Effect of telerehabilitation on long-term adherence to yoga as an antihypertensive lifestyle intervention: Results of a randomized controlled trial

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ABSTRACT

Background: and purpose: We aimed to investigate the adherence to yoga as an antihypertensive intervention through telerehabilitation.

Materials and methods: In a randomized controlled trial patients were consecutively enrolled and randomly assigned to intervention or control group. Both groups received standardized yoga training during three weeks of inpatient rehabilitation. The intervention group received telerehabilitation after discharge; the control group received the usual care. Data was collected at admission (t1), discharge (t2) and at follow up after six (t3) and 12 months (t4). The primary endpoint was follow-up adherence assessed in an intention-to-treat analysis.

Results: 228 male rehabilitation patients (mean age 53.3 $\pm$ 5.8 years, mean blood pressure 139.5 $\pm$ 10.2/ 86.7 $\pm$ 8.0 mmHg) The intervention resulted in significantly increased adherence compared to control group (t3: 40.0% vs. 19.5%, p = 0.001; t4: 36.5% vs. 23.9%, p = 0.038); blood pressure and quality of life improved.

Conclusion: Telerehabilitation significantly improves yoga adherence maintaining achieved health benefits in the long term.

1. Introduction

Hypertension is associated with an increased risk of cardiovascular disease and stroke, the leading causes of death worldwide [1]. According to the World Health Organization, hypertension is responsible for 9.4 million deaths every year [2]. Since almost a third of the world's adult population is affected, hypertension has become a considerable global public health problem nowadays [3].

Theoretically, hypertension is both preventable and manageable. Good management of hypertension – consisting of antihypertensive agents and additional non-pharmacological lifestyle interventions – substantially decreases cardiovascular morbidity and mortality [4]. Yoga, an increasingly popular mind-body intervention derived from ancient Indian philosophy, presents a feasible non-pharmacological treatment option. Numerous studies have shown yoga to result in various health benefits including blood pressure reduction [5–9].

Despite the clinical effectiveness of available blood pressure therapies, the overall blood pressure control rates are poor [10,11]. One of the major contributing factors is non-adherence to blood pressure management recommendations; Recent evidence suggests that non-adherence affects approximately 30% of hypertension patients [12]. Particularly, this seems to be crucial for non-pharmacological lifestyle interventions where greater effort than simple pill-taking is required. The results of a previous study by the authors suggest that cardiac rehabilitation patients struggle to adhere to yoga as a therapeutic option [8]. This is consistent with further research indicating that long-term adherence to lifestyle interventions, e.g. yoga, remains particularly challenging among patients with chronic conditions [13–15].

Since low adherence is associated with poor clinical outcomes, it is becoming crucial to identify strategies in order to improve it [13,15,16]. Even so, a paucity of research exist examining strategies to maximize adherence. An effective approach to maximize yoga adherence among rehabilitation patients could be telerehabilitation [17]. Telerehabilitation allows communication between rehabilitation patients and clinic healthcare professionals after discharge by utilization of information and communications technologies in order to support implementation of the rehabilitation program in the patients' daily routine at home. Trials suggest that telerehabilitation could improve post-rehabilitation adherence to physical activity, nutritional counselling, behavioural change and risk factor modification interventions [18–20]. Hence, we aimed to investigate in this study whether adherence to yoga among rehabilitation

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patients could be maximized by a telephone based post-rehabilitation approach.

2. Materials and methods

2.1. Study design

The OptiHyp study was a randomized, prospective, 2-arm controlled study. Participants were allocated in a 1:1 ratio to either the intervention group (IG) or the control group (CG). Yoga instructors and study physicians were not informed of participants' randomization status; Patients were not informed of their randomization status until discharge. Written informed consent was obtained from each participant. The study was approved by the Ethics Committee of the Medical Association North Rhine and was carried out according to the principles of Good Clinical Practice and the Declaration of Helsinki of 1975, as revised in 1983. The trial was registered at the German Clinical Trials Register (ID: DRKS00005428).

2.2. Participants

The study population consisted of male cardiac patients at the rehabilitation center Roderbirken in Leichlingen, Germany. The restriction to male rehabilitants was made for both content and economic reasons. First, men are under-represented as users of yoga [21,22]. Moreover, approximately 85% of the patients at the Roderbirken rehabilitation center are men. In order to recruit a study population with a balanced gender ratio, significantly higher temporal and financial resources would have been necessary.

Eligible patients were aged 18–60 years with mean systolic BP > 135/85 mmHg. Patients with blood pressure (BP) above 160/100 mmHg (hypertension stage $\geq$ 2) were not eligible, since these would probably be under medical adjustments. Exclusion criteria were surgical interventions or myocardial infarction within four weeks prior to the start of the study or expected physical incapacity to carry out yoga practice. Patients with diagnosed heart failure (New York Heart Association (NYHA) stage $\geq$ II), hemodynamically relevant arrhythmia, clinically relevant lung diseases and patients requiring dialysis were also excluded. Patients were not given incentives for participation in the study.

2.3. Study intervention

Patients were randomly assigned to receive either telerehabilitation (IG) or current standard care without further support after discharge (CG). The telerehabilitation included six motivational telephone counselling sessions scheduled within the first year after discharge from inpatient rehabilitation (1, 2, 3, 6, 9, 12 months after rehabilitation). The telephone sessions were conducted by trained staff following a standardized interview guide with a set-up of open and closed questions. The main topic discussed in the phone conversations was practising yoga at home including training habits, training goals, actual training schedule, motivational aspects and perceived barriers. Health-related topics such as BP monitoring were addressed as well. Additionally, participants of the IG were also invited to a yoga "refresher" unit six months after discharge (t3). The CG was invited for data collection only; and received neither the "refresher" nor the telerehabilitation.

During the three-week in-patient rehabilitation, all participants (IG + CG) received standardized yoga training which was delivered by certified instructors to small groups of 5–10 patients. The yoga form practiced in the present study was Viniyoga [23], a therapeutic yoga style that allows modifying postures with respect to a patient's physical condition and individual needs. The method focused on the synchronization of body movements and slow, deep breathing in order to reach relaxation. The program was conducted five times per week for three consecutive weeks. Each session was of 45 min duration and started with a warm-up exercise followed by a sequence of eight simple movements (postures). The sessions ended with a short meditation unit. All patients received an exercise sheet for training at home.

2.4. Outcomes

The primary outcome was continued yoga adherence at six (t3) and twelve months (t4) after discharge. Adherence was assessed by a patient-reported questionnaire. The proportion of study participants who practiced yoga at t3/ t4 (yoga prevalence) was then compared between the groups.

Secondary measures consisted of changes in BP (self-measured), endothelial function (EndoPAT®), blood tests, health related quality of life (Short Form Health Survey SF-12) and lifestyle (smoking, physical activity). Clinical status and laboratory values were assessed at baseline (t1: at the beginning of the in-hospital phase) and at discharge (t2: at the end of the in-hospital phase). Endothelial function was recorded within the first days of inpatient rehabilitation.

We decided to assess patients' BP via self-measured BP. Patients were instructed to measure their BP according to the European Society of Hypertension practice guidelines for home blood pressure monitoring [24,25]. They also received an upper-arm device and a standardized BP measurement protocol to document their BP for three consecutive weeks. The baseline BP was calculated as the arithmetic mean of the measurements at the second and the third morning of the inpatient rehabilitation. The discharge BP was calculated as the arithmetic mean of the morning measurements of the two days before discharge. Thereafter, clinical status, endothelial function and laboratory values were collected at t3. To obtain BP during the follow up, the postal follow-up questionnaire (t3 & t4) included a BP protocol. Patients were advised to record their BP for 7 consecutive days and to conduct three measurements each time, separated by 2 min. The mean follow up BP values (t3 & t4) were calculated as the arithmetic mean of the second and the third measurement taken on the second and third day.

2.5. Sample size

We hypothesized that those participants who received the telerehabilitation would achieve a significant improvement of yoga adherence. It was determined that a sample size of 93 participants per study group (in total: n = 186) would provide sufficient power (0.80) to detect a difference between groups, with a two-tailed α of 0.05, for a comparison of two independent proportions if there was an absolute difference of 20% in the primary outcome measure. Taking into account a potential dropout rate of 15%, this results in a total required number of 120 patients per group (in total: n = 240).

2.6. Statistical analyses

The primary analysis was conducted using an intention-to-treat approach, and therefore included all randomized patients. Baseline characteristics of patients in the two treatment groups were reported using frequency distributions and descriptive statistics including measures of central tendency and dispersion. Descriptive statistics are presented as means and standard deviations. The principal analysis was an unadjusted Chi-Square test comparing the proportion of adherent patients ("yoga prevalence") in each treatment group at t3 and t4. Continuous variables were compared using the Mann-Whitney U test. In cases of within-group significance of differences, paired evaluations were also assessed by means of the Wilcoxon signed-rank (WSR) test. P-values were two-sided and considered statistically significant if < 0.05. All analyses were conducted using SPSS (Statistical Package for Social Science IBM®, Version 23).

To reduce the potential bias created by missing data a Multiple Imputation [26] was conducted using the Markov chain Monte Carlo (MCMC) method. The imputation procedure used all the known covariates thought to be associated with the missing mechanism to help predict the values for the missing data. The fully observed baseline

variables were also included to preserve its relationships with the incomplete variables. Twelve imputed data sets were created with a run length of 10–20 iterations. Continuous variables with a highly skewed distribution were transformed (e.g. log-transformed, squared or polynomial) to approximate a normal distribution. Completed data were transformed back to their original scale before analysis. Results of imputed data and complete cases were compared. Since a conducted sensitivity analysis has not revealed any differences between the available cases analysis and the intention-to-treat (ITT) analysis after Multiple Imputation, only the results of the ITT are presented here.

Missing values of the primary outcome (adherence) were not imputed as missing at random assumption could not be justified. Documented drop reasons indicate that individuals who did not fill in the questionnaire were less likely to maintain yoga after inpatient rehabilitation. Hence, study participants who did not provide information about their current yoga training (due to drop out or because they were lost to follow up) were regarded as being non-adherent (worst case assumption).

3. Results

3.1. Participants

A total of 4000 cardiac rehabilitation patients were screened for eligibility between March 2014 and June 2015. Fig. 1 provides a flow chart of the study.

The baseline characteristics of the study patients (n = 228) are presented in Table 1. The average age was approximately 53 years, all study participants were male. In both groups, there was a predominance of blue collar workers (62.3%) with less than 10 years of formal education (87.3%). Most of the study patients did not live alone at the beginning of the rehabilitation program (74.6%), about two-thirds (64.5%) were married. Nearly 96% were on antihypertensive medication (mean 3.2 ± 2.2 daily defined doses). Beta-blockers were prescribed most frequently (76.3%), whereas most daily doses were for angiotensin-converting-enzyme (ACE) inhibitors (1.66 ± 1.63 daily defined doses). There were no significant differences between the groups regarding any parameter.

3.2. Primary endpoint

During the follow-up period, the intervention resulted in a substantially increased Viniyoga adherence. At t3, a total of 151 patients provided information about their current yoga training routines. Of those, 68 study patients reported that they were still practicing yoga. Comparing both groups, we observed a significantly higher prevalence of yoga adherence in the IG at this time (available case analysis (n = 151): IG: 60.5% vs. CG: 29.3%, p < 0.0001). Assuming that patients who did not provide any information about their yoga training status were no longer practicing yoga and could therefore be labeled as "non-adherent", the difference in yoga adherence remains significant (ITT (n = 228): IG: 40.0% vs. CG: 19.5%, p = 0.001). At t4, the intervention was associated with a significantly higher adherence as well (available case analysis (n = 152): IG: 56.0% vs. CG: 36.0%, p = 0.014 & ITT (n = 228): IG: 36.5% vs. CG: 23.9%, p = 0.038).

Referring to participants who were still practicing Viniyoga at t3 (n = 68) the intervention was further associated with a significant
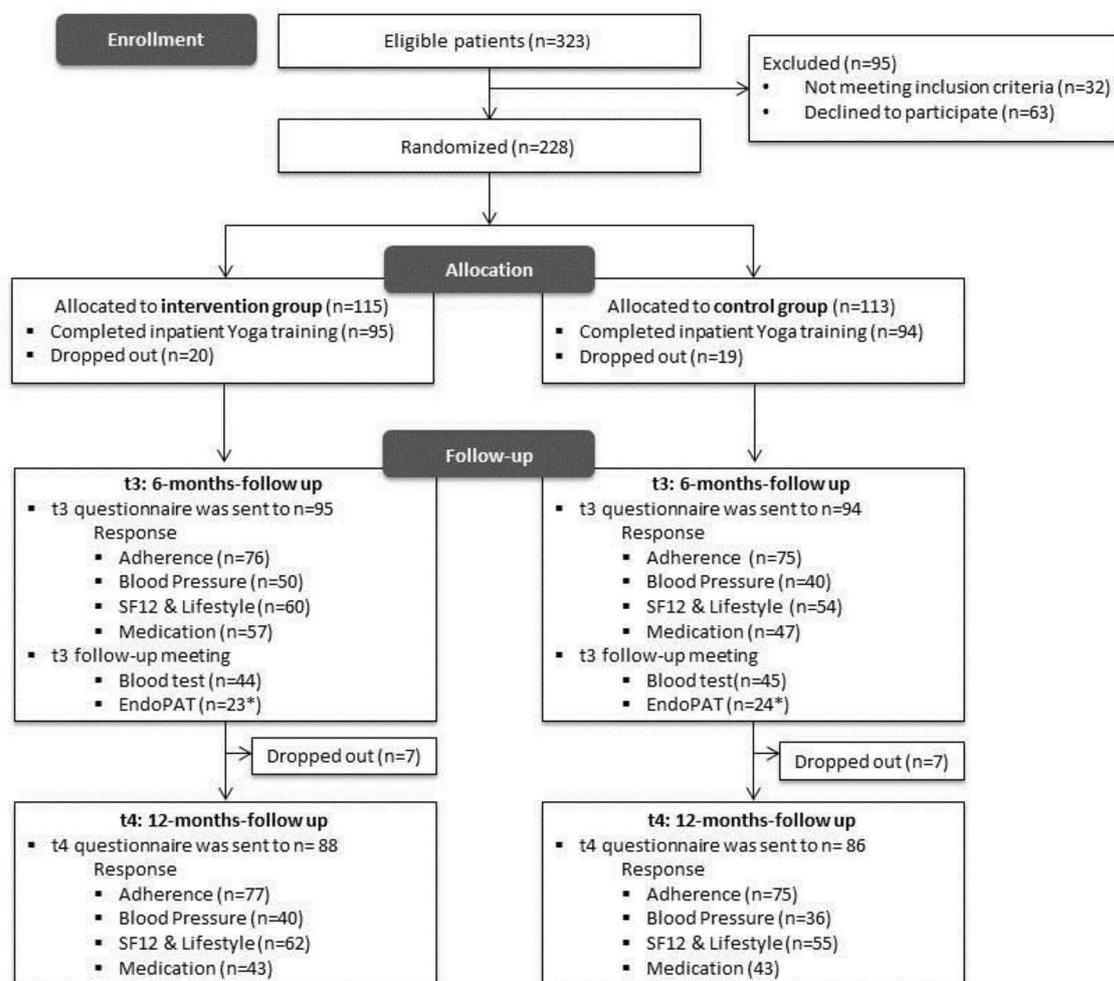

Fig. 1. Flow chart of the Optihyp study.

Table 1
Baseline characteristics of participants.

Age (years); mean, SD	Intervention group n = 115		Control group n = 113	
	53.2	6.0	53.4	5.7
BMI (n = 228) (kg/m^2); mean, SD	30.8	5.7	30.9	5.8
Blood Pressure (n = 228); mean, SD				
Systolic (mmHg)	139.6	12.0	139.5	11.3
Diastolic (mmHg)	86.5	8.4	86.4	9.3
Pulse (mmHg)	72.7	10.3	71.0	12.1
Blood test (n = 225); mean, SD				
High density-cholesterol (mg/dl)	44.4	12.4	43.7	10.6
Low density-cholesterol (mg/dl)	134.3	41.1	127.7	33.3
Triglyceride (mg/dl)	191.8	112.3	178.0	105.5
Blood Glucose (mg/dl)	106.1	31.8	105.3	35.7
Baseline diagnoses (n = 228); n, %				
Hypertension	89	77.4	89	78.8
Heart failure	8	7.0	6	5.3
Coronary heart disease	75	65.2	65	57.5
Myocardial infarction	50	43.5	52	46.0
Diabetes	23	20.0	21	18.6
Metabolic syndrome	15	13.0	15	13.3
Psychological disorder	16	13.9	21	18.6
Smoking status (n = 184); n, %				
Current smoker	22	23.2	26	29.2
Non-smoker	73	76.8	63	70.8
Physical activity (n = 181); n, %				
No activity	66	70.2	54	62.1
> 1 h per week	28	29.8	33	37.9
School education (n = 167)				
< 10 years, n (%)	72	87.8	74	87.1
> 10 years, n (%)	10	12.2	11	12.9
SF-12 Health related quality of Life (n = 166)				
MCS; mean, SD	41.7	12.6	41.7	11.5
PCS; mean, SD	38.5	9.5	36.3	9.7
Number of antihypertensive agents; n, %				
0	2	1.7	5	4.5
1	16	13.9	22	19.8
2	45	39.1	35	31.5
> 3	52	45.3	49	44.2

Abbreviations: n, number of participants; BMI, body mass index; SF-12, short form of the SF-36 health related quality of life questionnaire; PCS, Physical Health Component Score; MCS, Mental Health Component Score; mean, arithmetic mean; SD, standard deviation.

increase of weekly training frequency (p = 0.021) and duration of single training units (p = 0.014). Yet observed differences at t4 did not reach statistical significance. Patients who were not practicing yoga reported various reasons for discontinuation. The main reason was "lack of time" which was reported by one third of non-adherent participants. Additionally, frequently reported reasons were "low health status" and "lack of motivation". The between-group comparison showed that time-related and motivational reasons were more

frequently mentioned in the CG, whereas disease-related terminations were reported with comparable frequency in both groups.

3.3. Secondary endpoints

Blood pressure: Following the 3-week inpatient yoga training, a significant systolic and diastolic BP reduction was observed in the entire sample (WSR: n = 228: sys$_{t1}$ vs. sys$_{t2}$, p < 0.0001; dia$_{t1}$ vs. dia$_{t2}$, p < 0.0001). At follow-up, mean systolic BP remained significantly different to baseline BP in the IG, but not in the CG (Table 2). No change in antihypertensive medication was observed in any of the groups.

Endothelial function and heart rate: The results of the EndoPAT® (data not presented), did not differ significantly between the IG and the CG. However, the IG showed consistently better outcomes in all endothelial parameters. With respect to heart rate, we found a significant difference favoring the IG (IG: 63.7 ± 9.8 vs. CG: 70.2 ± 11.9, p = 0.031).

Health-related quality of life: During the follow-up period the SF-12 mental health score (MCS) increased significantly in the IG (t1 vs. t3: MCS + 4.8 ± 11.4, p < 0.001; t1 vs. t4: MCS + 5.3 ± 13.2, p = 0.003) whereas no significant change could be observed in the CG (t1 vs. t3: MCS + 0.8 ± 12.7, p = 0.386; t1 vs. t4: MCS + 1.8 ± 14.4, p = 0.156). The between-group difference (Table 3) regarding the mean mental health score in favor of the IG reached statistical significance six months follow-up. No significant difference existed between the groups in terms of physical health component score (PCS).

Lifestyle: The questionnaire showed that the participants in the IG were less frequent smokers, but were more frequently active in sports (Table 3). Although the differences were small, the IG showed relatively better outcomes regarding health-related lifestyle.

4. Discussion

Adherence to lifestyle interventions (e.g. yoga) remains challenging in the rehabilitation of patients with cardiovascular disease. This was confirmed by the results of a previous study conducted by the authors indicating that adherence to Yoga remained as low as 29% if no further intervention is being offered (8). However, our present study also shows that adherence can be doubled by a simple telephone based intervention following inpatient rehabilitation. The intention-to-treat analysis showed that the primary objective could be clearly confirmed: in this middle-aged male low education cohort, adherence during follow-up was significantly better in the IG than in the CG.

An interesting trend regarding yoga adherence was further observed in the CG. Contrary to expectation, there had been a gradual increase in training units and training duration over time (t3 vs. t4). A likely explanation for this might be that all study participants were invited to a follow-up meeting at the rehabilitation center six months after completion of the inpatient rehabilitation. Although this meeting was

Table 2
Secondary outcomes: Blood Pressure.

Blood pressure (mmHg)	Intervention group n = 115 Within-group analysis (WSR test)[+]		Control group n = 113 Within-group analysis (WSR test)[+]	
	Change	p-value	Change	p-value
Baseline to 3 weeks	systolic −8.6 ± 12.0	< 0.001***	systolic-9.5 ± 11.1	< 0.001***
	diastolic −4.7 ± 6.7	< 0.001***	diastolic −5.6 ± 7.9	< 0.001***
Baseline to 6 months	systolic −6.5 ± 17.2	< 0.001***	systolic −2.8 ± 16.6	0.162
	diastolic −3.6 ± 10.6	0.002**	diastolic −3.3 ± 10.5	0.062
Baseline to 12 months	systolic −5.4 ± 16.6	0.005**	systolic −2.7 ± 15.9	0.173
	diastolic −2.1 ± 10.7	0.222	diastolic-1.7 ± 10.1	0.201

Abbreviations: n, number of participants; mean, arithmetic mean; SD, standard deviation; WSR, Wilcoxon signed rank test; Probability: *P < 0.05, **P < 0.01; ***P < 0.001, +Data are derived from multiple imputation.

Table 3
Secondary outcomes: Lifestyle and quality of life.

6-months-follow-up	Intervention: n = 115	Control: n = 113	U test
	Between-group analysis[+]		p-value
Smoking, n (%)	39 (34.1)	47 (41.4)	0.182
Physical activity, n (%)	72 (63.0)	62 (55.2)	0.310
SF-12 PCS, mean ± SD	40.6 ± 10.9	38.7 ± 10.7	0.254
SF-12 MCS, mean ± SD	46.2 ± 11.5	42.3 ± 11.9	0.030*
12-months-follow-up	Between-group analysis[+]		p-value
Smoking, n (%)	38 (33.2)	45 (39.7)	0.333
Physical activity, n (%)	55 (47.7)	60 (52.9)	0.371
SF-12 PCS, mean ± SD	39.9 ± 11.3	41.4 ± 11.2	0.362
SF-12 MCS, mean ± SD	46.6 ± 11.1	43.3 ± 12.0	0.064

Abbreviations: n, number of participants; SF-12, short form of the SF-36 health related quality of life questionnaire; PCS, Physical Health Component Score; MCS, Mental Health Component Score; t3, 6-months-follow-up; t4, 12-months-follow-up; mean, arithmetic mean; SD, standard deviation; Probability: *P < 0.05, **P < 0.01; ***P < 0.001, +Data are derived from multiple imputation.

initiated for the CG only to collect data (e. g. laboratory values, endothelial function) without yoga training, it could have unintentionally influenced the motivation in the CG. Nevertheless, yoga adherence remained significantly higher in the IG which generally supports the effectiveness of telerehabilitation. In the IG, adherence declined slightly after t3 which may be explained by the less frequent telephone calls from the sixth to the twelfth month of the follow-up period. We therefore suggest that telerehabilitation should be delivered within a small interval framework. Comparable results have been reported in other studies examining rehabilitation aftercare [18, 27–29].

With respect to BP, the findings of the present study support the results of previous research suggesting that yoga may be effective in lowering BP. In a previous study, we found a significant difference of SBP after 3 weeks of inpatient rehabilitation with Viniyoga training whereas no significant reduction was observed in the CG treated with Progressive Muscle Relaxation (8). Other research groups have shown comparable results regarding BP reduction through yoga [6, 7, 30–32]. Our findings therefore contribute to the existing knowledge and strengthen the potential of yoga as suitable non-pharmacological therapeutic option for hypertensive patients. Especially for high-risk patients whose BP is insufficiently controlled despite multidrug therapy, such supportive therapy options are of prognostic relevance. To maintain the favorable BP effect of regular yoga training, simple telephone based intervention appeared to be a helpful method for a majority of patients randomized in this study.

The telerehabilitation seemed to have a favorable influence on further outcomes. We observed a consistent but non-significant trend towards benefits in terms of endothelial function. Additionally, the study results indicate a positive impact on health-related quality of life due to telerehabilitation. We observed a significant increase of the SF-12 MCS after inpatient rehabilitation in the IG which resulted in significant between-group difference at six-months-follow-up. In contrast, no additional benefit regarding PCS could be observed. It may be that telephone based counselling affects the emotional aspect of well-being more than the somatic aspect. As mental quality of life is particularly linked to return-to-work after rehabilitation [33], these results are quite promising. In patients adherent to yoga we saw higher health related quality of life (HRQL) scores, both physically and mentally. Since any lifestyle-change is more likely to be maintained if it immediately increases well-being, this could be a possible underlying mechanism of maintaining adherence to yoga. A qualitative analysis of the telephone protocols supports this assumption as it revealed that perceived (mental) health improvement due to yoga was the most important factor influencing adherence to regular yoga training. These results are

consistent with those of Wolff et al. [34] who conducted a qualitative analysis revealing improved well-being as the main motive of hypertensive yoga users. Post rehabilitation interventions promoting lifestyle changes therefore should focus particularly on the aspect of perceived health benefits.

There are limitations to our study. First, as only male patients were observed, these findings cannot be extrapolated to female patients. However, since men are underrepresented relative to women in current research concerning yoga, this trial enriches the existing state of research [21,22,35]. Another limitation is that patients were recruited from only one inpatient rehabilitation center limiting the overall generalizability of our results. Since our results appear to be quite promising, efficacy in other cardiac patient populations might be evaluated in future studies.

5. Conclusion

We conclude that, particularly for this middle-aged male low-education cohort, this simple telephone based program aiming to enhance yoga practice at home is feasible and effective in supporting long-term adherence as a non-pharmacologic intervention. The benefit of regular yoga training after inpatient rehabilitation was not only reflected in maintaining goal BP but also in improving health related quality of life. Taken together, increased yoga adherence through telerehabilitation resulted in improved rehabilitation outcomes. The findings of this study therefore strengthen the idea that yoga may be a viable adjunct intervention in cardiac rehabilitation for the holistic management of hypertension. Future research might explore specific barriers to yoga adherence as well as factors that motivate patients to adhere to yoga as a therapeutic lifestyle intervention.

Declarations of interest

None.

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