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ORIGINAL REPORT

EFFECTS OF AEROBIC INTERVAL TRAINING ON MEASURES OF ANXIETY, DEPRESSION AND QUALITY OF LIFE IN PATIENTS WITH ISCHAEMIC HEART FAILURE AND AN IMPLANTABLE CARDIOVERTER DEFIBRILLATOR: A PROSPECTIVE NON-RANDOMIZED TRIAL

Kjetil Isaksen, MD[1,2], Peter Scott Munk, MD, PhD[1], Rune Giske, PhD[3] and Alf Inge Larsen, MD, PhD[1,2]

From the [1]Department of Cardiology, Stavanger University Hospital, Stavanger, [2]Institute of Internal Medicine, University of Bergen, Bergen and [3]Institute of Sports Science, University of Stavanger, Stavanger, Norway

Objective: **To evaluate the short- and long-term effects of aerobic interval training on quality of life and on symptoms of anxiety and depression among patients with ischaemic heart failure and an implantable cardioverter defibrillator.**
Design: **Prospective, non-randomized controlled study.**
Subjects: **Patients with ischaemic heart failure and an implantable cardioverter defibrillator, willing to undergo an aerobic interval training programme. A total of 31 patients were enrolled (19 were assigned to the aerobic interval training group and 12 to the control group).**
Methods: **The aerobic interval training group performed a 12-week exercise training programme. All patients were evaluated with the Short Form-36 (SF-36), the Hospital Anxiety and Depression Scale (HADS) and the International Physical Activity Questionnaire at baseline, after 12 weeks and at 2 years.**
Results: **The aerobic interval training group showed significant improvements in several SF-36 subscores at 12 weeks. There was an unadjusted significant reduction in the HADS depression (HADS-D) score. At follow-up, results in the aerobic interval training group moved towards baseline or remained stable, whereas in the control group HADS-D scores and some SF-36 subscores deteriorated.**
Conclusion: **Participation in a 12-week aerobic interval training programme resulted in significant improvements in several measures of quality of life and the unadjusted HADS-D score in patients with ischaemic heart failure with an implantable cardioverter defibrillator. At follow-up there was significantly less sedentary activity in the aerobic interval training group, while psychometric measures were no longer significantly different from baseline.**

Key words: ICD; heart failure; cardiac rehabilitation; exercise training; aerobic interval training; depression; quality of life.

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Correspondence address: Kjetil Isaksen, Stavanger University Hospital, Department of Cardiology, Post-box 8100, NO-4068 Stavanger, Norway. E-mail: kjetil.isaksen@lyse.net

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INTRODUCTION

The beneficial effects of exercise training (ET) on mortality and morbidity in patients with coronary artery disease (CAD) (1, 2) and heart failure (HF) (3, 4) are well documented. A large proportion of patients with an implantable cardioverter defibrillator (ICD) experience one or both of these conditions. Patients with an ICD have either survived cardiac arrest (secondary prevention) or are at increased risk for developing malignant arrhythmias (primary prevention) (5). The presence of HF alone is known to significantly impair quality of life (QoL) (6). Among patients with an ICD clinically significant anxiety disorders are prevalent, ranging between 13% and 38% (7). Regarding depressive symptoms, the prevalence varies between 24% and 33% in different studies (8). Regardless of ICD shock exposure, avoidance of ET has been described in a considerable proportion of patients with an ICD (9, 10). Such fear of exertion-triggered shock is especially troublesome, since it may promote a sedentary lifestyle.

Beneficial effects of ET on depressive disorders in the general population have been documented in several studies (11), including among elderly patients (12). However, data describing the effects of ET on ICD recipients with regard to QoL and symptoms of anxiety and depression are limited. Six studies have been published (13), but none of these have employed aerobic interval training (AIT) as the ET modality. In addition, 2 studies have combined ET with a psychological intervention/education (15, 16). Although only a relatively small number of patients have been assessed in these studies, the results indicate a beneficial effect of participation in ET programmes. While the 4 studies cited above employ quantitative measures, 2 recent studies have used qualitative measures to assess the impact of programme participation (17, 18). Both studies have reported increased confidence related to participating in an organized ET programme.

Considering the positive effects of ET, we aimed to elicit whether the benefits related to psychosocial aspects can be extended to the ICD population with ischaemic HF. We have

previously published data regarding safety, feasibility and effects of a 3-month AIT programme in HF patients with an ICD (19). The aims of the current study were:

- to assess the impact of AIT on self-reported quality of life and symptoms of anxiety and depression;
- to evaluate to what extent the potential differences/beneficial effects following the intervention are of lasting character using a 2-year follow-up survey;
- to assess whether participation in an AIT programme leads to increased levels of physical activity and less sedentary activity at follow-up.

METHODS

We conducted a prospective, non-randomized, controlled, single-centre study. The AIT programme and test protocols have been described in detail previously (19).

Patients

During the period 2008–2012 a total of 31 patients with ischaemic HF and an ICD or a cardiac resynchronization therapy defibrillator (CRT-D) were enrolled. A flow chart of inclusion, intervention and follow-up is shown in Fig. 1.

Inclusion criteria were: stable ischaemic HF, an ejection fraction $<40\%$ or $\geq 40\%$ and symptoms of HF (New York Heart Association; NYHA ≥ 2). All patients were 18 years of age or older, and both primary and secondary indications for a first-time ICD/CRT-D implantation were included. Exclusion criteria included: significant symptomatic valvular heart disease, inability to give informed consent, inability to participate in regular training due to serious comorbidity or planned surgery within 3 months. All patients who were able to participate in the training programme 3 times a week for 3 months were assigned to the AIT programme. Patients who were unable to participate regularly for logistic reasons (e.g. travel distance from rehabilitation centre) served as controls.

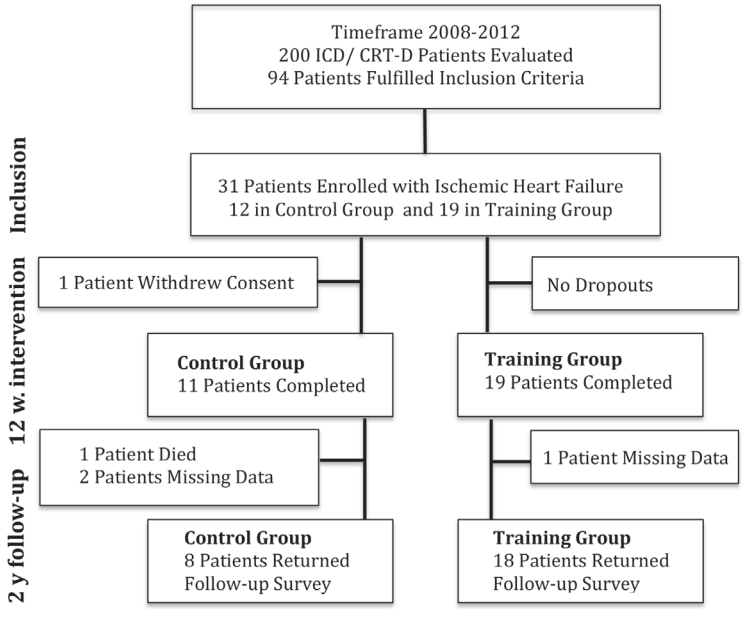

Fig. 1. Study inclusion, intervention and follow-up. ICD: implantable cardioverter defibrillator; CRT-D: cardiac resynchronization therapy-defibrillator; MET: metabolic equivalent.

Aerobic interval training and test protocol

Patients exercised for 60 min, 3 times a week over a 12-week period. The patients exercised on a cycle ergometer or treadmill. Exercise sessions comprised a 15-min warm-up followed by 4 high-intensity intervals, each lasting 4 min, with 3 min of active recovery between intervals. A 20-min period of cool-down and stretching followed the intervals. Exercise intensity was at 85% of maximal heart rate during the intervals (Borg scale 15–17), participants used heart rate monitors for intensity guidance during each session. The AIT was conducted in training groups of up to 10 individuals. All subjects completed a maximal ergospirometry-stress test at baseline and at 12 weeks.

Psychometric and physical activity measures

All psychometric measures were assessed at baseline, following the intervention and at 24 months following the intervention in both groups. Assessment of lifestyle with regard to daily physical activity level and sedentary activity was performed at follow-up.

Quality of life

The Norwegian validated version of the Short Form-36 (SF-36) was employed to assess patients self-reported QoL (20, 21). This tool has been widely used to assess health-related QoL. The questionnaire consists of 36 items measuring QoL across 8 subscores: physical functioning (PF), role-physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role-emotional (RE) and mental health (MH). Scores are calculated for each component and also as a Physical and Mental Component Summary score (PCS and MCS). The different scores range from 0 to 100, where increasing scores indicate better health.

Symptoms of anxiety and depression

The Norwegian version of the Hospital Anxiety and Depression Scale (HADS) was used to assess symptoms of anxiety and depression (22). The HADS questionnaire scores 14 items, 7 measuring symptoms of anxiety (HADS-A) and 7 items measuring symptoms of depression (HADS-D). In both cases scores range from 0 to 21, a higher score indicating more distress. The psychometric properties of both scales have been found to be good with regard to factor structure, subscale intercorrelation, homogeneity and internal consistency. The HADS questionnaire has also been found to be robust across a large spectrum of subsamples (23). According to reviews by Bjelland et al. (24) and Stafford et al. (25) we used a HADS-A score of ≥ 8 and a HADS-D score of ≥ 5 as cut-offs for caseness. The HADS total score (HADS-S) has also been widely used, and is a global measure of overall psychological distress. Scores range from 0 to 42, with an increasing score indicating more distress. Cut-off values for caseness vary from 10 (emotional distress) to 18/19 (major mood disorders) (26).

Assessment of lifestyle with regard to sedentary and physical activities

The short version of the International Physical Activity Questionnaire (IPAQ) was used. This questionnaire exists in a Norwegian translation and has been found to be a valid and reliable tool (27). It measures the amount of time spent daily on physical activities during the last week. Three types of activities: vigorous-intensity, moderate-intensity and walking are registered. The IPAQ assesses these physical activities across various domains: domestic-, work-, transport-related, and leisure activities. It also measures the amount of time spent daily sitting, again measures refer to the previous 7 days. Data recorded with IPAQ can be presented as a continuous measure. Scoring is performed according to the IPAQ scoring protocol (28). The combined total physical activity score is expressed in metabolic equivalent (MET)-min/week. This was calculated by assigning different MET levels

to different activities as specified in the scoring protocol (walking = 3.3 METs, moderate intensity = 4.0 METs, vigorous intensity = 8.0 METs). Each category was calculated by multiplying MET level by the min and days each activity was performed. Finally, the 3 categories of MET-min/week were added to form the combined total physical activity score. As suggested, we present the continuous variables of the IPAQ as medians with interquartile range. The IPAQ was not designed to measure effects in small-scale interventional studies and we have merely used it to assess participant's level of physical activity at follow-up.

Charts review

Information regarding ICD therapies and hospitalizations were collected at the end of the intervention and at the time when the 2-year follow-up survey was conducted through patient's charts review and designated ICD interrogation outpatient visits. This was done to collect information about factors that might influence the degree of anxiety/depressive symptoms or QoL.

Ethical considerations

The trial was performed in accordance with the principles of the Declaration of Helsinki. The study protocol was approved by the local ethics committee, and all patients gave written informed consent.

Statistical analysis

Data analyses were performed with SPSS version 20 (IBM Corp., Armonk, NY, USA). Data are expressed as mean and standard deviation (SD) unless otherwise stated.

Categorical variables were compared using Pearson χ^2 test or Fisher's exact test. Comparisons between groups were analysed by 2-sided *t*-test or Mann-Whitney *U* Test, depending on normality of distribution. The Wilcoxon Signed-Rank Test was used to compare related samples. Bonferroni adjustments were performed for multiple comparisons of the HADS and SF-36 results. Due to the conservative nature of Bonferroni correction, adjusted as well as unadjusted results are presented here. A *p*-value below 0.05 was considered significant.

RESULTS

A total of 30 patients (19 AIT group/11 control group) completed the 12-week programme, while 26 patients (18 AIT group/8 control group) completed the follow-up assessment 2 years after the intervention. Patient characteristics did not show any statistically significant differences between the groups, at baseline (Table I) or at follow-up.

Training effects and compliance with the aerobic interval training programme

Following the AIT intervention a significant increase in peak oxygen uptake, from 17.6 to 18.7 (ml/kg/min) was seen in the AIT group only ($p = 0.02$). In the control group a non-significant decrease, from 16.9 to 16.2 (ml/kg/min), was seen ($p = 0.28$).

The mean attendance rate was 97.5%, with no participant completing less than 75% of the programme, while 16 patients completed all 36 AIT sessions. Regarding exercise intensity during the intervals, the mean reported Borg scale score was 15.2.

Short Form-36

Table II shows the mean SF-36 scores across groups and time-points. While the 2 groups had no significant differences at baseline there were significant improvements in the AIT group in the component scores GH, VT, SF, MH and the summary scores MCS and PCS, at week 12. These improvements remained stable or moved towards baseline values at

Table I. *Baseline characteristics*

Baseline characteristics	Control $n = 11$	Training $n = 19$	*p*-value
Male sex, *n* (%)	11 (100)	17 (90)	0.52
Age, years, mean (SD)	69 (9)	66 (9)	0.74
Smoking habits, *n* (%)			0.89
Current smoker	2 (18)	4 (21)	
Former smoker	5 (45)	10 (53)	
Never	4 (36)	5 (26)	
BMI, kg/m^2, mean (SD)	27.3 (4.2)	27.2 (3.8)	0.9
Comorbidity, *n* (%)			
Hypertension	4 (36)	6 (32)	0.79
Diabetes	1 (9)	1 (5)	0.69
Atrial fibrillation[a]	5 (46)	3 (16)	0.12
Stroke/TIA	2 (18)	2 (11)	0.61
Peripheral vascular disease	3 (27)	4 (21)	0.52
COPD	3 (27)	2 (11)	0.33
NYHA class, *n* (%)			0.44
1	0	2 (11)	
2	11 (100)	16 (84)	
3	0	1 (5)	
LV ejection fraction, mean (SD)	30 (8.1)	34.2 (7.3)	0.09
Revascularization, *n* (%)			
Previous CABG	6 (55)	5 (26)	0.24
Previous PCI	7 (64)	17 (90)	0.16
ICD indication, *n* (%)			1
Primary	6 (55)	9 (47)	
Secondary[b]	5 (45)	10 (53)	
Sudden cardiac death survivor, *n* (%)	2 (18)	9 (47)	0.14
Device type, *n* (%)			1
ICD	10 (91)	17 (90)	
CRT-D	1 (9)	2 (10)	
Baseline rhythm, *n* (%)			0.61
Sinus rhythm	10 (91)	18 (95)	
Atrial fibrillation	1 (9)	0	
Pacemaker rhythm	0	1 (5)	
Baseline exercise capacity, mean (SD)			
VO_{2peak} (ml/kg/min)	16.9 (2.8)	17.6 (3.6)	0.59
Max workload (watts)	130 (26.3)	136 (33.6)	0.46
Medication, *n* (%)			
Platelet inhibitors	10 (91)	19 (100)	0.37
Warfarin	3 (27)	1 (5)	0.13
Amiodarone	1 (9)	1 (4)	0.66
ARB or ACE-inhibitors	10 (91)	18 (95)	1
Statins	9 (82)	19 (100)	0.13
Aldosterone antagonists	7 (64)	9 (47)	0.47
ß-blockers	11 (100)	17 (90)	0.52

[a]Including paroxysmal.

[b]Survivor of sudden cardiac death, sustained ventricular tachycardia or fibrillation causing haemodynamic instability.

No statistical significant differences between groups. TIA: transient ischaemic attack; COPD: chronic obstructive pulmonary disease; NYHA: New York Heart Association; CABG: coronary artery bypass graft; PCI: percutaneous coronary intervention; ICD: implantable cardioverter defibrillator; CRT-D: cardiac resynchronization therapy-defibrillator; ACE: angiotensin-converting enzyme; ARB: angiotensin receptor blocker; BMI: body mass index; SD: standard deviation; $VO_{2\ peak}$: peak oxygen uptake; SD: standard deviation.

Table II. *Short Form-36 (SF-36) scores at baseline, 12-week and 2-year follow-up*

	Aerobic interval training group			Control group			
	Baseline *n* = 19 Mean	Week 12 *n* = 19 Mean	2 years *n* = 18 Mean	Baseline *n* = 11 Mean	Week 12 *n* = 11 Mean	2 years *n* = 8 Mean	*p*-value
Physical Functioning (PF)	68.4	78.2	75.9	66.3	65	47.9	0.33
Role-Physical (RP)	71.9	75	70.8	60	70	62.5	0.31
Bodily Pain (BP)	65.5	69.6	75.5	64.8	63.2	58.4	0.62
General Health (GH)	66	78.1[a,b]	66.8	64.3	53.6	44.1	0.61
Vitality (VT)	52.1	63.7[a,b]	57.5	65.6	61.9	42.9[a,b]	0.08
Social Functioning (SF)	85.5	92.1[a]	85.2	81.3	80.4	67.9	0.71
Role-Emotional (RE)	91.7	95.8	88.9	80	77.8	93.3	0.27
Mental Health (MH)	81.1	86.9[a,b]	84.7	82	79.5	73.1	0.91
Mental Component Score (MCS)	56.1	59[a]	57.6	55.4	54.9	51.4[a]	0.87
Physical Component Score (PCS)	44	47.1[a]	46.1	42.3	41.3	35.3	0.57

p-value in right-hand column refers to baseline data between groups (Mann-Whitney *U* test).
[a]$p < 0.05$ compared with baseline within group (Wilcoxon signed-rank test).
[b]$p < 0.01$ Bonferroni-corrected *p*-value within-group.

2-year follow-up in the AIT group, although the differences were no longer statistically significant. In the control group no significant changes occurred from baseline to week 12, but the VT and MCS scores significantly deteriorated from baseline to the 2-year follow-up.

Hospital Anxiety and Depression Scale

Table III shows the mean HADS scores on a group level. In the AIT group a significant reduction in HADS-D and HADS-S scores was recorded following the intervention compared with baseline. The differences were no longer statistically significant after adjusting for multiple comparisons. In the control group no significant changes were noted following the intervention; however, a significant increase in HADS-D score was noted at 2-year follow-up compared with baseline data within the group. HADS-D levels at week 12 and at 2-year follow-up were significantly higher in the control group compared with the AIT group at corresponding time-points.

There was a trend towards decreased HADS-A in the AIT group following the intervention, however at no time-point were any significant changes measured, either within- or between-groups.

On an individual level, at baseline 2 patients from the sedentary control group, but none in the training group, had HADS-A scores ≥ 8. Two patients from the sedentary and 3 from the training group had HADS-D scores ≥ 5.

At 12 weeks the same 2 control group patients had HADS-A scores ≥ 8, defined as caseness. Regarding the HADS-D score, 2 patients in the sedentary group and 1 in the training group scored ≥ 5. At 2-year follow-up 4 patients in the control group, compared with 5 patients in the training group, had HADS-D ≥ 5.

Assessment of lifestyle at follow-up

The 2-year follow-up survey detected differences in habits related to physical and sedentary activity in daily life (Fig. 2). The median time spent sitting during daytime was significantly higher in the control group; 585 min/day in the control group vs 340 min/day in the AIT group ($p = 0.04$). The AIT group reported more physical activity (median 1398 MET-min/week) compared with the sedentary control group (median 520 MET-min/week) at the 2-year follow-up; however, this difference between groups was not statistically significant ($p = 0.1$).

Hospitalizations and implantable cardioverter defibrillator shock during the 2-year follow-up period

In the AIT group the average rate of "any cause" hospitalization was one per patient over the 2-year period. Within the same group and time-frame, the hospitalization rate for a "cardiac cause" was 0.3 per patient. The matching data related to the control group was 0.8 and 0.4 hospitalizations, respectively. There were no statistically significant differences between groups.

Table III. *Hospital Anxiety and Depression Scale (HADS) scores at baseline, 12-week and 2-year follow- up*

	Aerobic interval training group			Control group			
	Baseline *n* = 19 Mean	Week 12 *n* = 19 Mean	2 years *n* = 18 Mean	Baseline *n* = 11 Mean	Week 12 *n* = 11 Mean	2 years *n* = 8 Mean	*p*-value
HADS (anxiety)	3.5	2.8	3.2	4.7	5.1	4.9	0.62
HADS (depression)	2.8	1.8[a, b]	2.7[b]	2.7	3.6	5.1[a]	0.91
HADS (total score)	6.3	4.6[a]	5.9	7.4	8.7	10.0	0.91

p-value in right-hand column refers to baseline data between groups (Mann-Whitney *U* test).
[a]$p < 0.05$ compared with baseline within group (Wilcoxon signed-rank test).
[b]$p < 0.05$ compared with control group at same time-point (Mann-Whitney *U* test). No statistically significant findings after Bonferroni corrections.
HADS: Hospital Anxiety and Depression Scale.

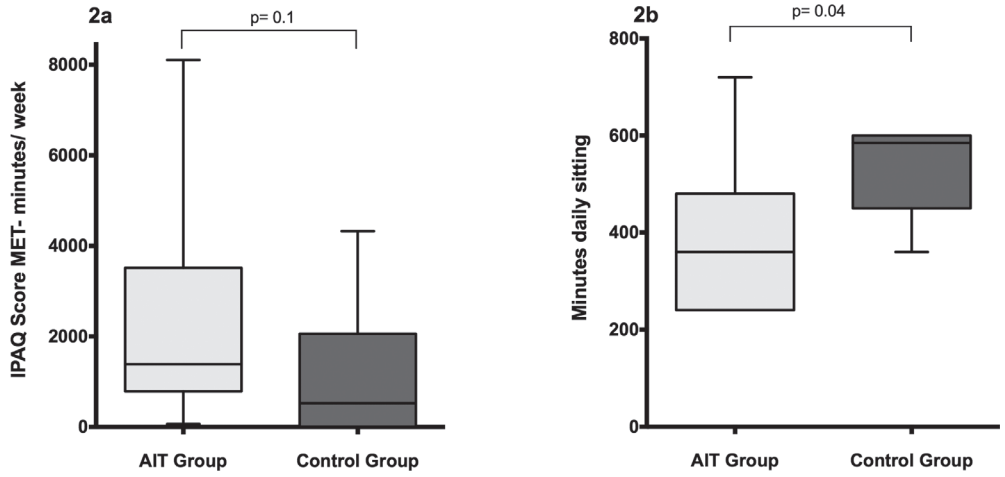

Fig. 2. (a) Total amount of physical activity in metabolic equivalent (MET)-min/week. (b) Time spent sitting daily during last week. Medians and 25th and 75th percentiles; whiskers indicate range. AIT: aerobic interval training; IPAQ: International Physical Activity Questionnaire.

No shocks occurred during the intervention in either group. During the follow-up period 6 ICD shocks were recorded in 4 patients in the control group and 7 shocks in 2 patients in the AIT group. Again, there was no significant difference ($p = 0.1$) between the 2 groups regarding ICD shocks.

DISCUSSION

The main finding in the current study was a significant improvement in self-reported QoL and unadjusted depressive symptoms following participation in the AIT programme. At 2-year follow-up sedentary control patients displayed significantly worsened QoL and an unadjusted increase in symptoms of depression. In contrast, the AIT patients did not experience this deterioration. There was a trend towards more physical activity and significantly less sedentary activity in the AIT group at follow-up.

This is the first study among HF patients with an ICD demonstrating short- and long-term beneficial effects of a group-based AIT programme on measures of depression and QoL.

Early assessment of Hospital Anxiety and Depression Scale and quality of life

Several item scores of the SF-36 questionnaire improved following the intervention in the AIT group, notably the GH, VT, SF, MH, PCS and MCS. A small non-controlled study from 2008 did not show any significant impact on QoL following an ET intervention (14). A recent study (16) with combined moderate continuous ET and a psycho-educational intervention found significant improvements only in the GH and MCS components of the SF-36.

Baseline levels of anxiety and depressive symptoms were quite low in this population compared with similar populations reported in other studies (8). Participating in a 12-week AIT programme did, however, lead to an unadjusted significant decrease in symptoms of depression, as demonstrated by reduced HADS-D scores compared with baseline scores, as well as compared with sedentary control patients.

A report on ET in ICD patients from 2003 also demonstrated significant reductions in both HADS-A and HADS-D scores following participation (15). However, that study also implemented the use of a health psychologist to educate patients about coping strategies. The ET modality was also different, employing moderate continuous exercise. In the current study AIT is the sole form of intervention. A recent study demonstrating a 2-fold increase in all-cause mortality among depressed ICD patients, underlines the importance of improving this psychological state (29).

Two-year follow-up assessment of Hospital Anxiety and Depression Scale, quality of life and level of physical activity

SF-36 scores remained stable to a great extent in the AIT group at follow-up, although the improvements from baseline were no longer statistically significant. Interestingly, in our study the control group experienced a significant deterioration in some subscores at follow-up. Similarly, the HADS-D score remained stable in the AIT group, while an unadjusted statistically significant deterioration occurred in the sedentary control group at follow-up 2 years later.

A recent publication did not reveal any long-term impact of cardiac rehabilitation on rate of hospitalizations and ICD shocks (30). Similarly, in our study, no differences in statistical significance were found regarding hospitalizations and ICD shock rates during follow-up. However, there was a trend towards more shocks in the control population during follow-up ($p = 0.1$). We repeated the statistical analysis in the control group excluding the 4 patients who received shocks during follow-up. Although still a trend towards worsened QoL (VT $p = 0.06$ and MCS $p = 0.1$) and HADS-D ($p = 0.06$), the results were no longer statistically significant. Caution must, however, be applied in dealing with analyses of such small numbers of subjects. Although the literature is not uniform, ICD shocks have been demonstrated to negatively affect both QoL and symptoms of depression (31), possibly explaining some of the decline in psychosocial functioning at follow-up in the control group.

In addition to more physical activity in the AIT group at follow-up, these patients also reported significantly less sedentary activity (Fig. 2). The HADS and SF-36 scores remained stable at follow-up in the AIT group. It is possible that some *psychological* effects of the AIT intervention in this ICD population may persist beyond the effects measured through peak oxygen uptake. The rationale for this may be that the exposure to intense AIT sessions reduces fear of exertion-induced shock, related to everyday activities, sexual activity and ET. This is in accordance with findings of increased confidence to engage in physical exertion and on psychosocial benefits related to ET programme participation among patients with an ICD (17). These effects may manifest as reduced levels of depressive symptoms as well as improved measures of QoL in the long term.

Study limitations

This study has some limitations. First, the study size is relatively small despite the long recruitment period. Secondly, due to the single-centre design and frequent AIT sessions, logistic reasons prevented us from employing a randomized design. A selection bias thus cannot be excluded, although the patient's ability to attend the AIT programme for 12 weeks was the only criterion used to group the patients.

Conclusion

Participation in a 12-week AIT programme significantly improved measures of QoL in patients with an ICD. The AIT intervention also led to an unadjusted decrease in depressive symptoms. At the 2-year follow-up, a significant unadjusted deterioration in depressive symptoms and some QoL scores occurred in the control group, while results in the AIT group remained stable or moved towards baseline values. The AIT group reported significantly less sedentary activity at follow-up compared with the control group.

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