4.0 AIMS AND OBJECTIVES

4.1 AIMS OF THE STUDY

Study 1: The aim of the study was to compile and validate a Yoga model for cardiovascular health with the help of experts.

Study 2: The aim of the study was to evaluate the efficacy of Integrated Approach of Yoga Therapy (IAYT) based rehabilitation program adjunct to conventional pharmacological management in the improvement of cardiac function, quality of life, serum lipid levels and reduce anxiety and depression in patients with left ventricular dysfunction secondary to coronary artery disease.

4.2 OBJECTIVES OF THE STUDY

The objectives of this study were

- ✓ to compile and perform expert validation of a yoga module useful for patients under cardiac rehabilitation.
- ✓ to evaluate the efficacy of Yoga therapy on cardiac function in patients with LVDF.
- ✓ to assess the effectiveness of Yoga therapy in reducing anxiety and depression of the patients with LVDF.
- ✓ to evaluate the efficacy of Yoga therapy in improving the quality of life of patients with LVDF.
- ✓ to evaluate the efficacy of yoga therapy in normalizing serum lipid levels in patients with LVDF.

4.3 JUSTIFICATION OF THE STUDY

Translation of research findings into clinical practice, even in primary care needs to overcome a number of barriers. It has been agreed that multifaceted approach would be ideal

to implement the recommendations for the management of heart disease effectively at the primary level (Hickling, Nazareth, & Rogers, 2001). The safety and clinical efficacy of pharmacological and device based therapies have been well established, but the translation of the same in the real world population is still not clear. Within 30 days following discharge from the hospital, one in four cardiac failure patients are readmitted and between 60 to 90 days, 30 to 40 % of them are either readmitted or are diseased (Atherton, 2012).

An effective heart care program should ideally involve a multidisciplinary team approach which incorporates discharge planning and development of an individualized health care plan. A variety of strategies could be adapted in order to close the treatment gaps, including reminder systems, timely feedback and alternative modes of care. These programs are known to improve quality of care, decrease the rate of mortality and also reduce the hospitalization cost of high risk patients (Atherton, 2012). There is a misconception among a section of health care professionals and the general public that following MI, limitation of physical activity is inevitable to prevent recurrences (Dinnes, Kleijnen, Leitner, Thompson, & Thompson, 1999).

Following diagnosis of heart disease, cardiac rehabilitation facilitates patients to adapt new life practices. Adherence to the self care practices is vital for the reduction of long term morbidity, for which patient education towards the disease is an essential step. Studies have clearly demonstrated that cardiac rehabilitation programs are able to meet the needs of the patient with a high degree of satisfaction from the patients' side. Supervised rehabilitation help the patient overcome their apprehension towards physical activity which reflects in a confident perusal of their activities of daily living (Tully, Morgan, Burke, & Mcgee, 2010).

It is very clear that cardiac rehabilitation benefits all cardiac patients irrespective of the stage

of the disease, whether it is pre or post MI or it is managed conservatively or surgically and that all patients may be recruited for such programs (Longfellow, 1993). A meta analysis depicted a reduction of 20% of overall mortality and 26%of cardiac mortality with exercise based rehabilitation compared to usual pharmacological therapy. The observed benefits for CHD patients with low Socio Economic Status (SES) is encouraging and indicates the need to broaden accessibility of lifestyle programs through health insurance (Govil, Weidner, Merritt-worden, & Ornish, 2009).

In spite of the documented benefits of cardiac rehabilitation, only a handful of cardiac patients participate in such programs. Out of the eligible patients in America, only 14% to 35% of heart attack survivors and 31% of post CABG patients participate in the cardiac rehabilitation/secondary prevention programs. It has been noted that female patients, those belonging to the ethnic-minority, elderly patients, patients with co-morbidities, poorly motivated patients, those with less medical insurance coverage and patients with a lower socioeconomic status are less likely to participate in such programs with greater distance from cardiac rehabilitation facility, is associated with lower use rate (Kwan & Balady, 2012; Wenger, 2008). Education level, spouse involvement, inadequate information are significant predictors of uptake of program (Dinnes et al., 1999).

A four year follow up study on the adherence of cardiac rehabilitation program and its relation to risk of death and that of MI demonstrated an inverse relation between them, but reported only a meager proportion of the participants, that is 18%, to have completed the total duration of rehabilitation (Kwan & Balady, 2012).

The drop out percentage among the participants of exercise programs in the first three months was around 20-25% and that between 6 to 12 months was 40 to 50% (Dinnes et al.,

1999). Many reasons are being proposed for the poor attendance of cardiac patients in the rehabilitation programs. Compared to the medical management which has evolved over the past 30-40 years, cardiac rehabilitation is still an evolving field which need lots of validation (West, Jones, & Henderson, 2012). Previously the health care planners were not given any clear guidelines as to where the programs are to be conducted and the health care staff themselves were not clear about the benefits and safety of such programs in patient population. One of the surveys showed that over 60% of cardiac rehabilitation centers across England, Wales and Northern Ireland did not cater to a wide spectrum of cardiac patients although majority of them accepted that they were aware of the scientific benefits of these programs in patient population (Dalal, Wingham, Palmer, & Taylor, 2012) .

A study conducted among post MI patients, which was published in 2012 reported reasons for not attending rehabilitation programs as lack of interest (8%), illness (7%), transportation issues (5%), return to work (2%) and holidays (2%) (West et al., 2012). High intensity and poorly organized programs, patients who smoke and patients with more than one MI are major contributors for dropout from exercise programs (Dinnes et al., 1999).

The perception of cardiac rehabilitation would profoundly differ when a cardiac specialist would prescribe it as part of the treatment program rather than a nurse or any other health care professional presents it as an optional life style improver, which is currently the trend in the UK practice (Dalal et al., 2012; Dinnes et al., 1999; Wenger, 2008). Options other than centre based rehabilitation for patients are less available which partly explains the suboptimal uptake of such programs by the patient population. There is a need to design a home- based, facility based rehabilitation and community based group programs monitored by non physician health care providers with proper evidence to support the same as well as to

improve reference to such centers (Dalal et al., 2012; Kwan & Balady, 2012; Wenger, 2008). Telephone, internet-based portals, electronic mail and social media outlets are some of the alternative ways of health care delivery systems, particularly disease management and lifestyle coaching interventions, which may be considered for large majority of eligible patients who are not accessible to the conventional cardiac rehabilitation/ secondary prevention programs (Kwan & Balady, 2012).

Although yoga is being used as a therapeutic intervention in India for centuries and is an integral part of Ayurveda- the Indian system of medicine (Gokal, Shillito, & Maharaj, 2007), historically it is a spiritual discipline. The beneficial effects of yoga practice which is of therapeutic importance is nothing but the positive side effects of yoga (Khalsa, 2004). More recently its therapeutic aspect is being validated, especially in medical conditions such as psycho-pathological, cardiovascular, respiratory, metabolic diseases etc. Under the broad umbrella of mind body medicine, yoga therapy is being recognized worldwide as an alternative approach to many health related issues (Khalsa, 2004).

A bibliometric analysis of the published research studies in yoga reported that psychological, cardiovascular and respiratory conditions are the most explored areas through yoga research and the disorders that received maximum attention were asthma, hypertension, diabetes, depression, heart disease and anxiety. These disorders are a long term consequence of stress. Yoga being an effective intervention to counteract stress and autonomic arousal, it is likely that the researchers have chosen the above mentioned areas to assess the efficacy of yoga. Secondly, there is usually a socio-political drive to prioritize those conditions with the highest mortality rates among which heart disease, asthma, diabetes and hypertension are the foremost (Khalsa, 2004).

Therapeutic yoga is defined as the application of yoga postures and practices to treat health conditions which includes instruction in yoga practices and teachings in an attempt to prevent/reduce or alleviate structural, psychological, emotional and spiritual pain, suffering or limitation (Woodyard, 2011).

Yoga, which has been practiced for centuries in the Indian subcontinent incorporates an unconventional form of physical exercise. The role of yoga in the modification of cardiovascular risk factors and incorporating the same in the rehabilitation of post MI patients are less explored. There is also a necessity to explore the practicality and suitability of incorporating yoga into the comprehensive cardiac rehabilitation program in an effort to add value and increase the efficacy (Jayasinghe, 2004).

Yoga, in the form of Asana (postures) and Pranayama (breathing exercises) is known to benefit cardiovascular patients during the rehabilitation phase. Even though yoga has a widespread appeal, literatures related to the efficacy of yoga in improving cardiac function in heart failure patients are sparse (Hari Krishna et al., 2014).

Harikrishna et al, incorporated yoga therapy along with standard pharmacological therapy in their study on heart failure patients which resulted in improvements of cardiac function which was evident in LVEF and Tei index as well as a reduction in the myocardial stress which was measured by NT pro BNP. The authors concluded that moderate physical activity in the form yoga, including asana, pranayama and meditation would benefit patients with heart failure. The study was limited by the fact that heart failure due to specific etiology was not assessed (Hari Krishna et al., 2014).

The present study attempts to assess the effectiveness of IAYT, particularly on left ventricular dysfunction secondary to coronary artery disease.

4.4 HYPOTHESIS

Null hypothesis:

Study 1:

There will be no consensus among the experts on yoga practices useful for patients under cardiac rehabilitation.

Study 2:

In comparison to the control group, Yoga group will not show any improvements in cardiac function, psychological parameters and quality of life in patients with LVDF secondary to coronary artery disease.

Alternate hypothesis:

Study 1:

There will be a consensus among the experts on Yoga practices useful for patients under cardiac rehabilitation.

Study 2:

In comparison to control group, Yoga group will show improvements in cardiac function, psychological parameters and quality of life in patients with LVDF secondary to coronary artery disease.

5.0 METHODS

Methodology for the development of the IAYT model.

The ontogeny of the yoga program was conducted in two phases (Fig. 25). 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 needs of the patients. 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 needs.

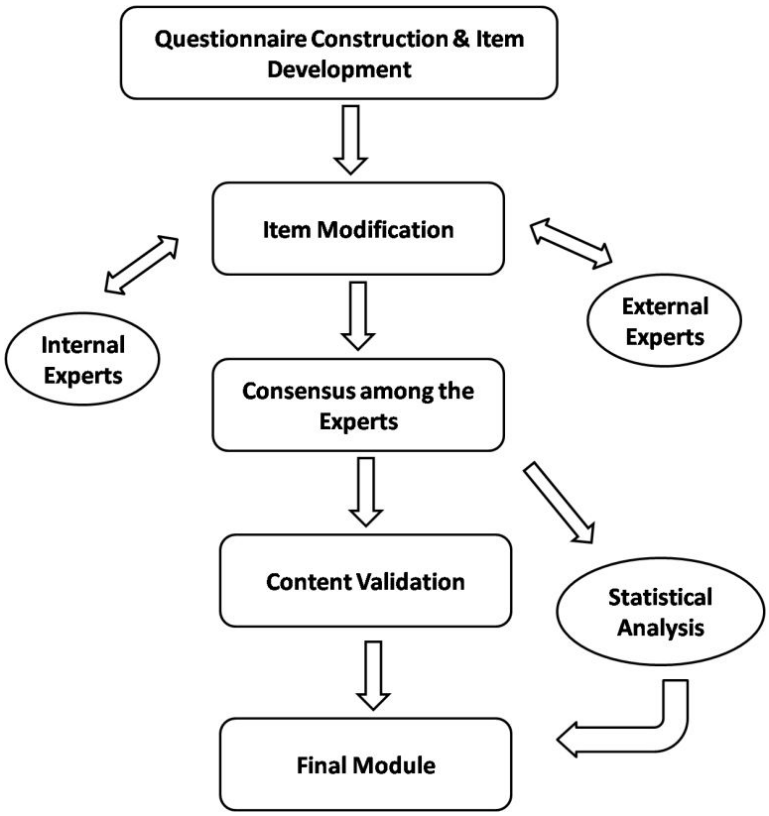

Figure 25 Sequence of module development.

The conceptual basis of IAYT for cardiac disease.

According to the World Health Organization (WHO) the state of health is defined as a state of complete physical, mental, social and spiritual well being and not merely an absence of disease or infirmity. It is clear from this definition that health and ill-health are not two discrete entities as commonly understood, but health should be conceived as a continuous function indicating the state of well being.

The integrated approach of yoga therapy also deals with the state of well being at all aspects of personality. The description of the human being is found under the name of panchakosha

viveka in yoga texts (Raghuram et al., 2001). These are:

1. Annamaya Kosa,
2. Pranamaya Kosa,
3. Manomaya Kosa,
4. Vijnanamaya Kosa and
5. Anandamaya Kosa.

The integrated approach of yoga therapy works on five different levels. Annamaya kosa (AMK), pranamaya kosa (PMK), manomaya kosa (MMK), vijnanamaya kosa (VMK) and anandamaya kosa (ANMK). The tables 1, 2 and 3 summarizes the working of IAYT with respect to the Pancha Koshas.

Sl No	KOSA	PRACTICES	EFFECTS
1.	Annamaya Kosa	Kriyas	a) Activating and revitalizing the organs b) Toning up their functions c) Desensitization d) Development of deep internal awareness.
		Shithilikarana Vyayama	a) Loosen the joints b) Stretch and relax the muscles c) Improve the power d) Develop stamina.

		Asanas	a) physical revitalization, b) deep relaxation and c) mental calmness
2.	Pranamaya Kosa	Kriyas	Development of deep internal awareness Titiksha – stamina building
		Breathing practices	Regulation of breath
		Pranayama	Remove the random agitations in Pranic flows
3.	Manomaya Kosa	Dharana	Culturing of mind accomplished by focusing of the mind
		Dhyana	The relaxed dwelling of the mind in a single thought for longer durations leads to deep rest of the organs
4.	Vijnanamaya Kosa	Lecture & Yogic Counselling	Knowledge burns the strong attachments, obsessions, likes and dislikes which are the basic reasons for the agitations of the mind.
5.	Anandamaya Kosa	Working in blissful awareness	Self-awareness and learn to maintain equipoise (samatva) in all actions.

Table 1. Effect of Integrated Approach of Yoga Therapy on the Pancha Koshas (Raghuram et al., 2001)

The intervention integrates the practices from four levels to lead to the anandamaya kosha which is the seat of all healing.

Practice	Effect	Pancha Kosha mapping

1. Lecture/ counseling	To educate the mind about the disease.	Low health literacy associated with poor self care results in increased mortality in chronic illness like heart failure, especially in the elderly population.
2. Shithilikarna Vyayama	To loosen the body Preparation for the asanas. Done with breath and body awareness.	AMK-Burns calories – helps in weight reduction. PMK- Release of locked up prana MMK- Reduces hyperactivity of the brain.
3. Sun salutation	Exercise of all body parts. Helps achieve target heart rate. (Mody, 2011)	AMK -Teasing out of fat from sub-cutaneous tissue by repeated muscle work outs PMK-Harmonizing effect at prana level
4. Asanas		AMK-Bring balance at prana level
a. Prone	Maintain in final posture effortlessness and expansion	AMK-Reduction of fat at shoulder and buttock level PMK- Balancing the prana

b. Standing		AMK- Reduction of fat at limbs, buttocks and abdominal regions PMK- Opening of *apana*
c. Supine		AMK- Reduction of fat at abdominal region PMK- Dislodges *apana*
d. Sitting		AMK- Reduction of fat at abdominal level PMK- Opening of *apana*
5. Relaxation	Deep progressive relaxation of the body/ mind	AMK, MMK- Stress reduction through alertful rest (reduced sympathetic activity)
6. Pranayama	Slowing down, improve rhythm of breathing	AMK- Stress reduction
a. Chandranuloma viloma	Left uninostril breathing	AMK- brings about a reduction in systolic blood pressure and mean pressure (Ananda Bhavanani Bhavanani, Meena Ramanathan, R Balaji, n.d.).

b. Nadi shuddhi	Balance Surya and Chandra nadis Cleanses and balances prana	PMK- Evidence for parasympathetic dominance, useful for hypertension (Ananda Bhavanani Bhavanani, Meena Ramanathan, R Balaji, 2014).
c. Bhramari	Three dimensional awareness	PMK- Vyana activation MMK- Calm state of mind MMK- Stress reduction
7. Bandha		
Jalandhara bandha	It acts as a stabilizer in yogic breathing exercise (Lepicovská V1, Dostálek C, 1988).	Decreases the vagal reflex
8. Kriya		
a.Kapalabhati	Activate and cleanse lungs, and brain. Decreases cardiac vagal tone (Stancák et al., 1991).	AMK- Vitalizes and releases locks in the pranic body.
b.Mukha Bastrika	Increase in parasympathetic activity and a reduced sympathetic activity and have beneficial effects on cardiac autonomic reactivity (Veerabhadrappa et al., 2011).	

9. Meditation	Stress reduction through alert-ful rest	MMK- Increased mental alertness, even while being physiologically relaxed shown by the reduced heart rate
10. MSRT	Powerful and synchronous increase in existing cardiovascular rhythm along with a significant increase in the baroreflex sensitivity (Bernardi et al., 2001; Raghuram et al., 2014).	Sound meditation

Table 3: The effect of IAYT practices on the Pancha Koshas

The current portion of the work is a non-experimental, descriptive study whose population comprised of experts in the subject area of cardiology and yoga. 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. The institutional review board of SVYASA University provided an exemption for ethics review since this study did not meet criteria for Human Subject Research. Based on this exemption, no informed consent was obtained. Nevertheless, the prospective RCT in which the module is proposed to be tested has cleared the ethics review.

Internal experts mean those who are directly associated with and those who are hired by the

university under which this work is being taken away. External experts are those who are going under various other universities across the nation and those who are not immediately affiliated with the university under which this work is being taken away.

A few preset criteria have been drawn to be stipulated as an expert to participate in the survey. Each criterion described presents a score and to be considered an expert, the person needs to obtain a minimum of five points.

(Criteria/points: Master Degree or higher qualification in Medicine with dissertation content directed to Yoga: 4; Master Degree in Yoga with dissertation content directed to medicine, preferably cardiology: 4; Publication of article in reference journals: 2; PhD in the field of Yoga in health sciences: 2; Clinical experience, at least 5 years in the study area of Yoga and/or Cardiology: 1). The higher the grade, the greater the effectiveness of the field.

A tool of data collection was disposed, which consisted of the proposed yoga practice along with the allotted time duration in minutes. Five patient needs were identified, such as to improve exercise capacity, to reduce edema and breathlessness, to reduce anxiety and depression, to overcome risk factors and to improve the quality of life. 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 where 0= not applicable; 1= very harmful; 2= harmful; 3= neutral; 4= helpful and 5= very helpful. The revaluation of the module was based on the agreement of the experts on a 5 point Likert scale where 1 represented not at all useful and 5 represented extremely useful in accomplishing the objectives of catering to the needs of cardiac patients (Table 4). Qualitative responses were also obtained from the experts to determine the rightness of the duration of each yoga session and the whole yoga training program. To go far at a consensus on the contents and methodology of the yoga program,

three cycles of iteration was conducted among the experts, i.e., the researcher made changes to the content based on the commentaries 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.

QUESTIONNAIRE FOR FACE AN CONTENT VALIDITY					
Needs in the questionnaire cover the 5 domains in HF (Exercise capacity, Anxiety, Depressio style change, Cardiac risk factor).					
Please mark the appropriate number to each component in the following grid, according to the needs of Heart failure.					
0	**1**	**2**	**3**	**4**	**5**
Not Applicable	**Very Harmful**	**Harmful**	**Neutral**	**Helpful**	**Very Helpful**

SL NO	PRACTICE	Duration In Min	Need 1 Improve exercise capacity	Need 2 Reduce edema and breathlessness	Need 3 Reduce anxiety and depression	Need 4 Helps to overcome risk factors	Need 5 Improve QOL
1	**BREATHING PRACTICES**						
	Prasarita hasta swasah (Hands in & out breathing)	1					
	Utkashita hasta swasah (Hands stretch breathing)	1					

	Vyaghra swasah (Tiger breathing)	1
	Ankle stretch breathing	1
	Straight leg raising breathing	1
	Sethubandhasana breathing	1
	Bhujangasana breathing (Serpent posture breathing)	1
2	**QUICK RELAXATION TECHNIQUE**	2
3	**ASANAS**	
	STANDING ASANAS	
	Tadasana	2
	Trikonasana (Triangle posture)	2
	Ardhakatichakrasana (Lateral half wheel posture)	2
	Vrikshasana (Tree posture)	2
	SITTING ASANAS	
	Vakrasana (Spinal twist with leg straight)	2
	Gomukhasana	2
	SUPINE ASANAS	
	Shavasana (Supine relaxation posture)	2
4	**PRANAYAMA**	
	Chandra nadi pranayama	4
	Nadishodha pranayama	2

	Brahmari pranayama	2
5	**DEEP RELAXATIONTECHNIQUE**	10
6	**MIND SOUND RESONANCE TECHNIQUE (MSRT)**	30

Please go through the yoga program and circle/fill in the appropriate responses.				
1. Is the program content developed in keeping with the aim of the study?				
1	2	3	4	5
Not at all	A Little	Moderately	Very Much	Extremely

2. Do you think overall the yoga program will achieve its objective of correcting the problem in HF patients?				
1	2	3	4	5
Not at all	A Little	Moderately	Very Much	Extremely

3. Suggestions for Adding/ Deleting any content from the program

4. Comments Signature and details of the Validation Expert
Signature Full name email id Mobile phone number

Designation Address

Table 4. Questionnaire for face and content validity

Descriptive analysis of the quantitative (Likert ratings) feedback and content analysis of the qualitative feedback received from the experts was conducted. Each and every comment was given importance and the researcher tried to accommodate all of it into the yoga program. The analysis of the responses of the experts in terms of mean, variance and correlation was performed using SPSS.

FINDINGS

Recruitment of the Experts

We sent twenty-one invitations to qualified professionals so that they could 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 sample consisted of 10 experts.

The age of the experts ranged from 28–72 years (mean 47.50 years SD ± 14.175). 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 was qualitatively analyzed and a range of questions from 0-5 was provided as data from the experts.

Expert views on the Module practices

We observed that there was a reliability in the experts' views on the 20 different practices conducted under 4 categories (Figure 26). 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 summarized in figure 9. 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 (Balaji, Varne, & Ali, 2012) (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 Figure 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 (Raghuram, Deshpande, & Nagendra, 2009). (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.

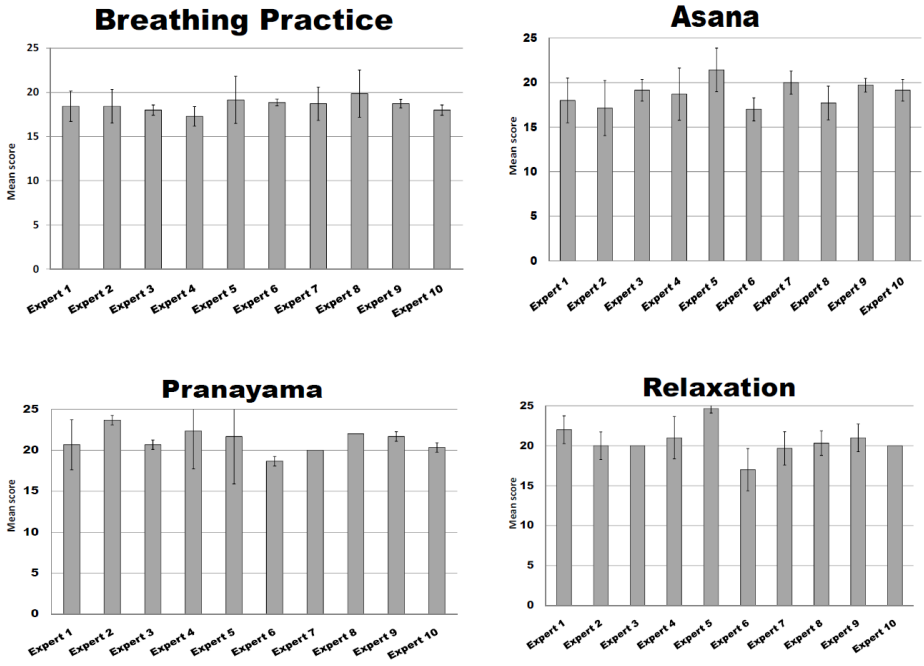

Figure 26: Experts' views on the 20 different practices conducted under 4 categories

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. Here in 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 5).

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	.249[b]	.125	.454	4.736	19	171	.000
Average Measures	.768[c]	.588	.893	4.736	19	171	.000
Two-way mixed effects model where people effects are random and measures effects are fixed.							

Table 5. Intraclass Correlation Coefficient. (ICC) for rater reliability from SPSS

Secondly, to determine the internal consistency of the 20 questions, we obtained the Cronbach's alpha value of 0.789, indicating good consistency (Table 6).

		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	.668
Item Variances	5.221	1.418	11.187	9.768	7.887	14.549
Inter-Item Correlations	.292	-.467	.985	1.451	-2.110	.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	.673	.766	.741	
Expert 2	174.3000	129.695	.583	.827	.754	
Expert 3	174.2000	120.695	.732	.735	.728	
Expert 4	172.1500	131.292	.490	.667	.773	
Expert 5	175.4000	177.411	.010	.608	.808	
Expert 6	173.8000	173.642	.094	.726	.803	
Expert 7	173.8000	153.642	.338	.665	.786	

Expert 8	173.4500	153.103	.752	.789	.755
Expert 9	174.2500	160.829	.588	.981	.770
Expert 10	174.2000	158.379	.636	.984	.765
			Alpha	Standardized Item Alpha	
Reliability Coefficients for 10 Items			.789	.805	

N: number of experts; SD: standard deviation

Table 6. Cronbach's Alpha analysis results from SPSS

Module content was fit for betterment cardiac patients

Furthermore, in an attempt to reevaluate the overall module, the experts were asked questions like " Is the module content developed in keeping with the aim of the study?" and "Do you think that the overall yoga program will achieve its objective of correcting the problem in heart failure patients?". The experts were expected to give a score between 1 and 5, where 1= not at all and 5= extremely. The mean and SD of the scores given by the ten experts was 4.2±0.42 and 3.9±0.31 respectively. We further used the Goodness of Fit Chi Square test to analyze these observations. We hypothesized that there would be no significant difference between the observed and the expected values. For both the questions, there was no significant difference between the observed and expected values, indicating that the set of questions put forth in the module was keeping with the aim of the study and the module constructed was favorable in addressing the symptoms of HF in patients. The final module is given in appendix-1.

DELEBRATION

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 (Bhat, Varambally, Karmani, Govindaraj, & Gangadhar, 2016). Yoga plays an important role in cardiac rehabilitation programs to address number of issues faced in the secondary prevention (Amaravathi, Ramarao, Raghuram, & Pradhan, 2018; Yeung, Chang, & Bensoussan, 2015). However there exists a lacuna in the methodological rigor, statistical validation and sufficient reporting to draw firm conclusions as to the efficient and long-term benefits 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 optimized 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 utilize a methodology of qualitative inquiry model for the development of a need-based yoga program for cardiac

patients in India. Further, we initiated to test the efficacy of this validated yoga program in rehabilitation of post MI patients with left ventricular dysfunction 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 (Mehta, Mehta, & Pai, 2017). Secondly, if incorporated into the rehabilitation program, better prognosis for cardiac patients may be anticipated (Longfellow, 1993; Pischke, Scherwitz, Weidner, & Ornish, 2008). Thirdly, it helps reduce chronic health-related anxiety and depression (Gard, Noggle, Park, Vago, & Wilson, 2014).

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 cardiac patients following MI, which can further be applied in the hospitals and at the community level.

The yoga module thus developed was incorporated into the cardiac rehabilitation program of the patients suffering from left ventricular dysfunction following acute MI in a randomized control trial, the methodology of which is described in the following section.

5.0 METHODS

5.1 PARTICIPANTS

5.1.1 SAMPLE SIZE