**Original Article** 



Effects of yoga versus hydrotherapy training on health-related quality of life and exercise capacity in patients with heart failure: A randomized controlled study

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#### Abstract

Aims: The aims of this study were to determine whether yoga and hydrotherapy training had an equal effect on the health-related quality of life in patients with heart failure and to compare the effects on exercise capacity, clinical outcomes, and symptoms of anxiety and depression between and within the two groups.

Methods: The design was a randomized controlled non-inferiority study. A total of 40 patients, 30% women (mean±SD age 64.9±8.9 years) with heart failure were randomized to an intervention of 12 weeks, either performing yoga or training with hydrotherapy for 45-60 minutes twice a week. Evaluation at baseline and after 12 weeks included self-reported healthrelated quality of life, a six-minute walk test, a sit-to-stand test, clinical variables, and symptoms of anxiety and depression.

**Results:** Yoga and hydrotherapy had an equal impact on quality of life, exercise capacity, clinical outcomes, and symptoms of anxiety and depression. Within both groups, exercise capacity significantly improved (hydrotherapy p=0.02; yoga p=0.008) and symptoms of anxiety decreased (hydrotherapy p=0.03; yoga p=0.01). Patients in the yoga group significantly improved their health as rated by EQ-VAS (p=0.004) and disease-specific quality of life in the domains symptom frequency (p=0.03), self-efficacy (p=0.01), clinical summary as a combined measure of symptoms and social factors (p=0.05), and overall summary score (p=0.04). Symptoms of depression were decreased in this group (p=0.005). In the hydrotherapy group, lower limb muscle strength improved significantly (p=0.01).

**Conclusions:** Yoga may be an alternative or complementary option to established forms of exercise training such as hydrotherapy for improvement in health-related quality of life and may decrease depressive symptoms in patients with heart failure.

#### **Keywords**

Anxiety, depression, exercise training, health-related quality of life, heart failure

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## Introduction

Heart failure (HF) has a significant impact on exercise tolerance, health-related quality of life (HRQoL), symptoms of anxiety and depression,1 the use of health services and survival.<sup>2</sup> Exercise training is strongly recommended to all patients with stable chronic HF as it has been found to improve their HRQoL and exercise capacity and decrease deterioration leading to hospitalization.<sup>3,4</sup> Three different types of exercise are generally <sup>1</sup>Department of Cardiology, Karolinska Institutet, Karolinska University Hospital Huddinge, Sweden

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prescribed for patients with HF: aerobic endurance (continuous and interval); strength/resistance training; and training of the respiratory muscles.<sup>5</sup> Hydrotherapy has shown improvements for patients with HF in HRQoL, exercise capacity, muscle function and cardiac function, such as a decreased heart rate, leading to an increase in systolic volume and left ventricular ejection fraction.<sup>6,7</sup> It is now implemented as an alternative to physical exercise training in standard care for patients with HF.

Yoga has become popular as a form of exercise in Western society. In addition to physical activity, yoga also involves controlled respiration, relaxation and meditation. A reduced breathing rate can increase vagal activation and decrease the influence of the sympathetic branch of the autonomous nervous system, measured by an increase in baroreflex sensitivity and heart rate variability. A shift to increased vagal influence may reduce blood pressure and heart rate. Afterload reduction may lead to an increased systolic stroke volume and improved left ventricular ejection fraction. Controlled breathing has also been shown to have positive effects on stress, anxiety and depression.<sup>8-11</sup> However, the use of yoga in patients with HF has only been investigated in a few small randomized trials<sup>10-13</sup> and none of them has compared yoga with other evidencebased training interventions such as hydrotherapy. Compared with yoga, hydrotherapy focuses more on the performance of skeletal muscle and less on controlled respiration and mental exercise.

There are many difficulties initiating and maintaining exercise training in patients with HF. Although patients are well aware of the importance of exercise, common barriers are physical symptoms and lack of energy.<sup>14,15</sup> In patients with HF, adherence to exercise training beyond six months is low.<sup>16,17</sup> Therefore there is an increasing interest in alternative models of physical and mental conditioning for these patients to improve their HRQoL. Although yoga has demonstrated improvements in exercise capacity and psychological well-being in earlier studies,<sup>10–13</sup> there is a further need to evaluate its effects compared with other training models. This study compared yoga with hydrotherapy based on the hypothesis that yoga would be a feasible and equally effective alternative form of physical training for patients with stable HF. The primary endpoint was therefore to determine whether yoga had an equal effect on HRQoL compared with hydrotherapy training. We wanted to compare the effects on exercise capacity, clinical outcomes, and symptoms of anxiety and depression between and within the two groups as secondary endpoints.

## Methods

## Design and setting

The study was a prospective, randomized controlled pilot study with a 12 week follow up period. Patients were recruited from the outpatient HF clinic at the Department of Cardiology at Karolinska University Hospital, Huddinge, Sweden. The study complied with the Declaration of Helsinki and the regional ethics committee in Stockholm, Sweden approved the research protocol (Dnr 2010/1452-31/4).

#### Sample

The recruitment period was between February 2011 and January 2012. A flow chart of the inclusion is shown in Figure 1. To be included in the study, the participants had to be between 18 and 80 years of age and diagnosed according to the European Society of Cardiology guidelines<sup>1</sup> with HFrEF and/or HFpEF of both ischaemic and non-ischaemic aetiology with New York Heart Association class I-III, measured at randomization, prior to enrolment. Patients should have been stable in their HF and on optimum doses of medical treatment for at least one month before enrolment. Participants were excluded if they had been diagnosed with dementia, other serious conditions with a life expectancy of less than six months or scheduled for heart transplantation. Adults who were unable to understand verbal instructions were excluded. The upper age limit of 80 years was chosen to recruit patients who had the expected ability to perform the study. Patients who had addictions to alcohol or drugs, were incontinent, had wounds or were allergic to chlorine were also excluded. No sample size calculation was made prior to the study because this was a pilot study.

## Yoga group

A 60 minute yoga session was conducted twice a week for 12 weeks in a silent room at the hospital. Patients sat on chairs to perform the yoga. Two different Mediyoga CDs entitled start 1 and 3, together with a handout on how to perform yoga postures, were given to the patients at their first appointment. In addition to the biweekly sessions at the hospital, participants in the yoga group were asked to perform yoga daily at home. The two different programmes, 1 and 3 (the same as on the CDs), were repeated every two weeks during the 12 week period.

During each session, the participants completed the following: a 10 minute warm-up phase including breathing exercises, a 40 minute period of seated yoga postures and a 10 minute relaxation/meditation phase. Yoga sessions were conducted by a certified instructor. The breathing exercises consisted of slow, deep inhalation and exhalation through the nasal passageways without breath retention. Inhalations were initially taught with sequential involvement of the abdomen, lower chest and then upper chest, with the same sequence in reverse during exhalation. There were also other breathing exercises with different tempos. The yoga postures consisted of a combination of forward, backward and sideward bends, twists and balance poses, individually modified according to medical or orthopaedic

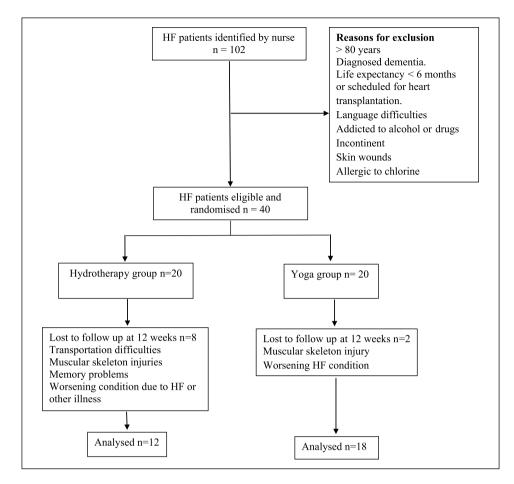


Figure 1. Consort flowchart of inclusion of patients with heart failure (HF) from identification to 12 weeks follow up.

limitations if needed. Meditation and relaxation were performed in a seated position according to the patient's comfort level.

## Hydrotherapy group

A 45 minute hydrotherapy session was conducted twice a week for 12 weeks in a heated therapy pool at the hospital. The water temperature was  $31-32^{\circ}$ C. Patients were able to stand in the water. Each session consisted of endurance training in a standing, sitting or lying position. Training a single muscle group at a time, the exercises involved the arms, shoulders, back, stomach, seat and leg muscles with the water as resistance. The exercise regime was designed to include muscles used in daily living, such as walking, dressing and household activities. The patients were encouraged to work as hard as they could with a single muscle group at a time with the limitation of a central exercise level of 11-13 on the Borg RPE-20 scale. The separate exercises were conducted with  $2 \times 15$  repetitions per muscle group, with every other set conducted on the right and left side.<sup>6,7,18</sup>

The hydrotherapy sessions were conducted by a certified physical therapist. Patients were asked to complement the hydrotherapy with a daily exercise programme consisting of easy exercise movements using the patient's own weight – for example, push-ups against a wall, bending the knees (squats), rising up and down a chair, and bicep and tricep exercises with a rubber band. This was supplemented by daily walks. The patients were asked to carry out the exercise programme and a walk on the days they did not take part in hydrotherapy at the hospital.

#### Procedures

Patients were enrolled in the study when they were stable and had received optimum medical treatment, HF education and verbal self-care instructions according to guidelines.<sup>1,19,20</sup> The recruited patients represented around 30% of patients admitted to our hospital for HF during this time period. After receiving written information about the study and signed consent, baseline measurements were obtained. Patients were then randomized using a computer-generated list of random numbers to either a supervised yoga group (n=20) or a supervised hydrotherapy group (n=20). The randomization was administered by a person not involved in the study. All patients were allowed maintain other regular daily activities or exercise training, but were prompted not to start any new exercise training during the intervention period. As a result of the nature of the intervention, the study could not be blinded.

#### Data collection

Data were collected at baseline and after 12 weeks with four different questionnaires regarding HRQoL and symptoms of anxiety and depression, together with clinical parameters including systolic and diastolic blood pressure in the right arm, resting heart rate, exercise capacity measured by six-minute walk test (6MWT),<sup>21</sup> functional lower limb muscle strength measured by the sit-to-stand test (STST)<sup>22</sup> and a peripheral oxygen saturation test using equipment from Nellcor OxiMax N-65P. Venous blood samples were collected for analysis of NT-pro BNP, sensitive C reactive protein, creatinine and haemoglobin; these were analysed at the local hospital laboratory.

The Kansas City Cardiomyopathy Questionnaire (KCCQ) was used to measure HRQoL. The KCCQ is a 23-item, self-administrated, disease-specific instrument that quantifies six domains and two summary scores of patients' health status. The six domains are physical limitations, total symptom score, symptom change, self-efficacy, social interference and quality of life. The two summary scores are labelled as clinical summary scores and overall summary scores. The items in the KCCQ have between five and seven response alternatives. All scale scores are transformed to a 0-100 scale, with a higher score indicating a better HRQoL.<sup>23</sup>

EuroQol is a generic instrument of general health outcome consisting of two different parts: the five descriptive dimensions (EQ-5D) and the Visual Analogue Scale (EQ-VAS). EQ-5D includes five dimensions (mobility, self-care, daily activities, pain/discomfort, anxiety and depression), with responses recorded as three levels of severity (no problems/some problems, moderate problems or moderate problems/extreme problems). The alternative answers in each of the scales are graded and given an index according to a particular set of weights, where 1.0 represents full health and -0.59 represents the lowest possible index. EQ-VAS evaluates self-rated health on a vertical, visual analogue scale where the endpoints are labelled as best imaginable health state (100) and worst imaginable health state (0).<sup>24</sup>

The Patient Health Questionnaire depression module (PHQ-9) is a brief self-rating scale for screening major depressive disorder and measuring the current level of symptoms of depression. The sum of the score can be used as a measure of current symptom level to assess depression depth and to follow a progression over time. Each of the nine items is scored from 0 (not at all) to 3 (nearly every day).<sup>25</sup>

The Hospital Anxiety and Depression Scale (HADS) was also used. The HADS consists of 14 items (response scale 0–3), divided into two subscales of seven items each, measuring anxiety and depression. In both instruments, a

higher score indicates more symptoms of anxiety and depression.<sup>26</sup>

All the instruments have been tested and validated in Swedish and used in populations with HF.

## Statistical analyses

Baseline characteristics are presented by descriptive statistics. Descriptive statistics are expressed as means and standard deviations for continuous variables. Categorical variables are presented as frequencies. Univariate statistics on differences between baseline variables were calculated by the  $\chi^2$ test, the Mann–Whitney test or Student's *t*-test. Differences between the hydrotherapy and yoga group were analysed using Student's *t*-test for independent samples. Within-group analysis were performed using a paired *t*-test. *p*<0.05 was considered statistically significant for all analyses. PASW statistics version 18 (IBM Corporation, New York, NY, USA) was used to perform the statistical analyses.

## Results

A total of 40 patients were randomized in the study and 30 patients, 12 in the hydrotherapy group and 18 in the yoga group, were included in the final analysis. Two patients in the yoga group did not complete all the planned sessions due to family issues and long travel distance to the hospital. Eight patients in the hydrotherapy group interrupted their training, seven due to muscular skeletal symptoms and one due to cognitive decline. We did not find any correlate of retention in the study.

As shown in Table 1, there was no difference between the patients in the yoga and hydrotherapy groups regarding sociodemographic and clinical variables at baseline, except for the number of prescribed drugs and mean creatinine values. There was no difference between the groups when comparing the number of patients above the reference value for renal insufficiency. With regard to medication, it could be interpreted that the control group was sicker; however, another explanation could be that they were more optimally treated.

No significant difference was found between the groups in patient-reported or clinical outcome at baseline. Yoga and hydrotherapy had an equal impact on quality of life, exercise capacity, clinical outcomes, symptoms of anxiety and depression after 12 weeks. Table 2 includes comparisons between the yoga and hydrotherapy groups regarding patient-reported outcomes on HRQoL, exercise capacity and symptoms of depression during 12 weeks follow up. Comparisons between the yoga and hydrotherapy groups regarding clinical and physiological variables after 12 weeks follow up are shown in Table 3.

Within-group comparisons (Tables 2 and 3) showed that in both groups exercise capacity measured by the 6MWT significantly improved (hydrotherapy p=0.02;

	Yoga group ( <i>n</i> =20)	Hydrotherapy group ( <i>n</i> =20)	Þ
Age (years)	64.1 ± 9.4	65.7 ± 8.5	ns
Female sex	5	9	ns
Drugs			
ACE inhibitors	18	18	ns
β Blockers	19	20	ns
Diuretics	15	19	ns
Statins	7	10	ns
Aldosteron antagonists	5	7	ns
Wafarin	7	9	ns
Total number of drugs	3.6 ± 0.89	4.2 ± 0.67	0.02
Co-morbidities			
Myocardial infarction	7	8	ns
, Ischaemic heart disease	4	4	ns
Atrial fibrillation	8	8	ns
Diabetes	3	3	ns
Stroke	1	I	ns
Hypertension	6	4	ns
COPD	0	0	ns
Cancer	1	I	ns
Total co-morbidities	1.5 ± 0.9	1.5 ± 1.3	ns
Lab test			
Creatinine	82.3 ± 19.5	110.2 ± 47.2	0.02
Haemoglobin	136.5 ± 17.4	134.0 ± 14.5	ns
NT-ProBNP	1408 ± 1419	1589 ± 1703	ns
Devices			
Pacemaker	2	2	ns
CRT	2	4	ns
ICD	3	7	ns
ΝΥΗΑ			
1	5	7	ns
II	8	6	ns
111	7	7	ns

**Table I.** Demographic and medical variables of the patients with heart failure (HF) at baseline randomized to the yoga and hydrotherapy groups (N=40).

Data presented as number of patients or mean±SD values.

ACE: angiotensin-converting enzyme; COPD: chronic obstructive pulmonary disease; CRT: cardiac resynchronization therapy; ICD: implantable cardioverter defibrillator; NYHA: New York Heart Association Classification; ns: non-significant; SD: standard deviation.

yoga p=0.008) and symptoms of anxiety decreased (hydrotherapy p=0.03; yoga p=0.01). Patients in the yoga group significantly improved their health measured by EQ-VAS (p=0.004) and their disease-specific HRQoL in the following domains of KCCQ; symptom frequency (p=0.03), selfefficacy (p=0.01), clinical summary score as a combined measure of symptoms and social factors (p=0.05), and the total overall summary score for the whole instrument (p=0.04) and decreased their symptoms of depression according to PHQ-9 (p=0.005). In the hydrotherapy group leg strength improved significantly (p=0.01).

## Discussion

The main purpose of this study was to compare the shortterm effects of two low to medium intensity training modes in patients with stable HF. Our hypothesis was confirmed that yoga and hydrotherapy were equal in their effects, with improved exercise capacity and decreased symptoms of anxiety in participants from both groups. Patients who performed yoga also significantly improved their HRQoL and had a decrease in depressive symptoms. Our findings confirm previous studies showing that yoga has the potential to balance both the physical and mental dimensions and be an alternative exercise method in patients with HF.<sup>12</sup>

Even though there was no significant difference in outcome between the interventions, participants who received hydrotherapy training demonstrated improvement in the performance of the muscles in the lower extremities. This finding was not surprising, since hydrotherapy predominantly involves leg muscle groups. However, more patients

<b>Table 2.</b> Comparisons between and within the yoga and hy weeks follow up.	en and within the	yoga and hydrother	apy intervention:	s of effects on healt	drotherapy interventions of effects on health-related quality of life and symptoms of depression at baseline and after 12	and symptoms of c	depression at base	ine and after 12
Scales	Y oga baseline ( <i>n</i> =20)	Hydrotherapy baseline (n=20)	Yoga follow up (n=18)	Hydrotherapy follow up (n=12)	Between-groups baseline \$ value	Between- groups follow up <i>þ</i> value	Within- groups yoga þ value	Within-groups hydrotherapy þ value
EQ-5D EO-VAS	0.67 ± 0.26 63.7 ± 19.2	0.76 ± 0.28 71.3 ± 19.5	0.72 ± 0.26 77 ± 13	0.84 ± 0.14 71 ± 26	0.34 0.22	0.11 0.50	0.85 <b>0.004</b>	0.39 0.64
KCCQ Physical Limitation	67.I ± 22.5	70.I ± 23.4	73.8 ± 23.9	77.4 ± 19.0	0.60	0.65	0.17	0.09
KCCQ Symptom Stability	53.8 ± 16.8	57.5 ± 16.4	51.4 ± 20.1	56.3 ± 18.8	0.48	0.51	0.67	0.50
KCCQ Symptom Frequency	71.8 ± 27.3	81.0 ± 21.0	81.9 ± 21.1	84.4 ± 12.4	0.23	0.70	0.03	0.50
KCCQ Symptom Burden	72.I ± 26.0	80.8 ± 20.8	79.2 ± 22.6	84.0 ± 17.2	0.25	0.51	0.29	0.54
KCCQ Total Symptom	72.0 ± 26.0	80.9 ± 19.2	80.6 ± 21.0	84.2 ± 14.0	0.22	0.57	0.08	0.48
KCCQ Self-Efficacy	58.I ± 24.4	71.3 ± 22.6	67.4 ± 22.3	76.0 ± 17.2	0.09	0.24	0.01	0.17
KCCQ Quality of Life	61.7 ± 28.1	65.8 ± 26.6	73.I ± 19.5	72.2 ± 18.9	0.63	0.90	0.09	0.21
<b>KCCQ Social Limitation</b>	60.6 ± 26.6	68.I±28.6	68.I ± 23.4	77.6 ± 21.2	0.40	0.26	0.21	0.20
KCCQ Clinical Summary	69.5 ± 22.8	75.9 ± 19.2	77.2 ± 21.8	80.8 ± 14.8	0.35	0.59	0.05	0.17
KCCQ Overall Summary	65.3 ± 22.5	71.4 ± 20.5	73.9 ± 18.1	77.9 ± 16.1	0.38	0.54	0.04	0.12
PHQ-9	7.6 ± 5.6	4.I ± 4.4	4.22 ± 3.3	3.0 ± 1.7	0.03	0.20	0.005	0.23
HADS-depression	3.I ± 3.I	<b>3.9 ± 5.5</b>	2.0 ± 2.2	1.9 ± 1.9	0.55	0.91	0.25	0.17
HADS-anxiety	4.6 ± 4.1	4.6 ± 43.2	2.7 ± 3.2	3.9 ± 3.4	0.1	0.34	0.01	0.03
Data presented as mean±SD values.	8							

EQ-5D index: EuroQol five dimensions summarized index; EQ-VAS: EuroQol visual analogue scale; HADS: Hospital Anxiety and Depression Scale; KCCQ: Kansas City Cardiomyopathy Questionnaire; PHQ: Patient Health Questionnaire.

	Yoga baseline ( <i>n</i> =20)	Hydrotherapy baseline ( <i>n</i> =20)	Yoga follow up ( <i>n</i> =18)	Hydrotherapy follow up ( <i>n</i> =12)	Between- groups baseline \$ value	Between- groups follow up ρ value	Within- groups yoga þ value	Within-groups hydrotherapy ¢ value
6-minute walk test	453.6 ± 126.7	455.8 ± 103.9	<b>486 ± 133</b>	488 ± 110	0.95	0.98	0.008	0.02
Sit-to-stand test	31.7 ± 14.6	26.8 ± 11.7	25.8 ± 13.2	21.1 ± 8.2	0.25	0.25	0.09	0.01
Systolic BP (mmHg)	119.8 ± 19.2	124.8 ± 21.9	122 ± 17	124 ± 22	0.45	0.76	0.86	0.77
Diastolic BP (mmHg)	71.3 ± 12.1	77.1 ± 10.6	77 ± 11	80 ± 10	0.12	0.25	0.26	0.60
Pulse (beats/minute)	63.7 ± 9.0	74.8 ± 14.4	70 ± 15	79 ± 21	0.07	0.21	0.29	0.57
Saturation (%)	98 ± I.6	97 ± 1.8	98 ± 2	97 ± 2	0.56	0.38	0.13	0.85
Sensitive CRP (mg/L)	2.6 ± 2.6	3.7 ± 6.8	2.0 ± 1.4	4.6 ± 5.1	0.61	0.20	0.14	0.18
NT-proBNP (ng/L)	1408 ± 1419	1589 ± 1703	<b> 523 ±  366</b>	1794 ± 1200	0.71	0.59	0.90	0.69

in the hydrotherapy group interrupted training, mostly due to increased muscular skeletal symptoms.

We used intensity of training on an exercise level of 11–13 Borg RPE-20 scale as recommended in guidelines at the time and known to be well tolerated and safe for HF patients.<sup>5,27,28</sup>

Long-term adherence to various training programmes is difficult to maintain without continuous professional support.<sup>16,17</sup> Our study did not evaluate long-term effects and maintenance, but during the short-term intervention of 12 weeks, adherence to the scheduled training was better in the yoga group compared with the hydrotherapy group.

In this study we have demonstrated that yoga can be performed by older patients up to 80 years of age. This is of importance when implementing it as an alternative exercise training mode for patients with HF, since their mean age is >75 years.<sup>1</sup> The possibility to offer HF patients a wider variety of training options including exercising at home is crucial since adherence to exercise advice in the HF group is generally low.<sup>15,16,29</sup> Furthermore, all hospitals cannot offer patients with HF access to hydrotherapy training and not all patients can manage water training due to wounds, incontinence, dizziness or allergy to chlorine.

Controlled breathing as performed in yoga may shift the autonomic balance towards an increased vagal tone. Recently, the Nectar-HF-study demonstrated improved quality of life measures by vagal nerve stimulation.<sup>30</sup> These findings may explain the positive effects of yoga shown in this study.

Yoga may have therapeutic potential for HF patients and our study has added important information by comparing a new treatment of yoga with a recommended existing treatment such as hydrotherapy. Despite the popularity of yoga training in society today, research on HRQoL and therapeutic benefits is still in its infancy compared with the number of studies conducted on other forms of physical exercise training for patients with HF.<sup>5,15</sup> For instance, there is still a lack of knowledge regarding intensity, duration, frequency and how to combine the best movements for patients with HF in a yoga group. Larger, international multi-centre trials are warranted.

## Limitations

The study was designed to compare two groups of different exercise training methods. To show a clearer impact of each training method, a control group should have been added. Training motivation through a diary would have been an important supplement to monitor adherence. Our sample was from one study site and the sample size was small, which makes it difficult to generalize the findings especially to the elderly-elderly as 80 years of age was the upper limit for study inclusion. Dropout in the hydrotherapy group was larger than in the yoga group and this might have affected the results towards a more positive result on the 6MWT for this group. It is likely that some of the most severely ill patients accounted for a part of the dropouts. Further, patients who dropped out from the hydrotherapy group experienced more muscular skeletal problems.

## Conclusion

Yoga improved HRQoL and decreased depressive symptoms and hydrotherapy improved the muscle performance of the lower extremities. Both yoga and hydrotherapy exercise training improved exercise capacity and decreased symptoms of anxiety in patients with HF after 12 weeks. Yoga was well tolerated and could be an alternative or complement to traditional forms of exercise training in patients with HF. Better understanding of the potential efficacy of yoga and its complex relationship between the mind and body, as well as its importance for health and recovery in patients with HF is needed.

## **Implications for Practice**

- This study is the first randomized controlled study to compare yoga and hydrotherapy in patients with heart failure.
- Both yoga and hydrotherapy were found to improve exercise capacity and decrease symptoms of anxiety. Yoga also improved healthrelated quality of life and decreased depressive symptoms. Hydrotherapy improved muscle performance of the lower extremities.
- Yoga is a safe, feasible and well tolerated alternative or complement to traditional forms of exercise training.

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#### **Conflict of interest**

The authors declare that there is no conflict of interest.

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