

Yoga Module for Somatoform Pain Disorders: Development, Content Validation, and Feasibility Testing

Abstract

Background: Yoga practices have been found to be useful in chronic pain conditions but studies focussing specifically on somatoform pain disorders (SPDs) are limited. **Aims:** Current study aims to develop and test the feasibility of a yoga program for patients with SPDs. **Materials and Methodology:** A thorough search of traditional and contemporary literature was performed with the objective of formulating a yoga program for reducing chronic non-specific pain and associated psychological distress. Content validity of the program was then determined by taking the opinion of 18 yoga experts (who had >5 years of experience in treating mental health disorders) using content validation ratio (CVR) through Lawshe's formula. The feasibility of the module was tested on 10 subjects diagnosed with SPDs as per the International Classification of Diseases (ICD) -10 criteria using standard scales. **Results:** In the finalized module, 70.83% (34 out of 48 items) of the practices were retained along with the modifications as suggested by the experts. Two practices were not found to be feasible (*Trikonasana* and *Shalabhasana*) and hence were removed from the final module. A significant reduction in pain severity was observed in the subjects after practising the yoga module for 2 weeks. The content validity index for the whole module (average of all CVRs) was 0.55. **Conclusions:** A yoga module was developed for SPD. The content validity of the module was found to be good. The module was found safe and potentially useful for reducing pain severity in patients with SPD. Future studies should test the efficacy of the developed program through a randomized controlled clinical trial.

Keywords: Feasibility, module, somatoform pain disorder, yoga

Introduction

Somatoform pain disorders (SPDs), a common subtype of somatoform disorders, are characterized by persistent pain that is distressing, cannot be explained fully by physiological processes or physical disorders, and that occurs in association with psychosocial problems.^[1] Prevalence rates of somatoform disorders are highly varied depending on the setting and the criteria used to assess somatoform disorders. A systematic review on the prevalence of somatoform disorders (at least one subtype of somatoform disorder as per ICD 10 or DSM IV) in primary care setting reported the prevalence ranging from 26.2% to 34.5%.^[2] Conventional treatment for somatoform disorders includes the use of both psychotropic and psychological therapies that aim at addressing the biological, emotional, and psychosocial aspects of

the disorder. Despite these conventional modalities of treatment the remission rates are low, and patients continue to have a chronic relapsing-remitting course.^[3,4] Thus, there is a need to explore traditional systems of medicine that offer a personalized holistic approach and can bring positive modifications to the lifestyle.

Yoga is a popular mind-body therapy which has been found to have role in the treatment of neuropsychiatric disorders.^[5] There is ample evidence to suggest that yoga-based interventions are clinically useful in conditions such as depression,^[6] anxiety,^[7] and functional pain syndromes.^[8] However, there is limited literature on yoga as a treatment modality in SPDs. In a previous pilot study on 64 subjects suffering from SPDs, we observed that after 12 weeks of yoga intervention there was a significant reduction in the severity of pain. The pain

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scores on visual analog scale (VAS) dropped from 7.24 to 2.88. Though we found the yoga program useful, we did not use a validated yoga protocol in the study.^[9]

Heterogeneity of yoga styles and duration of intervention hinder the application of yoga therapy in clinical settings. Moreover, some of these styles of yoga are copyrighted. Researches using such branded nomenclatures of yoga make it difficult to replicate such studies in settings where training in that style of yoga is lacking. Thus, it is important to standardize yoga interventions for specific disorders.^[10,11]

Our literature survey revealed that such validated yoga modules are available for some common neuro-psychiatric disorders such as depression,^[12] chronic back pain,^[13] schizophrenia,^[14] obsessive-compulsive disorders^[15] and mild cognitive impairment.^[16] However to the best of our knowledge, we could not find a validated yoga module for SPDs. Thus, the current study was planned with the objective of: (a) developing a yoga module for SPD, (b) determine the content validity of the developed yoga module, and (c) testing the feasibility of the developed and validated yoga module on 10 subjects diagnosed with SPDs as per ICD-10 criteria.

Methodology

Development

The content of the module was developed after a detailed review of the classical and contemporary yogic texts and related modern scientific literature. Various traditional texts like *Hatha Yoga Pradipika*,^[17] *Patanjali Yoga Sutras*,^[18] *Bhagwad Gita*^[19] were reviewed by two research scholars with a master's degree in yogic science. They read the full texts using the following keywords as synonyms for "pain" and "overall health" in the Sanskrit language: "vedana," "daah," "vyadhi," "vata vyadhi," "dukha," "sukha," "prasanna," "swasthya," "laya," "shanti," "visharanti" "unmani" and "ananda." Practices that aimed at reducing pain, stiffness, spasm and improving physical and mental well-being were included from the classical and contemporary texts. Specific practices were also selected for the reduction of psychological stress, depression, and anxiety. The practices which were difficult to teach or which were contraindicated for common co-morbid disorders such as hypertension, back pain, obesity, and cardiovascular diseases were excluded. Few practices were modified to make them easier for patients with predominant pain symptoms.

The formulated yoga practice list was a combination of joint loosening practices, slow and synchronized breath awareness practices, yoga postures (*asanas*), breathing practices (*pranayamas*), and relaxation techniques. The duration of the yoga module was 1-hour which included the time for practice and relaxation between each practice.

Content validation of the yoga module

Previous yoga validation studies have sought opinion from 10 to 20 experts.^[15,20] We chose 40 experts from different schools of yoga who were contacted by E-mail to participate in the content validation study. The validation form consisted of the name of the yoga practices, suggestions, and comments related to yoga practices and a three-point Likert scale (1 - Not necessary, 2 - Useful but not essential, 3 - Extremely essential) for rating the usefulness of each yoga practice in patients with SPDs. This form was circulated by E-mail to the experts for their evaluation. Reminders were sent to the yoga experts if they did not respond to the first E-mail. Out of 40, 18 experts responded by providing their scores, comments, and suggestions.

Content validity ratio (CVR) for the suitability of the practices was calculated using Lawshe's formula.^[21] According to Lawshe's formula, the mean CVR across items is used as an indicator of the overall test content validity. Equation below provide Lawshe's formula:

$$CVR = (Ne - N/2)/N/2$$

where,

Ne = total number of panelists indicating "essential" for each practice

N = total number of panelists

The critical value for Lawshe's CVR was determined using CVR critical table provided by Ayre and Scally.^[22] This table provides a respective cut-off CVR score for the specific number of panelists involved in the study. For 18 panelists, the cut-off CVR was found to be 0.44. Thus, the practices with CVR score ≥ 0.44 were included in the list, the rest were removed. Suggestions were requested from the experts on precautions, duration, and contraindications for each practice also to assess the appropriateness of the module. The inter-rater reliability between the raters was calculated using intraclass coefficient (ICC).^[23] The ICC estimates and their 95% confidence intervals along with content validity index (CVI) were calculated using IBM SPSS Statistics for Windows, Version 24.0 (Armonk, North Castle, New York) based on mean rating, absolute agreement, and two-way mixed-effects model.

Feasibility testing of the module

The inclusion criteria for the feasibility study were: Subjects of either gender, age range of 20–50 years, those who suffer from SPD as per ICD-10 criteria, and those with the ability to read and write in English language and providing written informed consent. We excluded the subjects suffering from severe psychological and neurological disorders, those undergoing psychotherapy, similarly subjects with substance use disorder, and those with comorbid medical conditions that may cause pain such as cancer, arthritis,

disc prolapse, inflammatory and autoimmune disorders, infections, or injury were excluded. Subjects were assessed using visual analog scale (VAS) for pain before and after 10 supervised sessions of yoga (1 h session for 5 days a week for 2 weeks) by a trained yoga therapist. VAS was presented using a straight horizontal line of 100 mm length, with descriptor extremes ranging from '0' to '10' representing the pain severity from 'no pain at all' to 'my pain is as bad as it could possibly be', respectively. Subjects were on stable doses of the medications during the study period of 2 weeks. Four subjects were on tablet Amitriptyline with an average dosage of 40 ± 28.57 mg and one subject was on tablet fluoxetine 40 mg. A record was maintained, for any exacerbation of pain in case they had taken any analgesics.

Ethical aspects

The current study was approved by the Human Institutional Ethics Committee of NIMHANS, Bengaluru. Written informed consent was obtained by the subjects and experts who participated in the study.

Results

Validation results

Of the 40 experts, 18 completed the content validation of the developed yoga module. The experts were trained in different institutions and were following different styles of yoga for personal practice (Bihar school of yoga experts; $n = 3$; Integrated Yoga experts; $n = 5$; *Patanjali Yoga* experts; $n = 3$; *Sudarshan Kriya* Yoga experts; $n = 2$; *Isha* Yoga experts; $n = 2$). All the experts were of Indian nationality. Of the 15 experts, 11 were medical graduates with postgraduation either MSc or MD or Ph.D. in yoga, one medical graduate in yoga with 10 years of experience, 3 of them were academic experts in yoga with a doctorate degree. The average (standard deviation [SD]) age of the experts was 35.46 (4.20) years with average (SD) years of experience in the field of yoga was 8.7 years (5.05). The CVI for the whole module (average of all CVRs) was 0.55.

Table 1 provides list of yoga practices given to the experts and the respective CVR scores along with the decision pertaining to their retention or deletion from the final yoga module.

The agreement between the raters was good (the average measure of ICC for inter-reliability was 0.86 and the 95% interval was 0.79–0.91) for various items included in the final module. Loosening practices and breathing practices were considered an essential part of this module by the majority of the experts. The duration of 60 min of practice (including relaxation) per session was found appropriate by the experts. The module was hence modified as per the suggestions given.

Feasibility results

The developed module was tested for feasibility on 10 out-patient subjects (5 females) diagnosed with SPD by a psychiatrist using ICD-10 criteria. The subjects belonged to the age range of 32.2 ± 8.62 years and had been suffering from SPD since 7.28 ± 6.1 years. The average years of education of the subjects was 12.12 ± 5.48 years. Baseline data suggested that subjects had moderate to severe pain. All 10 subjects completed the feasibility study. At the end of 10 sessions, baseline and post data were compared through Wilcoxon's signed-rank test. It was observed that there was a significant reduction in the visual analogue scale scores (VAS scores) for pain severity. The mean scores reduced from 7.0 ± 2.35 at baseline to 2.74 ± 1.41 after 10 sessions of yoga; $P < 0.01$.

While practicing the module, $\geq 50\%$ (5 or more) subjects reported difficulty in performing the following yogic practices: (1) *Trikonasana* and (2) *Shalabhasana*. Subjects reported exacerbation of pain in the back and thigh region with the above practices respectively. Thus, these two practices were deleted from the module though they scored above the cut-off score of 0.44. Otherwise, subjects managed well with all other practices without the need for extra pain medications during the study period. It was observed that the final module was easy to learn, safe, and feasible. Table 2 provides the finalized yoga module which was validated and tested for feasibility in patients suffering from SPD.

Discussion

The yoga module for SPDs was developed after a detailed review of the literature; it was later validated by taking the opinion of yoga experts. The experts agreed on the usefulness of the content of the developed module for the reduction of pain, stiffness and spasm in patients with SPD.

We modified the module based on two aspects: (1) Content validity ratio ≥ 0.44 which implies that the practices that were given the rating of three by $>80\%$ of the panelists; (2) The suggestions and comments given by the experts were taken into consideration. Total 70.83% (34 out of 48 items) of the practices (which were listed after the literature survey) were retained.

The practices which were scored below the cut-off values (rated CVR ≤ 0.44) during the process of validation were: (1) Passive rotation of toes, (2) Ankle crank, (3) Knee crank, (4) Half butterfly (5) *Suryanamaskara* (6) *Tadasana* (7) *Padahasthasana* (8) *Paschimottanasana* (9) *Vajrasana* (10) *Kapalbhati* (11) *Ujjayi* (12) *Surya anuloma viloma* and (13) *Bhastrika*. All major practices which may aggravate pain directly or indirectly or which were difficult to learn were excluded in this procedure. "Slow and synchronized practice of breathing with body movements" was suggested as useful method of practice by 60% of the experts and this instruction was included as part of the final module.

Table 1: List of practices included in the validation form given to the experts

Yoga practices	Total number of experts giving scores 1, 2 and 3			Number of experts rating=3 (%)	Content validity ratio	Remarks
	Score 1	Score 2	Score 3			
Loosening practices						
Passive rotation of toes	3	3	9	9 (60)	0.2	Deleted
Toe bending	1	1	13	13 (86)	0.73	Retained
Ankle bending	0	1	14	14 (93)	0.86	Retained
Ankle rotation	0	0	15	15 (100)	1	Retained
Ankle crank	0	6	9	9 (60)	0.2	Deleted
Knee bending	0	1	14	14 (93)	0.86	Retained
Knee crank	0	6	9	9 (60)	0.2	Deleted
Half butterfly	2	3	10	10 (67)	0.33	Deleted
Hip rotation	0	1	14	14 (93)	0.86	Retained
Full butterfly	3	1	11	11 (73)	0.46	Retained
Waist rotation	0	2	13	13 (87)	0.73	Retained
Hand clenching	0	3	12	12 (80)	0.6	Retained
Wrist bending	0	2	13	13 (87)	0.73	Retained
Wrist joint rotation	0	1	14	14 (93)	0.86	Retained
Elbow bending	0	0	15	15 (100)	1	Retained
Shoulder rotation	0	0	15	15 (100)	1	Retained
Neck bending (up and down, sideto side, twist)	0	1	14	14 (93)	0.86	Retained
Neck rotation	1	2	12	12 (80)	0.6	Retained
Breathing practices						
Hand stretch breathing	0	3	12	12 (80)	0.6	Retained
Tiger stretch breathing	1	2	12	12 (80)	0.6	Retained
Lumbar stretch breathing	0	2	13	13 (87)	0.73	Retained
Suryanamaskara	0	6	9	9 (60)	0.2	Deleted
Asanas						
<i>Tadasana</i>	1	8	6	6 (40)	-0.2	Deleted
<i>Padahasthasana</i>	2	4	9	9 (60)	0.2	Deleted
<i>Ardhacakrasana</i>	0	3	12	12 (80)	0.6	Retained
<i>Trikonasana</i>	0	4	11	11 (73)	0.46	Retained
<i>Paschimottanasana</i>	2	5	8	8 (53)	0.06	Deleted
<i>Vajrasana</i>	2	4	9	9 (60)	0.2	Deleted
<i>Ustrasana</i>	1	2	12	12 (80)	0.6	Retained
<i>Shashankasana</i>	0	2	13	13 (87)	0.73	Retained
<i>Vakrasana</i>	0	2	13	13 (87)	0.73	Retained
<i>Ardhamatsyendrasana</i>	0	8	7	7 (47)	-0.06	Deleted
<i>Bhujangasana</i>	0	2	13	13 (87)	0.73	Retained
<i>Salabhasana</i>	0	4	11	11 (73)	0.46	Retained
<i>Uttanapadasana/Vipareetkarni</i>	0	4	11	11 (73)	0.46	Retained
<i>Pavanmuktasana</i>	0	1	14	14 (93)	0.86	Retained
<i>Setubandhasana</i>	0	1	14	14 (93)	0.86	Retained
Pranayamas						
<i>Kapalbhati</i>	3	4	8	8 (53)	0.06	Deleted
<i>Sectional breathing</i>	0	3	12	12 (80)	0.6	Retained
<i>Ujjayi</i>	2	3	10	10 (67)	0.33	Deleted
<i>Surya anuloma viloma</i>	4	5	6	6 (40)	-0.2	Deleted
<i>Nadishuddhi</i>	0	0	15	15 (100)	1	Retained
<i>Bhastrika</i>	2	7	6	6 (40)	-0.2	Deleted
<i>Bhramari</i>	0	1	14	14 (93)	0.86	Retained
<i>Nadanusandhana</i>	0	1	14	14 (93)	0.86	Retained
Relaxation techniques						
Instant relaxation technique	0	4	11	11 (73)	0.46	Retained
Quick relaxation technique	0	2	13	13 (87)	0.73	Retained
Deep relaxation technique	0	0	15	15 (100)	1	Retained

Table 2: The final list of practices in the yoga module for somatoform pain disorder

Serial number	List of practices in the final yoga module for SPD	Duration (total 60 min)
Loosening practices		
1	Toe bending	10
2	Ankle bending	
3	Ankle rotation	
4	Knee bending	
5	Hip rotation	
6	Full butterfly	
7	Waist rotation	
8	Hand clenching	
9	Wrist bending	
10	Wrist joint rotation	
11	Elbow bending	
12	Shoulder rotation	
13	Neck bending (up and down, side to side, twist)	
14	Neck rotation	
Instant relaxation technique (quick part by part relaxation of body parts from toes to head in lying down position followed by relaxation)		2
Breathing practices		
1	Hand stretch breathing	6
2	Tiger stretch breathing	
3	Lumbar stretch breathing	
<i>Asanas</i>		
1	<i>Ardhachakrasana</i> (half wheel pose)	20
2	<i>Ustrasana</i> (camel pose)	
3	<i>Shasankasana</i> (rabbit pose)	
4	<i>Bhujangasana</i> (cobra pose)	
5	<i>Navasana</i> (boat pose)	
6	<i>Uttanapadasana/Vipareetkarni</i> with wall support (raised leg pose/leg up the wall pose)	
7	<i>Pavanmuktasana</i> (Wind relieving pose)	
8	<i>Setubandhasana</i> (bridge pose)	
Quick relaxation technique (synchronized deep breathing with prolonged exhalation with abdominal movement)		3
<i>Pranayamas</i>		
1	Sectional breathing	14
2	<i>Nadisuddhi</i> (alternate nostril breathing)	
3	<i>Bhramari</i> (humming bee sound)	
4	<i>Nadanusandhana</i> (yoga of inner sound)	
Deep relaxation technique with positive affirmation (slow part by part relaxation of body parts from toes to head with chanting of sounds and positive affirmation as “I am healthy, happy and satisfied”)		5s

SPD=Somatoform pain disorders

In the evaluation form, experts were also asked for suggestions on any other practices which we might have missed in our literature search but based on their clinical experience the experts may find useful in this condition. It was decided to add a practice in the module if >60% of experts recommend the same. Through this way, three more practices were added to the module for testing the feasibility: (1) Hands in and out breathing, (2) *Bhujangasana* and (3) *Navasana*. The practices of *Yoga Nidra* were suggested by one of the experts. However, since only one expert suggested this practice and other relaxation techniques including *Nadanusandhana* (relaxation with chants) were included in the final module thus, *Yoga Nidra*

was not added to the final module. Ankle stretch breathing was not added due to the level of difficulty, as patients might be at risk of fall during the practice. Hands in and out breathing, *Bhujangasana* and *Navasana* were added to the module as per the suggestion of the experts as these are safe practices and have no major contra-indications. *Suryanamaskara* was excluded as it was marked as not essential by 9 out 15 experts (CVR = 0.2) and was suggested to be difficult to practice by patients with painful conditions.

The joint loosening practices were considered very useful and were recommended by the experts to be done with breath synchronization and mindfulness. Loosening

practices such as passive rotation of toes, ankle crank, knee crank, and half-butterfly were not rated as useful in reducing pain by the experts and hence were excluded. *Asanas* like *Tadasana*, *Padahasthasana*, *Paschimottanasana* and *Vajrasana* were excluded based on their CVR Scores. *Kapalbhati*, *Ujjayi*, *Surya anuloma viloma* and *Bhastrika* were excluded based on the difficulty of the practice during painful conditions and/or lower CVR Scores.

Relaxation techniques like instant relaxation technique (IRT: Quick part by part relaxation of body parts from toes to head in lying down position followed by relaxation), Quick relaxation technique (QRT: Synchronized deep breathing with prolonged exhalation with abdominal movement) and Deep relaxation techniques (DRT: Slow part by part relaxation of body parts from toes to head with chanting of sounds and positive affirmation as “I am healthy, happy and satisfied”) were considered to be very useful and suggested to be incorporated and retained in the module for better relaxation after the physical and breathing related practices.

Experts were also asked about the sequence and duration of the yoga practices and most of them suggested that relaxation techniques like IRT should be taught after loosening practice, QRT after *asanas*, and Deep relaxation technique at the end of the whole practice. Experts also suggested that for testing efficacy on pain, this module should be taught under supervision of trained yoga therapist for at least 5 days a week for 2 weeks (i.e. 10 sessions). Thus, current module was designed keeping in mind the practices that patients with painful conditions could perform. The content of the module did not reflect any religious or personal practices, practices rather were taken from standard traditional texts.

During the feasibility testing, it was observed that >50% of subjects found it difficult to perform two practices: (1) *Trikonasana* and (2) *Shalabhasana*. All the subjects who had difficulty in doing these postures were complaining of either low back pain or pain in the thigh region. The practice of *Trikonasana* is done in standing position, it involves spreading of the legs for around 2 feet and then bending sideways. This practice might exert pull on low back which might exacerbate pain, especially if there is muscle spasm. The practice of *Shalabhasana* requires lying down prone and then raising both legs backward and upwards with keeping the knee joints straight. This practice needs strong hamstring muscles and requires good amount of stamina. It is especially difficult for people who are overweight or obese. Thus, subjects with pain in the thigh or lower back muscle spasm might have found it difficult to perform this practice. Apart from this, all other practices were performed quite comfortably by the subjects. Thus, these two practices were not included in the final yoga module.

This study has some limitations: (a) Of the 40 Yoga experts contacted for validation, only 18 responded. Obtaining

information from more experts would have been more useful; (b) all experts who responded were of Indian origin. This limits the generalizability of the module, especially in Western contexts; and (c) we did not use any objective marker for pain assessment (pain threshold assessments) in our feasibility study.

Conclusions

A yoga module was developed based on the traditional and contemporary yoga texts and related scientific literature reviews. This was followed by content validation from the field experts and feasibility testing in 10 subjects. The developed module was found safe, feasible, and potentially useful for patients with SPD. The clinical efficacy of the module needs to be tested in further studies with robust methodology.

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Conflicts of interest

There are no conflicts of interest.

Ethical clearance

The present study was approved by the Institutional Ethics Committee (IEC) of NIMHANS, Bengaluru on 4th January, 2020 with REF number NIMHANS/EC (BEH.SC.DIV.) 22ND MEETING/2019.

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