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Development of a yoga module targeting cardiovascular health for patients with post-myocardial left ventricular dysfunction in India

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ABSTRACT

Background: Yoga is known to contribute towards cardiovascular health. This paper describes the development of a need-based yoga program which is suitable to be integrated into the cardiac rehabilitation of post-myocardial infarction patients with left ventricular dysfunction.

Materials and Methods: Based on the assessment of the need of the patients, literature review, and expert opinion, a yoga module was developed using the qualitative method of inquiry. The program included warm-up exercises, yogic asanas, pranayama, meditation and counseling sessions. A structured questionnaire eliciting comments on the contents was given independently to ten experts working in the field of health and yoga for validation. The final module was derived after incorporating the suggestions of the experts.

Results: Using the raters' expertise in cardiology and yoga practice, the practices which constitute the module were optimized. Majority of the experts (raters) agreed with the duration of 1 h training for 1month under supervision as adequate for subsequent practice at home. There was a 0.786 inter-rater reliability estimated using the interclass coefficient (ICC) and 0.789 internal consistency of the questions, measured using Cronbach's alpha. Both values indicate "good" reliability and consistency of the yoga module.

Conclusion: The developed yoga module was found to be acceptable. Future randomized control trials will be necessary to validate the effectiveness of this module and if the module demonstrates to be effective by clinical studies, it may add a therapeutic option in the rehabilitation of patients with heart failure following myocardial infarction, which can be applied in the hospitals and community level.

1. Introduction

Heart failure is a state that develops when the heart cannot maintain an adequate cardiac output or can do so only at an expense of an elevated filling pressure. In the mildest form of heart failure, the cardiac output is adequate at rest and becomes inadequate only when the metabolic demand increases during exercise or some other forms of stress.[1]

In the past few decades, there has been a shift in the underlying etiology of heart failure from valvular heart disease and hypertension to ischaemic heart disease. The prognosis of heart failure secondary to ischaemic heart disease is not encouraging. It is important to view the heart failure on the basis of its etiology since the management is based on this and recent data suggest that the mechanism of sudden death differs with the ischaemic and non-ischaemic etiology of heart failure.[2] The prevalence of heart failure is estimated at around 2–3% of the adult population and tends to increase with age. Throughout the world, an approximate 26 million people suffer from heart failure.[3] The prevalence of cardiovascular disease in the Indian subcontinent was estimated to be around 29.8 million in the year 2003. This huge prevalence could be a consequence of large population and increased cardiovascular disease risk factors.[4] Heart failure is the most frequent cause of hospitalization in population over 65 years of age.[5]

1.1. Therapeutic strategy

The heart failure management aims to control causative pathology, prevent progression to heart failure once dysfunction is established, maintain the quality of life and improve patient survival.[6] The non-pharmacological management of heart failure may be focused on educating the patient as well as the family members, weight monitoring, dietary measures, management of obesity, smoking cessation, advice on traveling, sexual activity, immunizations, drug counseling, rest, and exercise prescription.[6]

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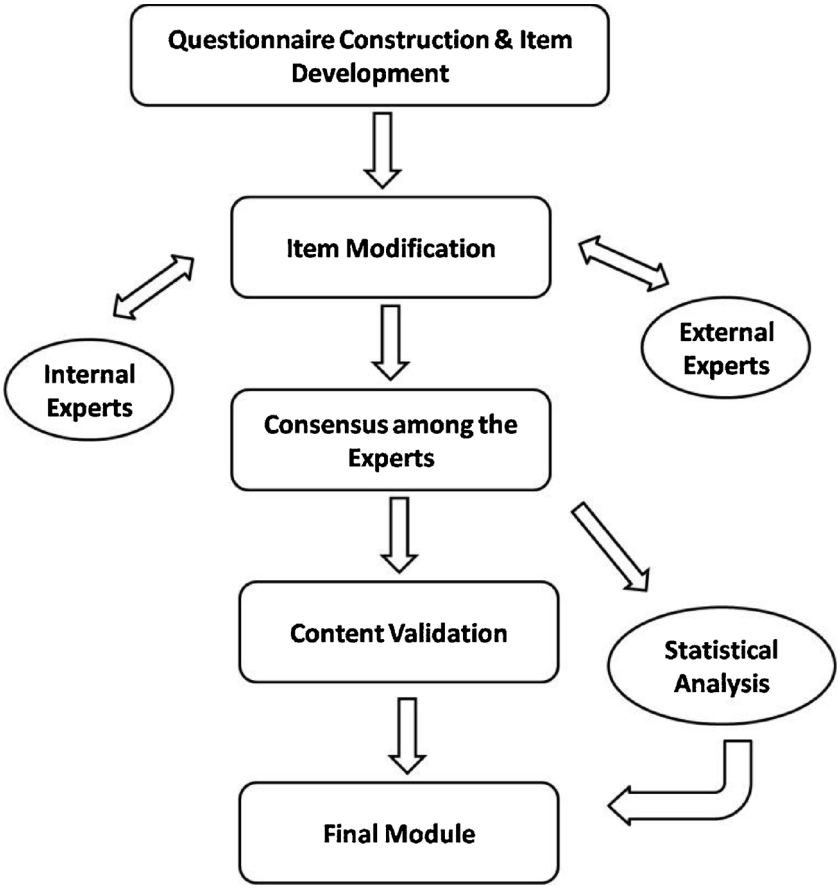

Fig. 1. Sequence of module development.

The American Heart Association and the American Association of Cardiovascular and Pulmonary Rehabilitation recommend a specific exercise program with details on the mode, intensity, duration, frequency and, the progression of exercises. Aerobic exercises are recommended for 20–60 min at an intensity between 50–80% heart rate for 3–5 days a week along with warm-up, cool-down and flexibility exercises included in each session.[7] Several studies have demonstrated improvements in the quality of life and functional capacity with exercise training.[8,9] Ornish et al have focused on lifestyle change programs incorporating daily stress management sessions besides

3-hour exercises per week and still reported a beneficial effect on patients with coronary artery disease. Stress management sessions included gentle yoga poses, breathing exercises, progressive muscle relaxation, meditation and guided imagery.[10,11]

1.2. Yoga as a therapy

Yoga is one of the practical adjuncts to improve the physiological and psychological functions of the heart. It reduces cardiac risk factors, improves the self-efficacy of the patients making them adhere to a healthy lifestyle on a long-term basis.[12–14] Contrary to the conventional exercises, yoga aims at minimizing the oxygen demand by inducing maximal relaxation. This helps to restore the resilience and contractility of the myocardium.[15] Ventricular wall tension is based on the thickness of the ventricular myocardium. The law of Laplace states that ventricular wall tension is proportional to ventricular radius and intraventricular pressure. Patients with coronary artery disease will have decreased blood and oxygen supply to the myocardium demonstrating reduced contractility and increase in the end systolic volume. The excess blood remaining in the ventricle will cause expansion of the ventricular radius and intraventricular pressure resulting in a higher wall tension.[16] With the practice of yoga, the deep internal awareness and rest of the myocardium helps relax the coronary smooth muscles and improves the perfusion of the myocardium.[15,17] Practices applied at the body level is aimed at offering awareness of the 'Prana', create awareness of the working heart and attempt to reduce the heart rate. 'Prana' in Indian philosophy, refers to all forms of energy in the universe. Breath is a dynamic bridge between the body and mind. Pranayama helps in bringing conscious awareness to breathing and the reshaping of breathing habits and patterns.[18] Pranayama is known to reduce the heart rate and rate pressure product implying better autonomic control, reduced oxygen consumption and rest to the heart.[19,20] Meditation is one of the frequently prescribed practices advocated to induce relaxation, but initially, direct control of the mind is not an easy task because of the randomness. According to Nagarathana et al breathing and mind coordination help track the mind into slowness and silence, whereas safe, and least exerting stretches create conscious awareness followed by deep local rest.[15]

Previously, researchers have worked on yoga-based protocols in cardiac patients and have incorporated them in their studies. Yeung et al published a 'Vinyasa Style' yoga protocol for the purpose of cardiac rehabilitation.[12] Krishna et al have published a yoga therapy schedule which they followed in their study on heart failure patients.[21] There was sufficient evidence to substantiate the addition of MSRT(Mind Sound Resonance Technique), a sound based meditation, in a randomized control trial (RCT) involving cardiac patients by Nagarathna et al [15,22] Yoga models described by earlier writers have offered their own rationale behind the choice of yoga practices. Nevertheless, there is no mention whether these programs have been supported by other specialists in the field other than the researcher themselves.

The Integrated Approach of Yoga Therapy (IAYT) intervention integrates the practices at physical (*kriyas, āsanas, prāṇayama*), mental

QUESTIONNAIRE FOR FACE AND CONTENT VALIDITY

Needs in the questionnaire cover the 5 domains in HF (Exercise capacity, Anxiety, Depression, life style change, Cardiac risk factor).

Please mark the appropriate number to each component in the following grid, according to the need Heart failure.

0 Not Applicable	1 Very Harmful	2 Harmful	3 Neutral	4 Helpful	5 Very Helpful

PRACTICE	Duration In Min	Need 1 Improve exercise capacity	Need 2 Reduce edema and breathlessness	Need 3 Reduce anxiety and depression	Need 4 Improve sleep Quality	Need 5 Improve QOL
BREATHING PRACTICES						
Prasārita hasta śvāsa (Hands in & out breathing)						
Utkaśita hasta śvāsa (Hands stretch breathing)						
Vyāgra śvāsa (Tiger breathing)						
Ankle stretch breathing						
Straight leg raising breathing						
Setubhandāsana breathing (Bridge posture breathing)						
Bhujaṅgāsana breathing (Serpent posture breathing)						
QUICK RELAXATION TECHNIQUE						
ASANAS						
STANDING ASANAS						
Tādāsana (Mountain pose or Tree pose)						
Trikoṇāsana (Triangle pose)						
Ardhakaṭi cakrāsana (Half waist wheel pose)						
Vṛkṣāsana (Tree pose)						
SITTING ASANAS						
Vakrāsana (Spinal twist with legs straight pose)						
Gomukhāsana (Cow-face pose)						
SUPINE ASANAS						
Śavāsana (Supine relaxation posture)						
PRANAYAMA						
Candranāḍi prāṇāyāma (Left nostril breathing)						
Nāḍiśodhana prāṇāyāma (Alternate nostril breathing)						
Bramari prāṇāyāma (Bee breathing technique)						
DEEP RELAXATIONTECHNIQUE						
MIND SOUND RESONANCE TECHNIQUE (MSRT)						

Fig. 2. Expert validation form.

(meditation), emotional (*bhakti* yoga), and intellectual levels (*Jnana* yoga) that help in reducing the heightened activity at all levels and dwell restfully in *vignana* and *ānandamaya kośas*. By regular practice of yoga, one moves from gross states of awareness to the subtle. The concept of awareness is deepened with each of the yoga practices of IAYT module.[23]

To date, there does not exist a valid yoga module for the cardiac patients based on the IAYT principles. The module presented in the current study is based on scientific methodology and inputs from the subject experts. We proposed the practices that could be incorporated into the present day lifestyle of the patient population simultaneously offering a holistic approach through practices addressing the physical, mental and the intellectual levels of the individual in a compact, one-hour framework. The current work is a non-experimental, descriptive, methodology generation study comprising individuals and a group of experts in the subject area of cardiology and yoga.

2. Aim and objectives

The aim of the study is to collate, curate and construct a suitable yoga module for cardiovascular patients and include it as a re-habilitation module.

The objectives of this study are to

- Develop a yoga module for heart failure patients following myocardial infarction based on the traditional yogic literature and

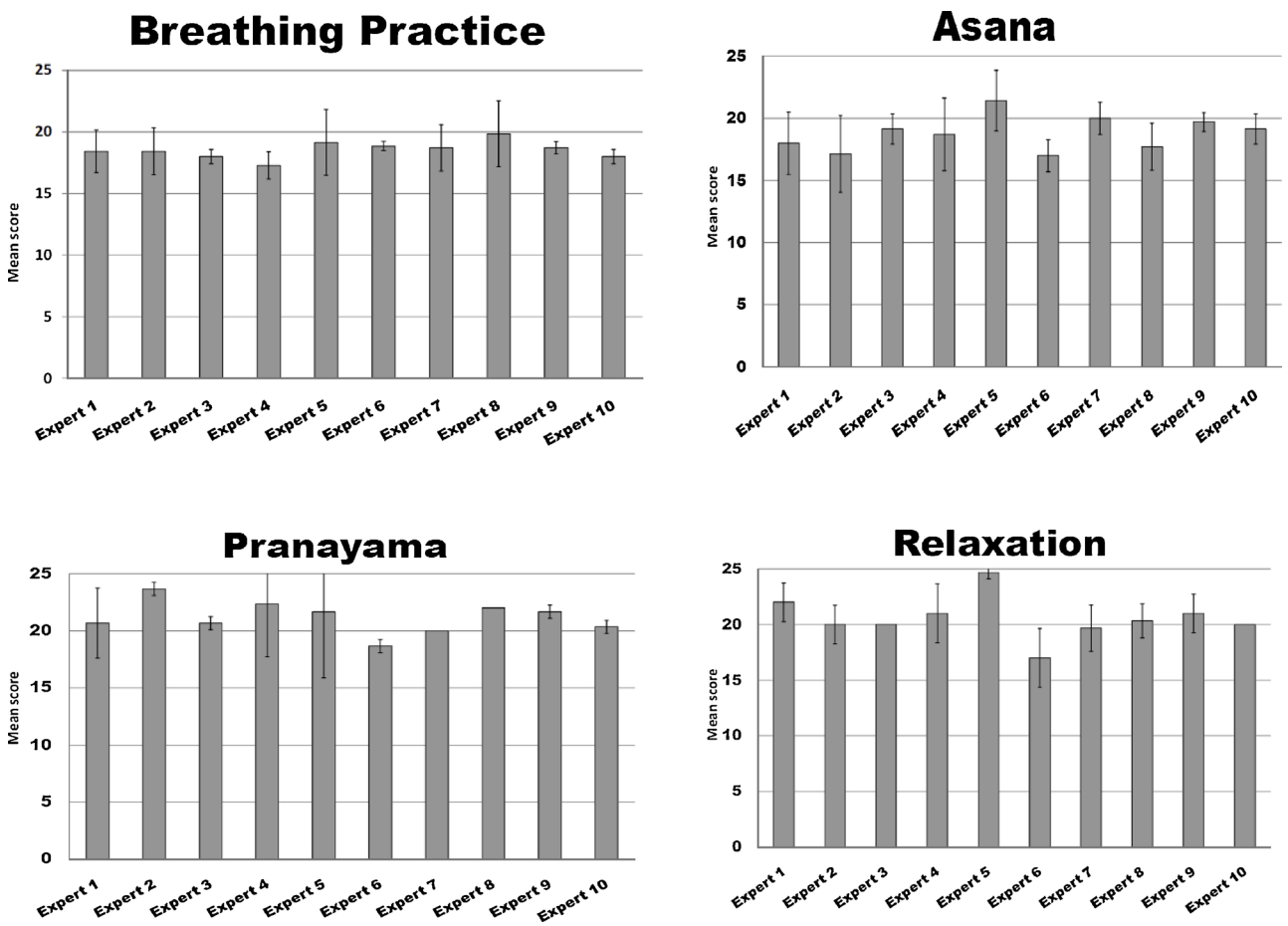

Fig. 3. Expert views on the different components of Yoga Practices included in the module.

literary review;
- Validate the developed yoga module with the help of experts.

3. Methodology

The ontogeny of the yoga program was conducted in two phases. Phase-one involved the development of the content and methodology of the yoga program. Phase-two involved the face validation and content validation of the program. Initially, a yoga program was built up by matching the need of the patients (Fig. 1). The National Health Service (NHS) states that "need" is the capacity to benefit from health care services. It is a qualitative term and is based on practitioners' judgment based on the impact knowledge, rooted in professional training and values, office culture and the assumptive world. In the logical sense, patient "need" means those that may be addressed through the available health care services and those considered medically necessary. It may also be defined as 'what patients and the population as a whole desire to receive from health care services to improve overall health'.[24] Classical texts such as *Patanjali Yogasutra, Rig Veda, Gheranda Samhita, Hatharatnavali and, Hatha Yoga Pradeepika* were reviewed to understand the yoga practices that would help directly or indirectly deal with each of the need. The content validation does not require the sample size to be estimated. Nevertheless, the authors came to a consensus after discussing with the innovators in this subject area that five external experts, as well as five internal experts, be invited for the substantiation operation.[25,26] The institutional review board of SVYASA University provided an exemption for ethics review since this study did not meet the criteria for Human Subject Research.

Internal experts were defined as those who are directly associated with and those who are hired by the university under which this work is being investigated. External experts were individuals who were not immediately affiliated with the university under which this work was conducted.

A few preset criteria were drawn for an individual to be eligible to be an "Expert". The criterion points are: Master Degree or higher qualification in Medicine with dissertation content directed to yoga: 4 points; Master Degree in yoga with dissertation content directed to medicine, preferably cardiology: 4 points; Publication of article in reference journals: 2 points; PhD in the field of yoga in health sciences: 2 points; Clinical experience, at least 5 years in the study area of yoga and/or Cardiology: 1 point. Each criterion described presents a score and to be considered an expert, the person had to obtain a minimum of five points.

A set of proposed yoga practice along with the allocated time duration in minutes was documented. Five patient needs were identified based on the patient symptoms as well as available literature which states that "there is a direct relationship between physical function, anxiety, and depression in patients with coronary artery disease". Physical function, anxiety, and depression in patients with coronary artery disease are directly related. Frustration, depression and reduced self-confidence could be a result of difficulty in performing the previously possible physical activities. The consequences could be a restriction of participation in social activities and disrupted relationship with family and friends.[27] The experts were expected to map each yoga practice to each of the patient needs and assign a score between zero and five on a Likert scale (Fig. 2). The evaluation of the module in accomplishing the objectives of catering to the need of heart failure patients was based on the agreement of the experts on a 5 point Likert scale. Qualitative responses were also obtained from the experts to determine the rightness of the duration of each yoga session and the

SL NO	PRACTICE	DURATION IN MIN
1	**BREATHING PRACTICES**	
	Prasārita hasta śvāsa (Hands in & out breathing)	1
	Utkaśita hasta śvāsa (Hands stretch breathing)	1
	Vyāgra śvāsa (Tiger breathing)	1
	Ankle stretch breathing	1
	Straight leg raising breathing	1
	Setubhandāsana breathing (Bridge posture breathing)	1
	Bhujaṅgāsana breathing (Serpent posture breathing)	1
2	**QUICK RELAXATION TECHNIQUE**	2
3	**ĀSANA (Body posture)**	
	STANDING ĀSANA	
	Tādāsana (Mountain pose or Tree pose)	2
	Trikoṇāsana (Triangle pose)	2
	Ardhakaṭi cakrāsana (Half waist wheel pose)	2
	Ardhacakrāsana (Half wheel pose)	2
	Pādahastāsana (Hand to Foot pose)	2
	SITTING ĀSANA	
	Vakrāsana (Spinal twist with legs straight pose)	2
	SUPINE ĀSANA	
	Śavāsana (Supine relaxation posture)	2
4	**PRĀṆĀYĀMA (Breath regulation)**	
	Candranāḍi prāṇāyāma (Left nostril breathing)	4
	Nāḍiśodhana prāṇāyāma (Alternate nostril breathing)	2
	Bramari prāṇāyāma (Bee breathing technique)	2
5	**DEEP RELAXATIONTECHNIQUE**	10
6	**MIND SOUND RESONANCE TECHNIQUE (MSRT)**	20

Fig. 4. Final Yoga module for cardiovascular health.

whole yoga training program. Experts provided three feedback cycles before reaching a consensus on the contents and methodology of the yoga program, i.e., the researcher made changes to the content based on the comments made by the professionals and went back (iteration) to them for their further inputs on the modified program, three times before all the ten experts agreed on the contents of the model.

Comments from the experts were thoroughly evaluated before constructing the yoga program. The analysis of the responses of the experts in terms of mean, variance and correlation was performed using SPSS.

Table 1
Intraclass Correlation Coefficient. (ICC) for rater reliability from SPSS.

Intraclass Correlation Coefficient							
		95% Confidence Interval		F Test with True Value 0			
	Intraclass Correlation[a]	Lower Bound	Upper Bound	Value	df1	df2	Sig
Single Measures	0.249[b]	0.125	0.454	4.736	19	171	0.000
Average Measures	0.768[c]	0.588	0.893	4.736	19	171	0.000

Two-way mixed effects model where people effects are random and measures effects are fixed.

Table 2
Cronbach's Alpha analysis results from SPSS.

		N	**Mean**	**Variance**	**SD**	
Statistics for Scale		10	19.330	5.221	2.13	
	Mean	**Minimum**	**Maximum**	**Range**	**Max/Min**	**Variance**
Item Means	19.330	17.900	21.150	3.250	1.182	0.668
Item Variances	5.221	1.418	11.187	9.768	7.887	14.549
Inter-Item Correlations	0.292	−0.467	0.985	1.451	−2.110	0.086

Item Total Statistics	Scale Mean If Item Deleted	Scale Variance If Item Deleted	Corrected Item total Correlation	Squared Multiple Correlation	Alpha If Item Deleted
Expert 1	174.1500	133.608	0.673	0.766	0.741
Expert 2	174.3000	129.695	0.583	0.827	0.754
Expert 3	174.2000	120.695	0.732	0.735	0.728
Expert 4	172.1500	131.292	0.490	0.667	0.773
Expert 5	175.4000	177.411	0.010	0.608	0.808
Expert 6	173.8000	173.642	0.094	0.726	0.803
Expert 7	173.8000	153.642	0.338	0.665	0.786
Expert 8	173.4500	153.103	0.752	0.789	0.755
Expert 9	174.2500	160.829	0.588	0.981	0.770
Expert 10	174.2000	158.379	0.636	0.984	0.765
			Alpha		Standardized Item Alpha
Reliability Coefficients for 10 Items			0.789		0.805

N: number of experts; SD: standard deviation.

4. Results

4.1. Recruitment of the experts

We sent twenty-one invitations to qualified professionals including cardiologists, exercise physiologists, ayurvedic physicians, researchers and yoga practitioners, to participate as experts. From the total invited, six did not respond to the invitation, two declined because they did not consider themselves experts on the subject of the research, one did not complete the questionnaire and could not be reached thereafter and two of them, even though willing to participate, could not, because of the time constraints. Thus, the study consisted of 10 experts.

The age of the experts ranged from 28 to 72 years (mean 47.50 years SD ± 14.17). The average experience in their subject area of expertise after formal training was 19.4 years with a range of 3–45 years. Twenty attributes, under 4 yoga methods were analyzed. An expert view was obtained using a questionnaire. The effect of the 20 attributes in a specific sequence (Fig. 2) was qualitatively analyzed and a range of questions from 0 to 5 was provided as data from the experts.

4.2. Development of optimized yoga module based on expert suggestions

We observed that there was a reliability in the experts' views on the 20 different practices conducted under 4 categories (Fig. 2). The experts agreed on the contents of the module and suggested it was appropriate for patients with LVDF following MI. The scores given by each of them against the yoga practice is summarised in (Fig. 3). Qualitative responses were gathered from the experts for adding and/ or removing any content and for the appropriateness of the allotted timings for each practice in the program. Several expert opinions were provided which assisted to develop the module (a) Experts 3 and 6 suggested exclusion of Vrikshaasana (Tree pose) from the module or incorporation of modified postures to avoid any episodes of shock which could be a consequence of any balancing postures. (b) Experts 6 and 9 advised the addition of forward-bending postures like Padahastasana (Hand to Foot pose) complementary to Ardhakatichakrasana (Half-waist wheel pose) to induce alternate stimulation and relaxation. A combination of stimulating and relaxing patterns are known to reduce physiological arousal better.[28] (c) Expert 1 suggested the removal of Gomukhaasana (Cow- Face pose). The module was modified as per the suggestions presented by the experts and the final module is tabulated in Fig. 4. (d) Expert 2 mentioned to add some practices for notional corrections such as, lecture sessions on concepts of body and disease according to yoga, which would assist our patient population, particularly those with type A personalities.[29] (e) Lastly, experts 2 and 9 suggested to include topics on yoga for anger management, smoking cessation, diet and sessions for individual yoga counseling following the intervention. The final module is given in Fig. 4.

4.3. High inter-rater reliability and consistency of yoga module

Two measures were estimated from the experts' questionnaire scores. The intraclass correlation coefficient (ICC) was used to measure the experts' (raters) views across 20 different practices in the yoga

module and the Cronbach's Alpha was used to estimate the internal consistency of the multiple Likert questions in the yoga module. Internal consistency is typically a measure based on the correlations between different questions on the same test. The ICC was computed by average measures, two way mixed effects models with 10 raters across 20 questions. Herein the obtained ICC value is 0.768, its 95% confidence interval ranges between 0.588–0.893. Therefore based on statistical inference, the level of reliability was "good" (Table 1). Secondly, to determine the internal consistency of the 20 questions, we obtained the Cronbach's alpha value of 0.789, indicating good consistency (Table 2).

5. Discussion

Numerous studies and evidence have indicated therapeutic profile of yoga across a wide spectrum of conditions. Successful modules have been developed and validated for depression, cognitive disorders and schizophrenia.[25] Yoga plays an important role in cardiac rehabilitation programs to address number of issues faced in the secondary prevention.[30,31] However there exists a lacuna in the methodological rigor, statistical validation and sufficient reporting to draw firm conclusions as to the efficient and longterm benifits of it.

In this study we optimized a pre-existing traditional text based yoga module for cardiac patients with proper documentation, consultation and statistical validation. The practices are drawn from standard traditional texts and hence are generic to facilitate any yoga instructor to teach the patterns in this module. Our objective was to develop and validate the yoga module with the help of experts. We further documented and performed statistical validation of experts' reports. We observed significant inter-rater reliability and consistency in the yoga module thus developed, indicating good methodological rigor and reliability of the module on cardiac patients.To the best of our knowledge, there is no validated yoga module that has been formulated to be clinically used in India. A time-tested IAYT module has been in practice and is found to be clinically efficacious at the 'Arogyadhama', a health center (SVYASA, Bangalore). However, the module reliability was not statistically validated. The pre-existing module was optimised based on patient needs in addition to the inputs from experts and was statistically tested to confirm the reliability and consistency. Furthermore our revised module can be executed in a short duration and has been customized specifically for cardiac patients, with an effort to blend with the present day lifestyle.

To the best of our knowledge, this is one of the first studies to utilise a methodology of qualitative inquiry model for the development of a need-based yoga program for patients with heart failure in India. Further, we initiated to test the efficacy of this validated yoga program in rehabilitation of post MI patients with heart failure in India in a larger randomized control trial.

The implications of this study are broad and comprehensive. Firstly, compared to the conventional exercises, yoga, besides being effortless, offers minimum risk for the patients [17] Secondly, if incorporated into the rehabilitation program, better prognosis for cardiac patients may be anticipated.[32,33] Thirdly, it helps reduce chronic health-related anxiety and depression.[34]

The limitations of the current study are the fact that there is no direct correlation with heart failure symptoms in traditional yoga texts and that most benefits indicated are purely interpretations. Most of the studies focusing on the physiological responses to various practices of yoga have been demonstrated on the healthy participants and similar effects are assumed in the patient population.

The module, if demonstrated to be effective by clinical studies, may add a safe and well-accepted therapeutic option in the rehabilitation of patients with heart failure following MI, which can further be applied in the hospitals and at the community level.

Declarations of interest

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