stress Scale-21 scores improved significantly only after *Takradhara*.<sup>[46]</sup> In our study, we observed similar results with *Takradhara* in terms of reduction in anxiety scores in patients with ADs. We observed a reduction of 39.35% and 38.50% in Hamilton Anxiety Rating Scale after YT and YA interventions, respectively. Similarly, state anxiety

scores reduced by 39.4% in the YT group and 38.4% in the YA group. This shows that adding *Shirodhara* did not change the anxiety scores further. This may be due to the fact that the effect size of YT intervention itself was high, and therefore, there was not much scope for further improvement after adding *Shirodhara*. Furthermore, it needs to be noted that addition of *Shirodhara* with YT intervention did not show any unfavorable interaction.

The effect of yoga intervention on DLST and Stroop Task has been tested before in a few studies on patients with AD. A study by Dhansoia *et al.* in 2015 showed that apart from reducing anxiety, MSRT technique also led to significant enhancement of psychomotor performance in GAD patients.<sup>[20]</sup> We found that Stroop performance improved in both the groups, but Stroop word performance was significantly (20%) better in the YA group than that in the YT group. This is an important finding in this population as impairment of cognitive functions has been observed not only as part of the psychopathology<sup>[47]</sup> but also as a side effect of anti-anxiety medications.<sup>[48]</sup> Therefore, addition of *Shirodhara* technique to yoga therapy intervention may be useful in providing added benefits on cognitive performance, especially the executive memory.

There are many studies which have proven the benefits of yoga intervention on sleep architecture and quality in health as well as disease.<sup>[23,24,49]</sup> *Shirodhara* has also been found useful in improving the same.<sup>[50]</sup> Therefore, we planned to add both the interventions to observe whether the addition has synergistic effects on sleep. We observed that overall sleep quality improved significantly in both the groups as compared to the baseline. Although between-group statistics

**Table 7: Comparison between yoga therapy and yoga therapy+Ayurveda groups for baseline scores and postintervention scores**

Variables	Group	n	Prescores, mean±SD	P <sup>a</sup>	Postscores, mean±SD	P <sup>a</sup>
HAM-A	YT	15	31±6.24	0.82	18.80±4.28	0.72
	YA	15	31.47±5.20		19.33±3.79	
BPRS	YT	15	30.20±10.44	0.56	16.87±8.97	0.72
	YA	15	32.33±9.80		17.93±7.53	
SR1	YT	15	62.00±40.21	0.76	32.67±19.89	0.77
	YA	15	66.00±31.64		30.67±17.20	
SR2	YT	15	6.16±1.33	0.49	6.43±1.96	0.57
	YA	15	5.83±1.31		6.73±0.62	
SR3	YT	15	2.33±1.50	0.20	1.20±1.01	0.86
	YA	15	3.13±1.84		1.27±1.03	
SR5	YT	15	0.07±0.25	0.55	0.93±0.25	0.55
	YA	15	0.13±0.35		0.87±0.35	
SR6	YT	15	0.27±0.45	0.45	0.20±0.41	0.63
	YA	15	0.40±0.50		0.13±0.35	
SR7	YT	15	15.00±25.98	0.26	6.00±16.81	0.87
	YA	15	30.00±43.54		7.00±18.68	
STAI	YT	15	63.00±7.50	0.30	38.13±3.70	0.20
	YA	15	65.67±6.30		40.40±5.69	
STROOP W	YT	15	142.47±131.67	0.34	146.80±13.60	0.01**
	YA	15	147.80±16.60		163.67±18.93	
STROOP C	YT	15	114.87±17.41	0.40	128.87±17.22	0.28
	YA	15	110.20±12.16		123.00±11.63	
STROOP CW	YT	15	37.80±10.51	0.92	48.60±9.68	0.61
	YA	15	37.47±9.28		46.80±9.46	
DLST T	YT	15	44.53±11.35	0.77	53.60±13.93	0.77
	YA	15	43.40±10.39		52.40±8.53	
DLST C	YT	15	44.53±11.35	0.77	53.60±13.93	0.77
	YA	15	43.40±10.39		52.40±8.53	

<sup>a</sup>Independent samples *t*-test, \*\**P*<0.01. HAM-A=Hamilton Anxiety Rating Scale, BPRS=Brief Psychiatric Rating Scale, SR1=Approximately how long (minutes) does it take you to fall asleep?, SR2=How many hours do you sleep each night?, SR3=How many times (if any) do you wake up during the night?, SR5=Do you feel rested in the morning? (“yes” or “no”), SR6=Do you sleep in the day time? (“yes” or “no”), SR7=If your answer to question 6 was “yes” for how long do your daytime naps last? (minutes), STAI=State Trait Anxiety Inventory, STROOP W=Stroop word test, STROOP C=Stroop colour test, STROOP CW=Stroop colour word test, DLST T=Digit letter substitution test total score, DLST C=Digit letter substitution test correct score, SD=Standard deviation, YT=Yoga therapy, YA=YT+Ayurveda

were not significant, the overall sleep quality scores were higher in the YA group with 10% reduction in sleep latency, 11% improvement in sleep hours, 11% reduction in sleep disturbances, and 40% reduction in incidences of daytime sleep. Smaller sample size may not have allowed the results to reach statistical significance. Future studies should assess the same using a larger sample size.

It has been demonstrated that yoga reduces stress and anxiety by improving autonomic functions via triggering neurohormonal mechanisms that suppress sympathetic activity through down-regulation of the hypothalamic–pituitary–adrenal axis.<sup>[51]</sup> Mindfulness-based practices may also enhance cognitive flexibility, which further helps in controlling anxiety.<sup>[52]</sup> The mode of action of *Shirodhara* has not been understood so far scientifically. However, studies have reported that immediately after *Shriodhara* there was a shift of the autonomic nervous system towards parasympathetic dominance.<sup>[53]</sup> Furthermore,

*Shirodhara* procedures led to reduction in heart rate and systolic and diastolic blood pressure<sup>[30]</sup> with improvement in sleep architecture.<sup>[32]</sup> All these factors point toward the fact that *Shirodhara* may induce the “relaxation response” without meditation. From Ayurveda perspective, *Shirodhara* may work by reducing the air humor (*Vata Dosha*) in the head region. Ayurveda provides an understanding that *vata dosha* is responsible for movements of thoughts in the mind. Both oil and *Takra* (*buttermilk*) have been used in Ayurveda system to mitigate *Vatadosha*. Thus, *Shirodhara* relaxes the mind by reducing the *Vata dosha* in the head region. The cumulative effect of the drugs and the procedure (slow stream flow and oscillatory dhara movement in calm environment) might have helped in soothing the mind and enhanced sense of well-being and sleep quality respectively.

The strengths of the study are as follows: (a) this is a multi-disciplinary study encompassing the fields of yogic science, Ayurveda, and psychiatry; (b) no earlier study has



reported feasibility, safety, and synergistic value of a yoga and Ayurveda intervention in ADs; (c) because the duration of yoga and Ayurveda intervention was short, acceptability and adherence to therapy was good; and (d) as yoga and *Shirodhara* were delivered through a standard protocol, the study is reproducible.

This study also has many limitations which restrict its generalizability. The most important limitation is the small sample size; this is a pilot study to serve as the base for a larger study in future. Second, in this study, we did not follow up the subjects, and thus, it is not known as to how long the obtained effects would last. In future, a dose–response curve could be generated by performing repeated measures. Third, no objective parameters were used to understand the mechanism of action of yoga and combined yoga + *Shirodhara* intervention at the electrophysiological, neurological, or biochemical levels. Furthermore, it has been observed that people suffering from ADs often suffer from comorbid depression. However, this was not assessed in the present study which focused only on anxiety-related symptoms. Finally, a four-arm study with (1) yoga, (2) Ayurveda, (3) yoga + Ayurveda, and (4) none (only conventional) groups would have been ideal to understand the synergistic value of yoga + Ayurveda intervention. This can be planned in future.

In future, a randomized controlled design with a larger sample size and robust design should be performed. Future studies should use objective variables of autonomic functions such as heart rate variability and galvanic skin resistance; advanced neuroimaging devices such as electroencephalography, functional near-infrared spectroscopy, and functional magnetic resonance imaging; and biomarkers such as serum serotonin, oxytocin, and endorphin levels to understand the mechanism of action. Effect of yoga and Ayurveda should also be tested in other neuropsychiatric disorders where psychomotor agitation, cognitive dysfunction, and sleep disturbances are prominent (e.g., early dementias or depression or bipolar disorders). Future studies should also compare the effect of yoga and Ayurveda with other mind–body relaxation techniques, including music therapy.

## Conclusion

This pilot study revealed that adding *Shirodhara* to integrated yoga program was feasible in patients with ADs. Addition of *Shirodhara* to yoga may help enhance executive memory and sleep quality further in this population. Studies with larger sample size are required in future to confirm these findings.

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## Conflicts of interest

There are no conflicts of interest.

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