

Implantable Cardioverter Defibrillator (ICD) – Get ready to care for more patients

Should we encourage ICD patients to exercise?

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-There is no conflict of interest-

Should we encourage ICD patients to exercise?

1. Why?- is it evidence based?
2. What about combined devices?
3. Magnitude of the problem vs participation
4. Conclusion and Future

Should we encourage ICD patients to exercise?

1. Why?- is it evidence based?
2. *What about combined devices?*
3. *Magnitude of the problem vs participation*
4. *Conclusion and Future*

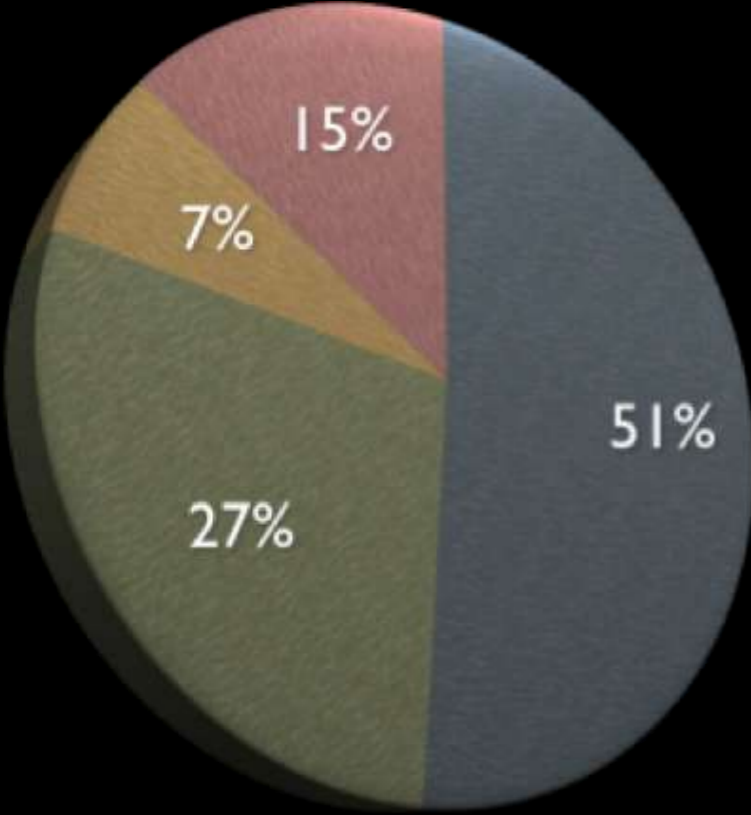
Should we encourage ICD patients to exercise?

Managing total CVD risk- PHYSICAL ACTIVITY

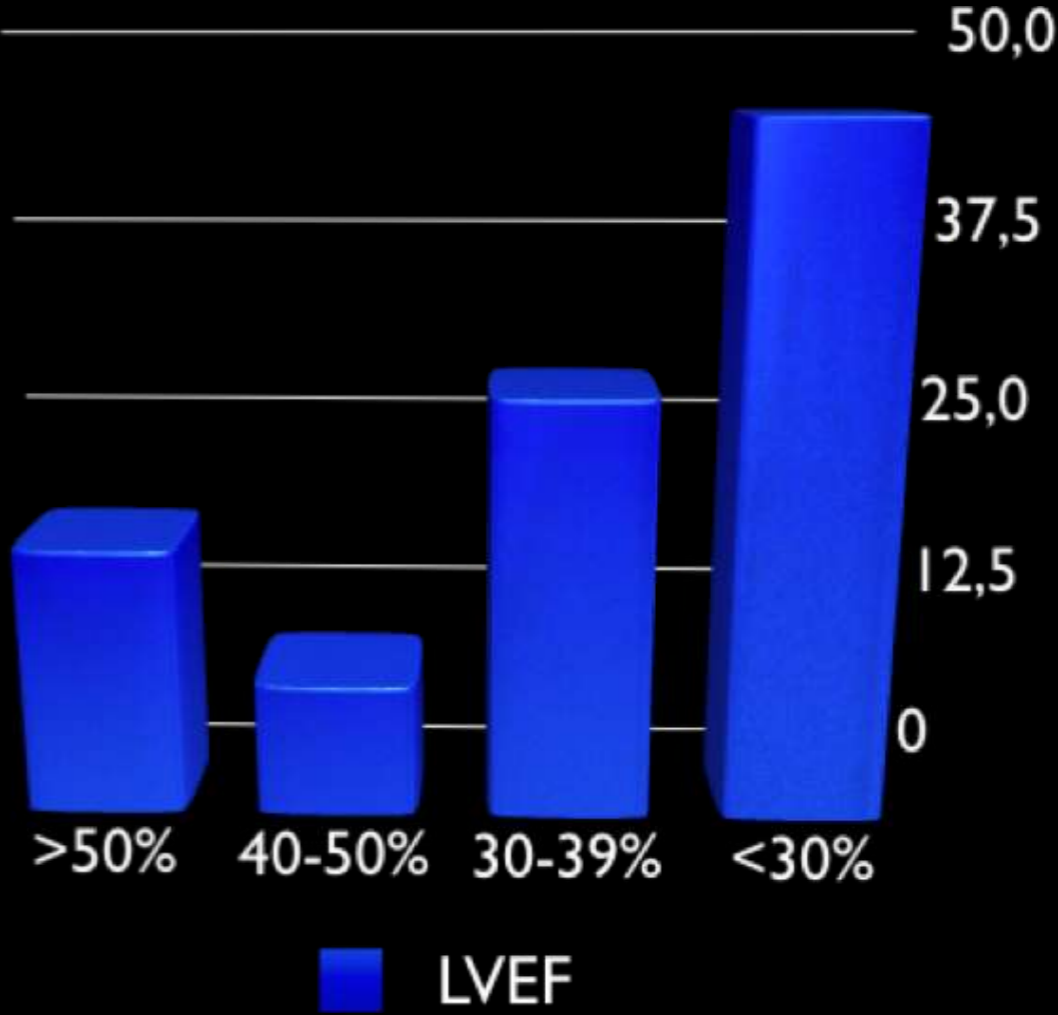
- (1) Stress that the positive health benefits occur with almost any increase in activity; small amounts of exercise have an additive effect; exercise opportunities exist in the workplace, for example by using stairs instead of the lift.
- (2) Try to find leisure activities that are positively enjoyable.
- (3) 30 minutes of moderately vigorous exercise on most days of the week will reduce risk and increase fitness.
- (4) Exercising with family or friends tends to improve motivation.
- (5) Added benefits include a sense of well being, weight reduction and better self esteem.
- (6) Continued physician encouragement and support may help in the long-term.

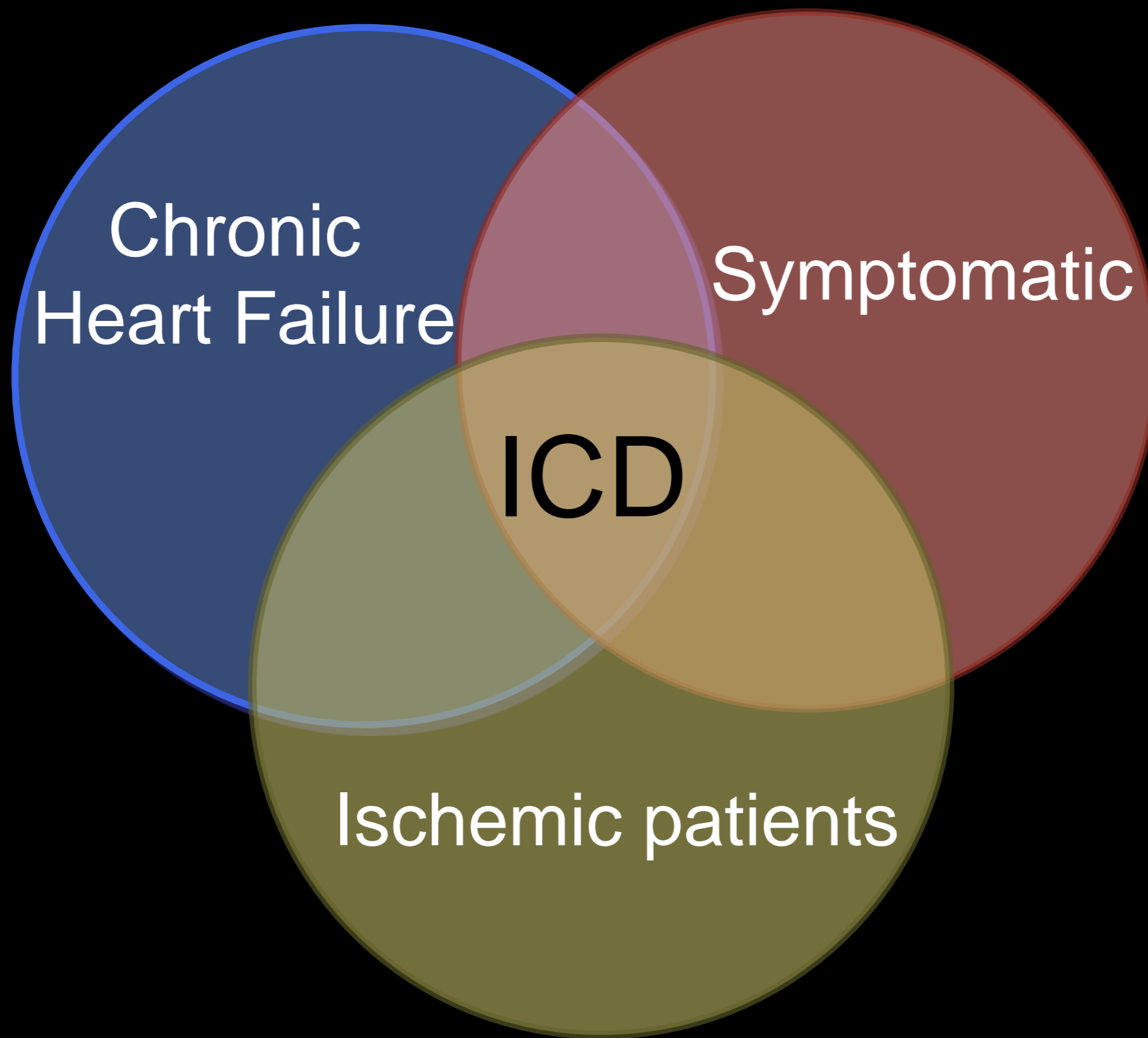
Spanish Implantable Cardioverter-Defibrillator Registry. Sixth Official Report of the Spanish Society of Cardiology Working Group on Implantable Cardioverter-Defibrillators (2009)

Alzueta J, et al. Rev Esp Cardiol. 2010;63(12):1468-81



- Ischemic
- Dilated CMP
- Hypertrophic
- Others





Chronic
Heart Failure

Symptomatic

ICD

Ischemic patients

Goals

General

- reduce mortality
- improve ex capacity
- improve quality of life

Specific

- safe
- reduce arrhythmia
- psychological effects

Exercise-based rehabilitation for coronary heart disease.

Jolliffe J, et al. Cochrane Database of Systematic Reviews 2001, Issue 1. Art. No.: CD001800.

Main results

This systematic review has allowed analysis of an increased number of patients from approximately 4500 in earlier meta-analyses to 8440 (7683 contributing to the total mortality outcome).

The pooled effect estimate for total mortality for the exercise only intervention shows a 27% reduction in all cause mortality (random effects model OR 0.73 95% confidence interval 0.54 to 0.98). Comprehensive cardiac rehabilitation reduced all cause mortality, but to a lesser degree (OR 0.87 95% confidence interval 0.71 to 1.05). Total cardiac mortality was reduced by 31% (random effects model OR 0.69 95% confidence interval 0.53 to 0.94) and 26% (random effects model OR 0.74 95% confidence interval 0.57 to 0.96) in the exercise only and comprehensive cardiac rehabilitation groups respectively. We found no evidence of an effect of the interventions on the occurrence of non-fatal myocardial infarction. There was a significant net reduction in total cholesterol (pooled WMD random effects model -0.57 mmol/l 95% confidence interval -0.83 to -0.31) and LDL (pooled WMD random effects model -0.51 mmol/l 95% confidence interval -0.82 -0.19) in the comprehensive cardiac rehabilitation group.

Exercise rehabilitation for heart failure.

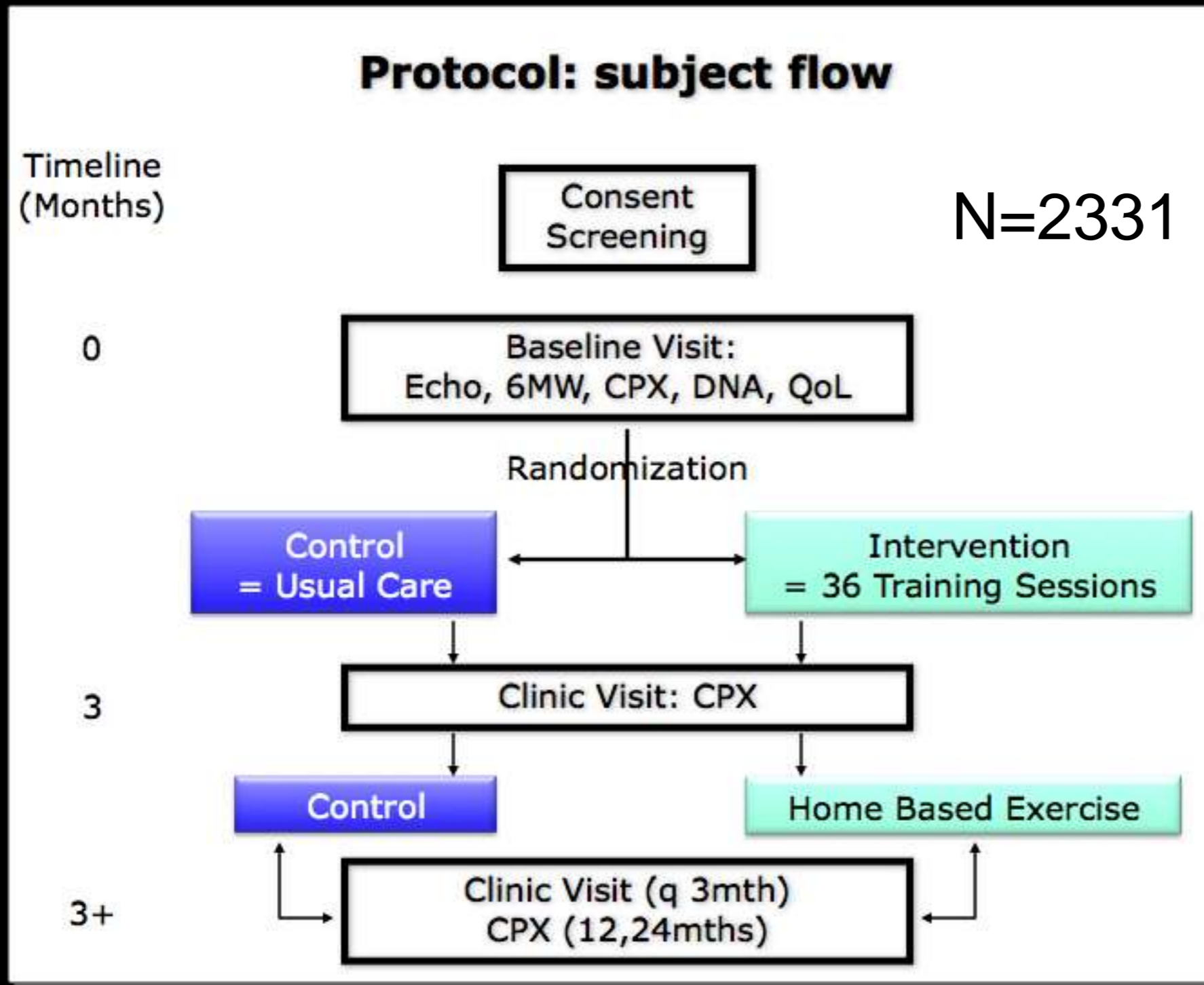
Rees K, et al. Cochrane Database Syst Rev. 2010;4:CD003331.

Main results

Twenty-nine studies met the inclusion criteria, with 1126 patients randomised. The majority of studies included both patients with primary and secondary heart failure, NYHA class II or III. Only one study specifically examined the effect of exercise training on mortality and morbidity. Exercise training significantly increased VO_2 max by (WMD random effects model) 2.16 ml/kg/min (95% CI 2.82 to 1.49), exercise duration increased by 2.38 minutes (95% CI 2.85 to 1.9), work capacity by 15.1 Watts (95% CI 17.7 to 12.6) and distance on the six minute walk by 40.9 metres (95% CI 64.7 to 17.1). Improvements in VO_2 max were greater for training programmes of greater intensity and duration. HRQoL improved in the seven of nine trials that measured this outcome.

Efficacy and safety of exercise training in patients with CHF: HF-ACTION randomized controlled trial.

O'Connor CM, et al. JAMA 2009;301:1439-1450

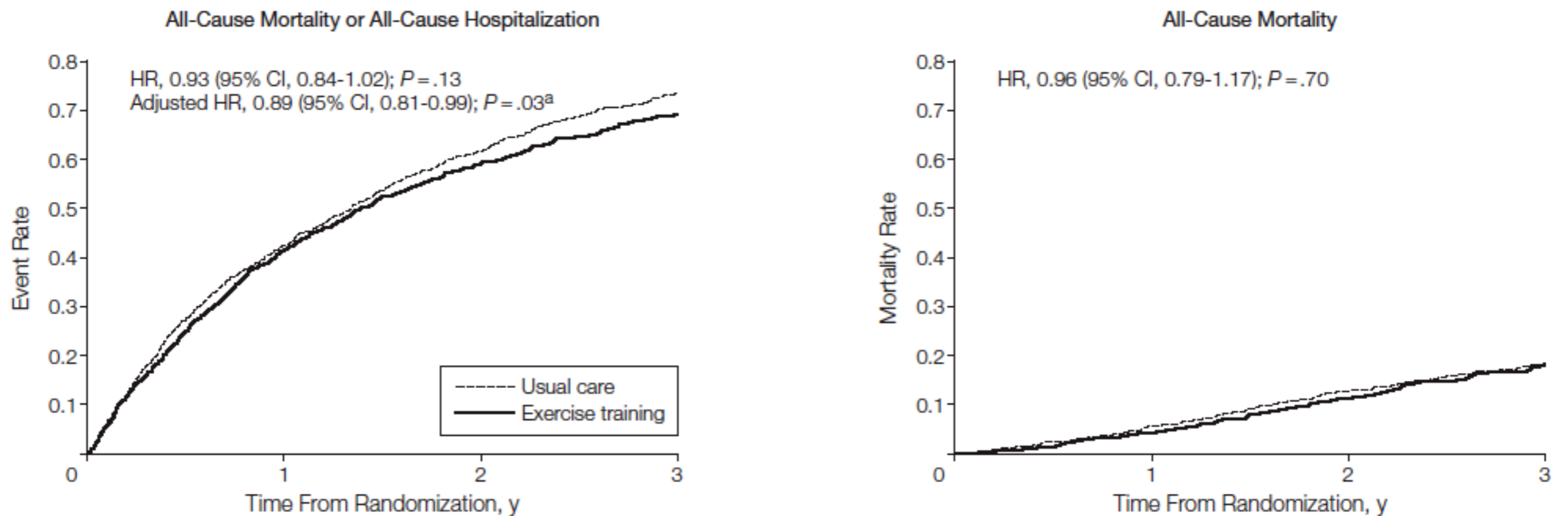


NYHA II-IV
LVEF \leq 35%

Efficacy and safety of exercise training in patients with CHF: HF-ACTION randomized controlled trial.

O'Connor CM, et al. JAMA 2009;301:1439-1450

Figure 2. Time to All-Cause Mortality or All-Cause Hospitalization and to All-Cause Mortality



No. at risk		0	1	2	3
Usual care	1172	651	337	146	
Exercise training	1159	656	352	167	

No. at risk		0	1	2	3
Usual care	1172	1067	760	455	
Exercise training	1159	1084	758	444	

CI indicates confidence interval; HR, hazard ratio.

^aAdjusted for key prognostic factors.

Efficacy and safety of exercise training in patients with CHF: HF-ACTION randomized controlled trial.

O'Connor CM, et al. JAMA 2009;301:1439-1450

Table 4. Change in 6-Minute Walk Test and Cardiopulmonary Exercise Test Results

	Median (IQR)		P Value
	Usual Care	Exercise Training	
Baseline to 3 mo ^a			
Distance of 6-minute walk, m (n = 1835)	5 (-28 to 37)	20 (-15 to 57)	<.001
Cardiopulmonary exercise time, min (n = 1914)	0.3 (-0.6 to 1.4)	1.5 (0.3 to 3.0)	<.001
Peak oxygen consumption, mL/kg/min (n = 1870)	0.2 (-1.2 to 1.4)	0.6 (-0.7 to 2.3)	<.001
Baseline to 12 mo ^b			
Distance of 6-minute walk, m (n = 1444)	12 (-30 to 55)	13 (-28 to 61)	.26
Cardiopulmonary exercise time, min (n = 1476)	0.2 (-1.0 to 1.7)	1.5 (0 to 3.2)	<.001
Peak oxygen consumption, mL/kg/min (n = 1442)	0.1 (-1.5 to 1.8)	0.7 (-1.0 to 2.5)	<.001

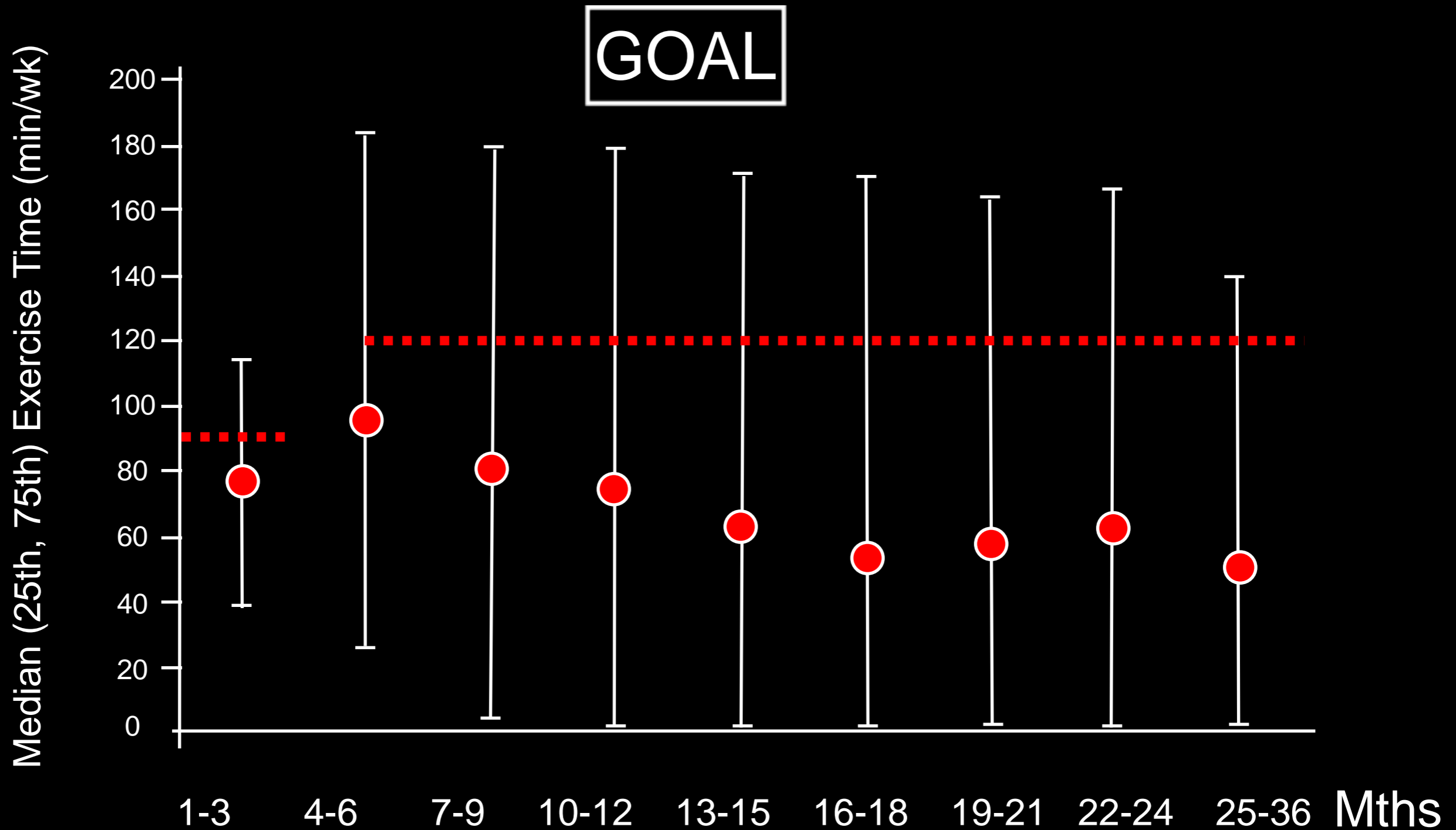
Abbreviation: IQR, interquartile range.

^aComplete case analysis. Expected 2284 patients at 3 months.

^bComplete case analysis. Expected 2159 patients at 12 months.

Efficacy and safety of exercise training in patients with CHF: HF-ACTION randomized controlled trial.

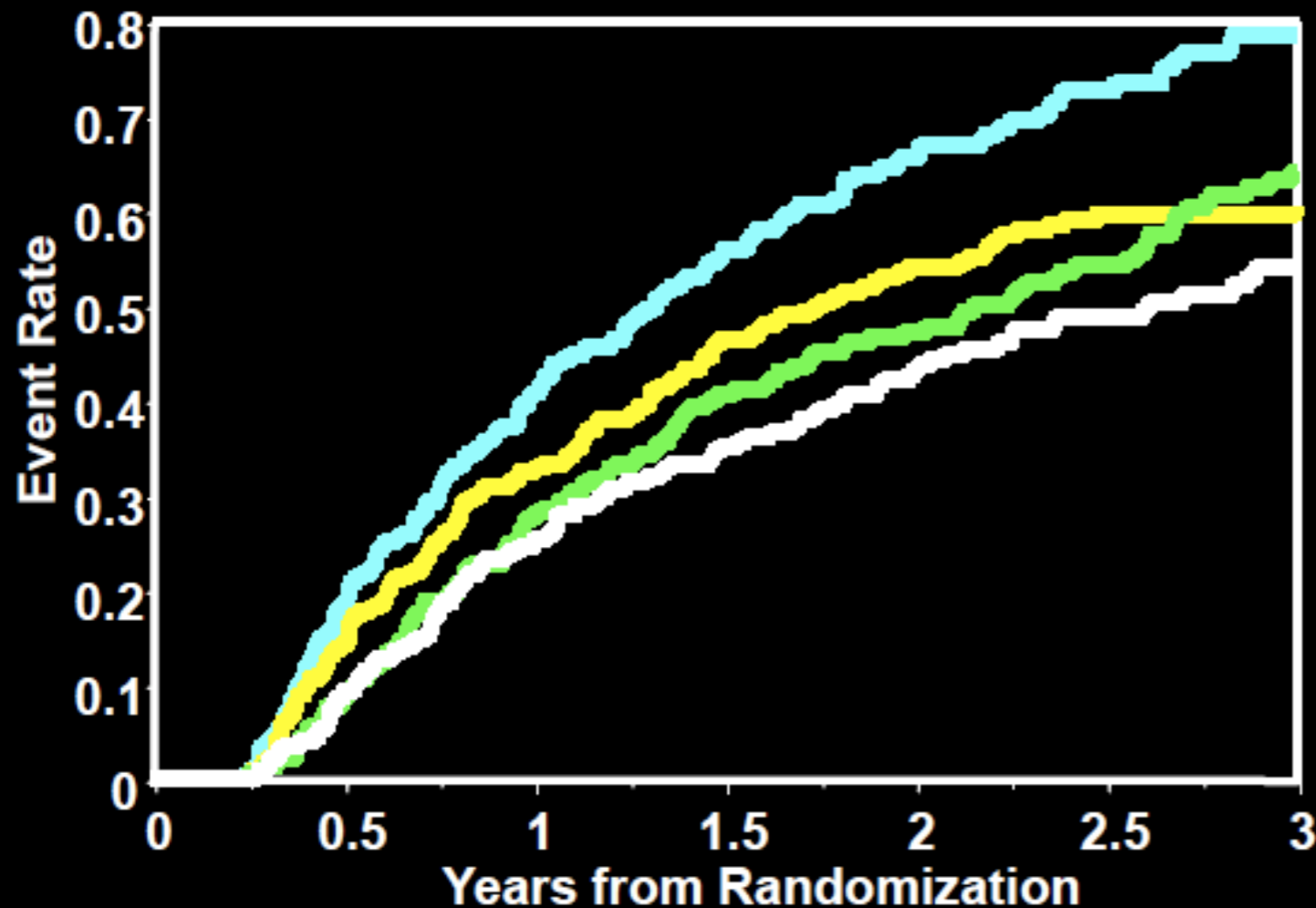
O'Connor CM, et al. JAMA 2009;301:1439-1450



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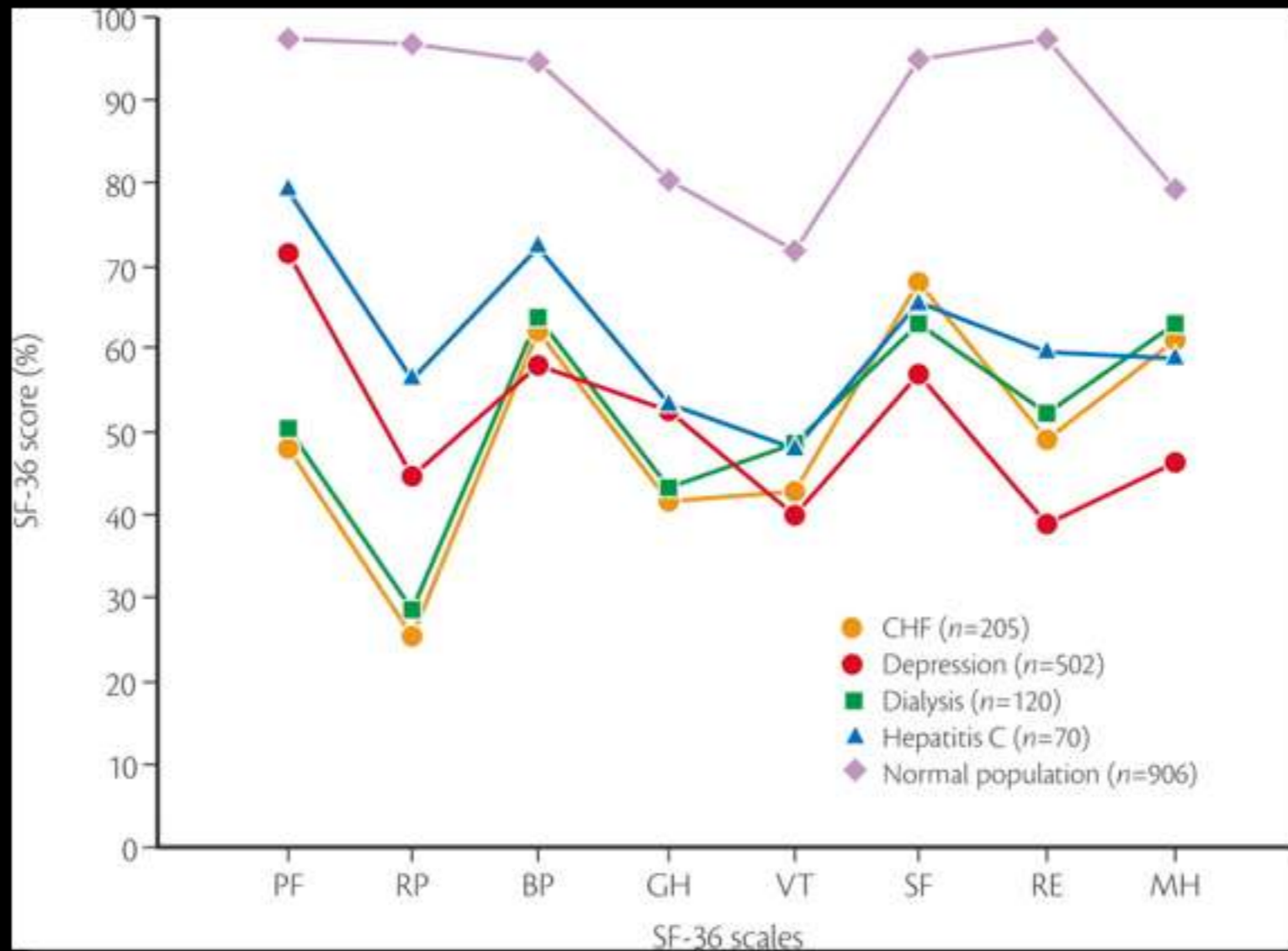
Unadjusted Kaplan-Meier Curves of the Primary
Endpoint by Quartiles of MET-hr/wk



	MET-hr/wk
Quartile 1	≤ 1.9
Quartile 2	$1.9 < 3.9$
Quartile 3	$3.9 < 6.2$
Quartile 4	> 6.2

1 MET=3.5ml/kg/min O₂ consumption

Chronic Heart Failure and QoL



Goals

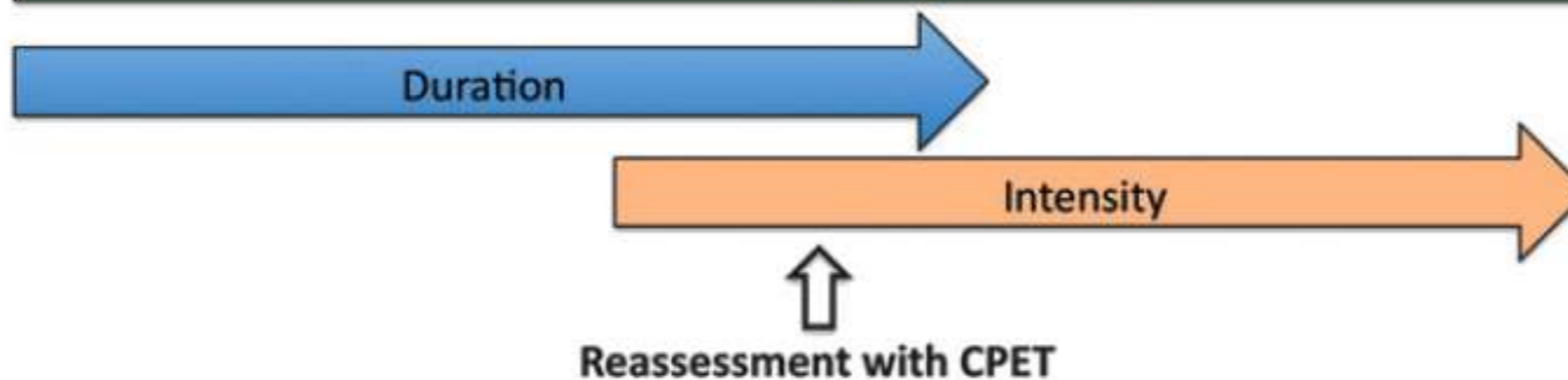
General

- reduce mortality
- improve ex capacity
- improve quality of life

Specific

- safe
- reduce arrhythmia
- psychological effects

5-10' warming-up		
severely debilitated	moderate	mild impairment
$\text{VO}_{2\text{peak}} < 10\text{ml/kg/min}$	$\text{VO}_{2\text{peak}} 10\text{-}18\text{ml/kg/min}$	$\text{VO}_{2\text{peak}} > 18\text{ ml/kg/min}$
Intensity (% $\text{VO}_{2\text{peak}}$)		
40-50%		60-80%
Duration		
5-10' (1 or several times/d)	15' (1-2/d)	30' (3-5/wk)
5-10' cooling-down		



- HR response to exercise
- Exercise induced arrhythmia
- Patient reassurance
- Exercise prescription

Safety of symptom-limited cardiopulmonary exercise testing in patients with chronic heart failure due to severe left ventricular systolic dysfunction.

Keteyian S, et al. Am Heart J 2009;158 (4Suppl): S72-S77

N=4411 CPET

└─ 40% ICD

└─ 293 ICDs fired once
688 discharges/2.5yr

1 VFib - next day
1 Sust. VTach - next day
No ex-related discharge

Precautions: stop early if 3-5 beats runs, 5-10 beats below treatment zone, deactivate ICD or increase ventricular discharge rate

Effect of exercise training in patients with an implantable cardioverter defibrillator. *Vanhees L, et al. Eur Heart J 2004;25:120*

2 centres
Leuven,
Leiden

N=106, eligible

4 dropouts,
6 non CV
morbidity
4 V tach

N=92 ICD

N=473 matched controls (1942)

Exercise training - 3 months - 3x90min/week
CPET: baseline/after 3 months
ICD: HR limit 20beats below threshold

Effect of exercise training in patients with an implantable cardioverter defibrillator. *Vanhees L, et al. Eur Heart J 2004;25:120*

Table 1 Patient characteristics

Variable	Control	ICD	p-Value	Total cohort
Number of patients (m/f)	473 (428/45)	92 (79/13)	0.18	1942 (1797/145)
Age (years)	56 ± 7.8	57 ± 12	0.37	55 ± 9.3
Body mass index (kg m ⁻²)	25.4 ± 2.8	25.9 ± 3.5	0.79	25.4 ± 3.1
Underlying heart disease				
Ischaemic heart disease				
AMI	351 (74%)	63 (68%)	0.26	1277 (66%)
CABG	116 (25%)	20 (22%)	0.57	712 (37%)
PTCA	109 (23%)	25 (27%)	0.39	558 (29%)
Valvular disease (artificial replacement)				
	29 (6%)	6 (5%)	0.80	101 (5%)
Cholesterol level (mg/100 ml)	226 ± 48	212 ± 40	0.009	223 ± 44
History of hypertension	115 (24%)	19 (20.6%)	0.45	495 (25.5%)
Family history for IHD	88 (19%)	14 (15%)	0.44	415 (21.4%)
ST-depression during exercise testing	80 (17%)	2 (2%)	0.001	288 (15%)
Smoking habits				
Current smoking	32 (7%)	7 (8%)	0.77	116 (6%)
Past smoking	371 (78%)	54 (59%)	0.001	1450 (75%)
Complaints in daily life				
Dyspnoea	71 (15%)	27 (29%)	0.001	335 (17%)
Angina pectoris	30 (6%)	3 (3%)	0.25	110 (6%)

LVEF only in 1/3 ICD patients
LVEF < 40%: 68% vs 13% (p < 0.001)

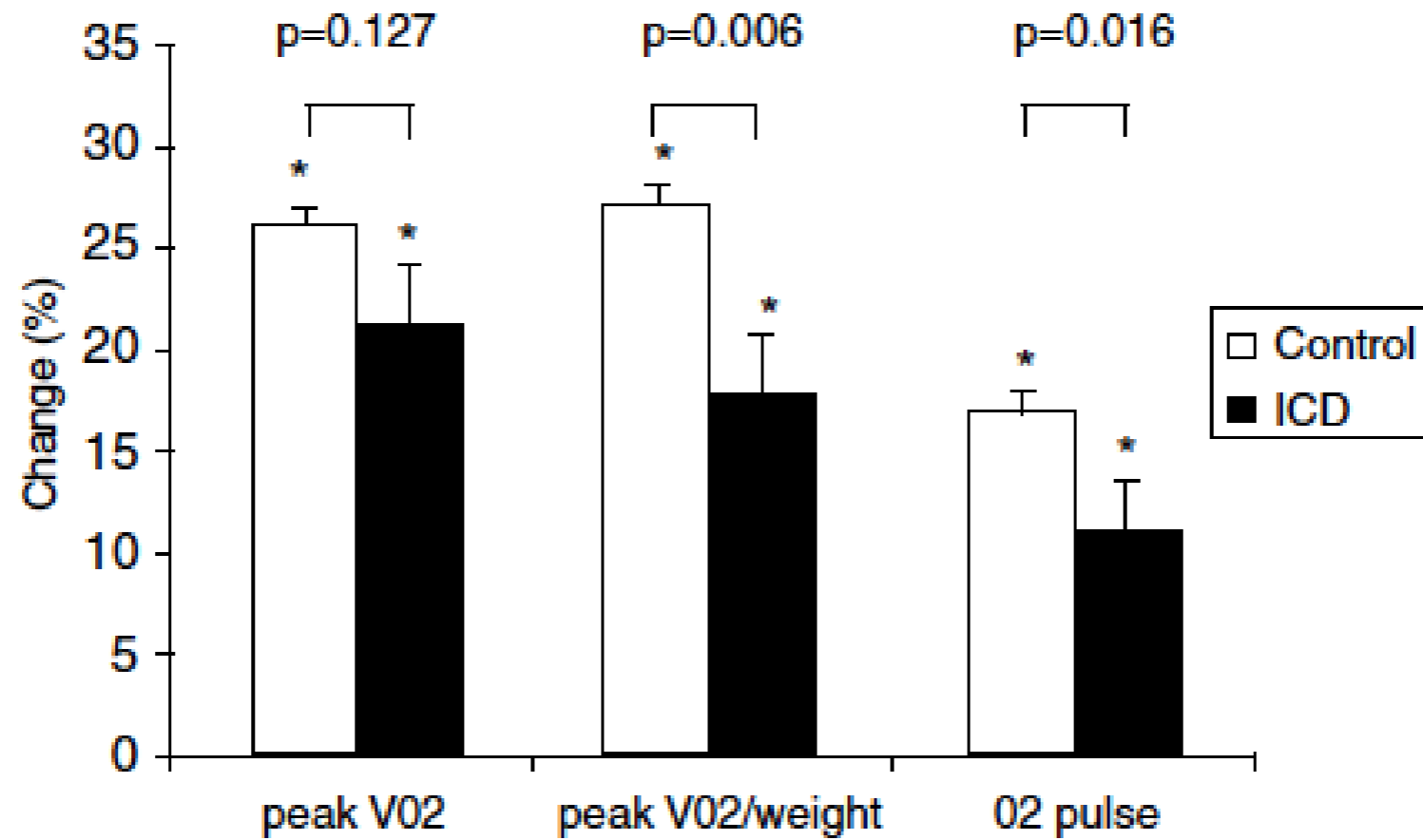
Effect of exercise training in patients with an implantable cardioverter defibrillator. *Vanhees L, et al. Eur Heart J 2004;25:120*

Table 2 Results of the baseline exercise test

Variable	Control group (n = 473)	ICD group (n = 92)	p-Value
Data at rest and submaximal exercise			
Heart rate (beats min ⁻¹)	67 ± 12	67 ± 13	0.91
Systolic blood pressure (mmHg)	129 ± 19	132 ± 24	0.24
Diastolic blood pressure (mmHg)	80 ± 12	81 ± 12	0.31
Heart rate at 80 W (beats min ⁻¹)	105 ± 16	101 ± 19	0.10
Data at peak exercise			
VO ₂ (ml min ⁻¹)	1705 ± 466	1417 ± 539	0.0001
VO ₂ (ml min ⁻¹ kg ⁻¹)	22.2 ± 5.6	17.7 ± 6.1	0.0001
Oxygen pulse (ml beat ⁻¹)	13.3 ± 3.1	12.4 ± 4.9	0.0002
Heart rate (beats min ⁻¹)	128 ± 22	117 ± 23	0.0001
RER (VCO ₂ /VO ₂)	1.10 ± 0.10	1.08 ± 0.13	0.10
V _E O ₂ (V _E /VO ₂)	36.2 ± 6.7	39.6 ± 8.4	0.0002

Data are presented as mean ± SD and as the p-value of the difference in the baseline result between both groups. Comparisons between groups are made by means of unpaired *t* test or Wilcoxon signed rank test. ICD, implantable cardioverter defibrillator; VO₂, oxygen uptake; RER, respiratory gas exchange ratio; VCO₂, carbon dioxide output; V_EVO₂, ventilatory equivalent for oxygen; V_E, ventilation.

Effect of exercise training in patients with an implantable cardioverter defibrillator. *Vanhees L, et al. Eur Heart J 2004;25:120*



Effect of exercise training in patients with an implantable cardioverter defibrillator. *Vanhees L, et al. Eur Heart J 2004;25:120*

2 centres
Leuven,
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N=106, eligible

4 dropouts,
6 non CV
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4 V tach

N=92 ICD

N=473 matched controls

17-20%	VPB (2-3-runs)	10-10%
1	VT-shock-CPET	
1	VT-shock-Training	
6	Inter-ex shocks	
1	Inappr shock	

Effect of exercise training in patients with an implantable cardioverter defibrillator. *Vanhees L, et al. Eur Heart J 2004;25:120*

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6	Inter-ex shocks	
1	Inappr shock	
55%	Beta-blocker	78%

Risk of Ventricular Arrhythmia After Implantable Defibrillator Treatment in Anxious Type D Patients

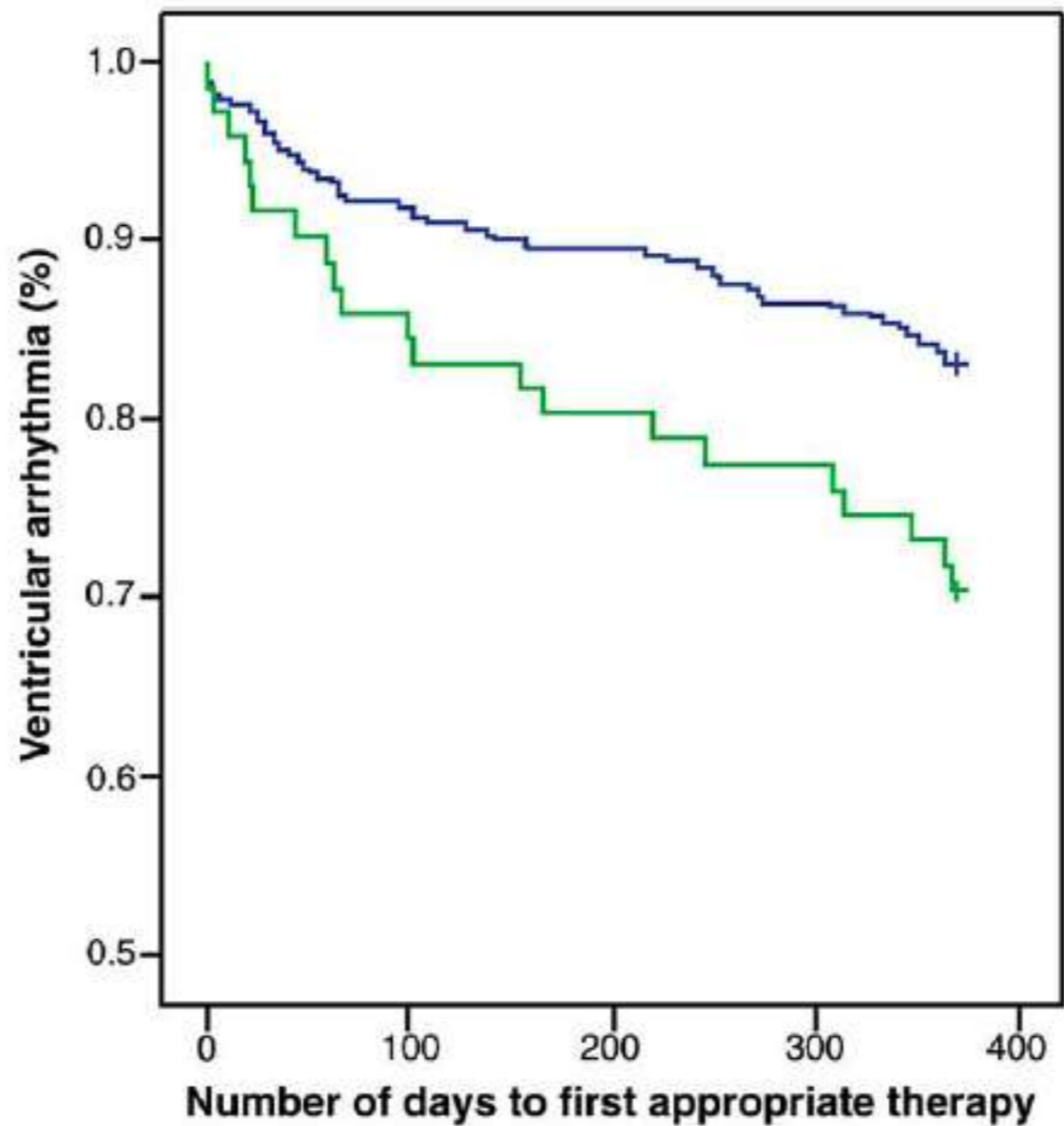
Van den Broek KC, et al. J Am Coll Cardiol 2009;54:531

N=391

Prim/sec prevention: 57/43%

STAI, BDI, DS14

	Ventricular Arrhythmias		
	HR	95% CI	p Value*
Male	1.02	0.56–1.86	0.94
Age	0.98	0.96–1.01	0.16
Secondary prevention	1.91	1.14–3.20	0.014
Nonischemic etiology	1.08	0.61–1.92	0.80
Severely decreased ejection fraction†	1.30	0.63–2.67	0.47
Prolonged QRS duration‡	0.98	0.59–1.61	0.92
No prescription of angiotensin-converting enzyme inhibitor	1.05	0.62–1.76	0.86
No prescription of beta-blocker	1.54	0.89–2.66	0.12
Anxious Type D cluster	1.72	1.03–2.89	0.039



Blue line	320	294	286	277	265
Green line	71	60	57	55	49

Figure 1

Kaplan-Meier Curve for Time to First Ventricular Arrhythmia in Type D Patients With Increased Anxiety ($p = 0.012$)

Other groups (blue line); anxious Type D patients (green line).

The Effect of Exercise Training on Anxiety Symptoms Among Patients

A Systematic Review

Matthew P. Herring, MS, MEd; Patrick J. O'Connor, PhD; Rodney K. Dishman, PhD

Background: Anxiety often remains unrecognized or untreated among patients with a chronic illness. Exercise training may help improve anxiety symptoms among patients. We estimated the population effect size for exercise training effects on anxiety and determined whether selected variables of theoretical or practical importance moderate the effect.

Methods: Articles published from January 1995 to August 2007 were located using the Physical Activity Guidelines for Americans Scientific Database, supplemented by additional searches through December 2008 of the following databases: Google Scholar, MEDLINE, PsycINFO, PubMed, and Web of Science. Forty English-language articles in scholarly journals involving sedentary adults with a chronic illness were selected. They included both an anxiety outcome measured at baseline and after exercise training and random assignment to either an exercise intervention of 3 or more weeks or a comparison condition that lacked exercise. Two co-authors independently

calculated the Hedges *d* effect sizes from studies of 2914 patients and extracted information regarding potential moderator variables. Random effects models were used to estimate sampling error and population variance for all analyses.

Results: Compared with no treatment conditions, exercise training significantly reduced anxiety symptoms by a mean effect Δ of 0.29 (95% confidence interval, 0.23-0.36). Exercise training programs lasting no more than 12 weeks, using session durations of at least 30 minutes, and an anxiety report time frame greater than the past week resulted in the largest anxiety improvements.

Conclusion: Exercise training reduces anxiety symptoms among sedentary patients who have a chronic illness.

Comprehensive cardiac rehabilitation programme for implantable cardioverter-defibrillator patients: a randomised controlled trial

Fitchet A, et al. Heart 2003;89:155

N=16, training 12wks - detraining 12wks

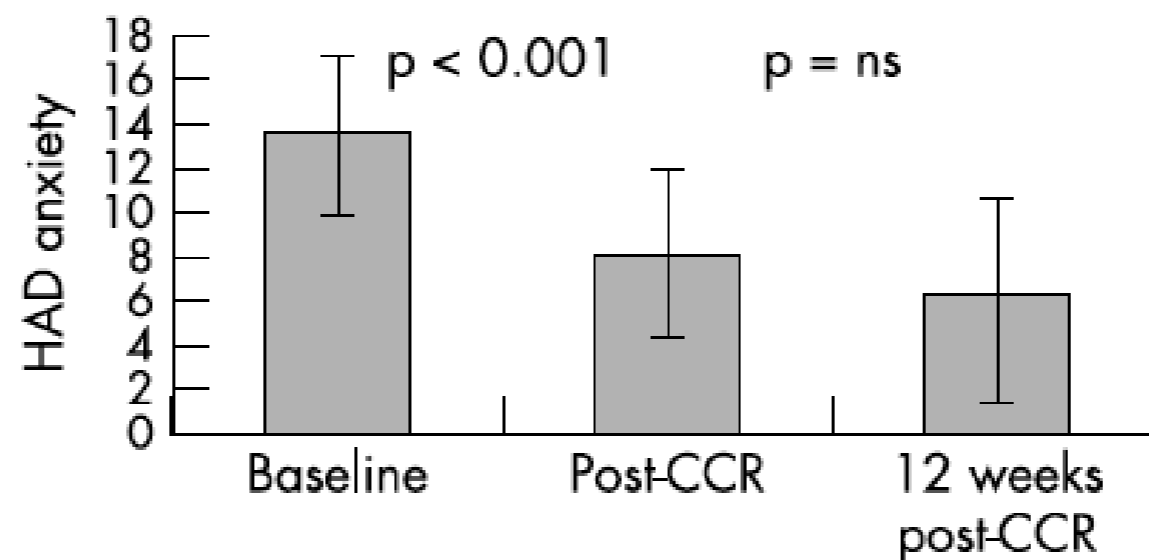


Figure 3 Hospital anxiety and depression (HAD) scores for anxiety. Values are means for the 11 patients who completed the comprehensive cardiac rehabilitation (CCR) and all the exercise tests. Error bars = SD.

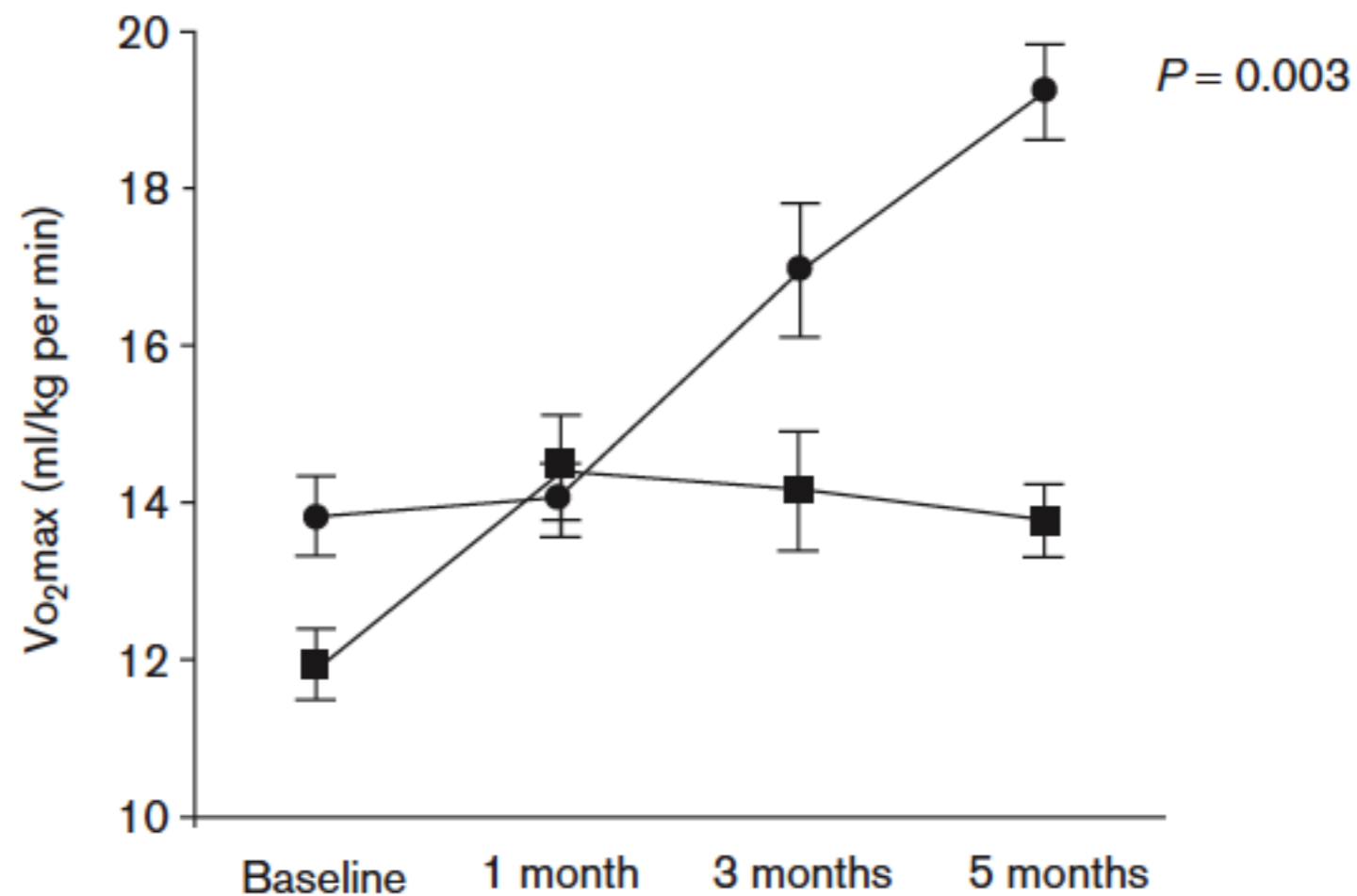
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The effect of endurance training on exercise capacity following cardiac resynchronization therapy in chronic heart failure patients; a pilot trial.

Conraads V, et al. *Eur J Cardiovasc Prev Rehabil* 2007;14:99

Fig. 2



Evolution of Vo_2max for the CRT+ (pharmacological therapy plus exercise training programme; ●) and CRT- (pharmacological therapy only; ■) groups.

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European utilization of the implantable defibrillator: has 10 years changed the 'enigma'?

John Camm A, et al. Europace 2010;12:1063

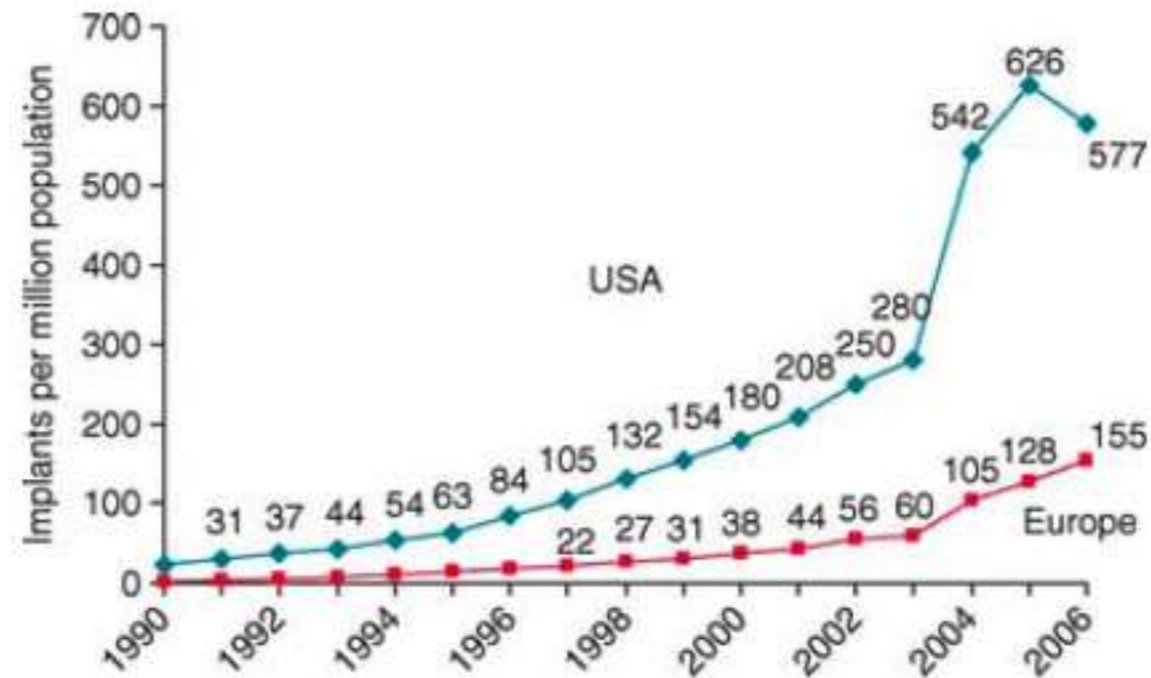


Figure 1 Implantable cardioverter defibrillator/CRT-D implantations per million of the population in Europe and the USA from 1990 to 2006.

European utilization of the implantable defibrillator: has 10 years changed the 'enigma'?

John Camm A, et al. Europace 2010;12:1063

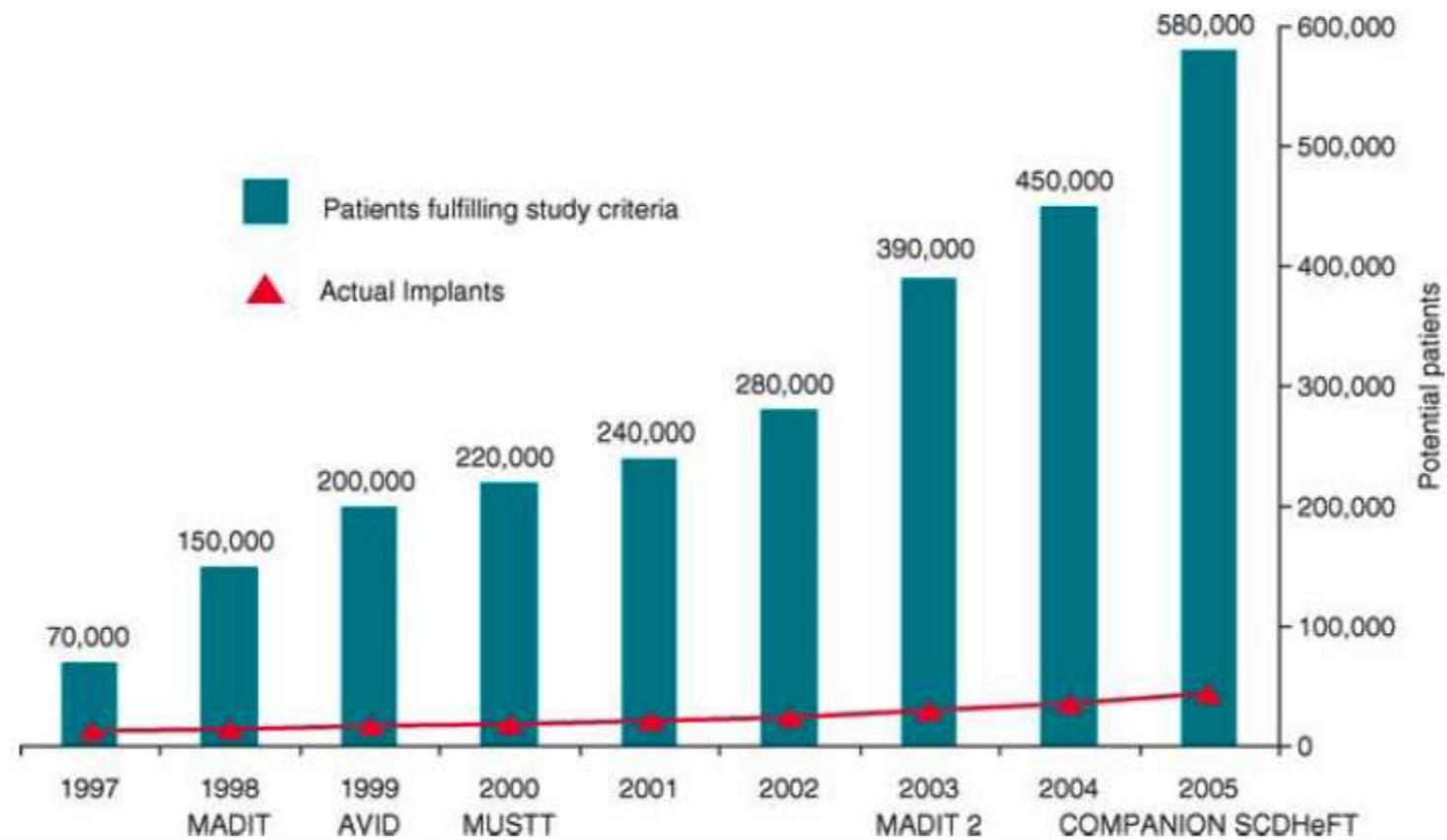


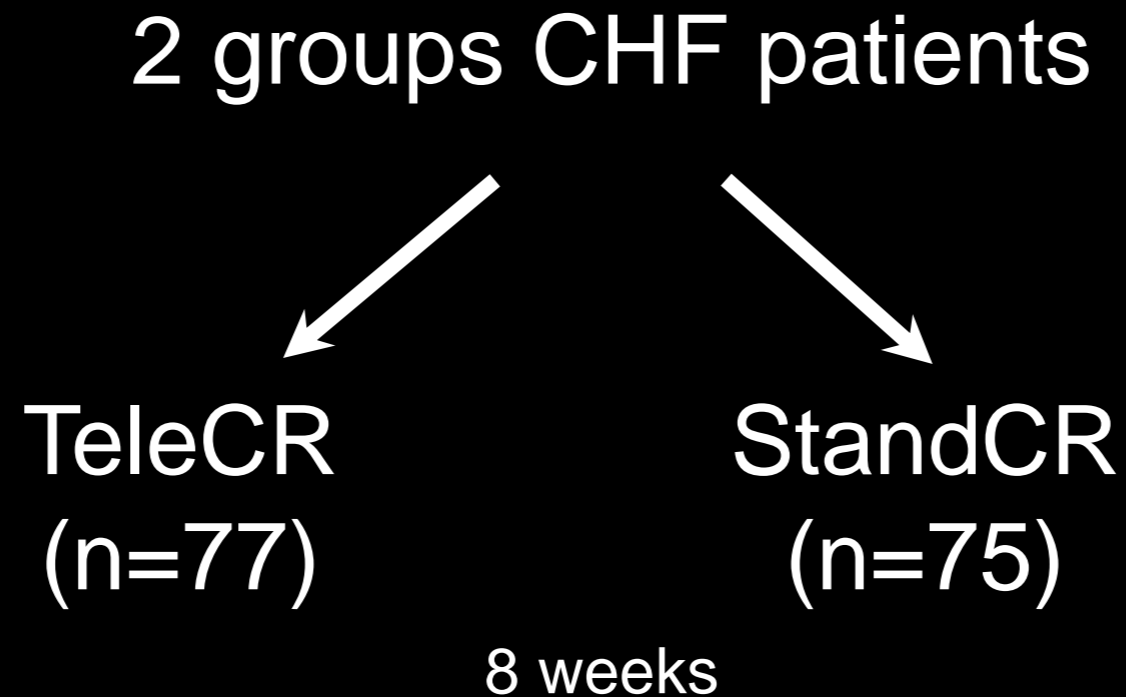
Figure 4 Percentage of patients fulfilling the criteria for the major randomized implantable cardioverter defibrillator (ICD) trials, which actually get implanted with ICDs in Western Europe. The histograms represent the total number of patients (W. Europe), who fulfil the study criteria. [In case of overlapping criteria, the patients are only counted once (the earlier indication); patients with high co-morbidity due to cancer or other diseases have been excluded.] The triangles represent the actual number of patients, corresponding to a given study, who were implanted with ICDs in the years indicated. Analysis from Ref. 17.

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A new model of home-based telemonitored cardiac rehabilitation in patients with heart failure: effectiveness, quality of life, and adherence.

Piotrowicz E, et al. Eur J Heart Fail 2010;12:164-171



30.2 + 8.2%	LVEF	30.8 + 6.7%
50/50%	NYHA II/III	55/45%
17.8 + 4.1	VO ₂ peak (ml/kg/min)	17.9 + 4.4

A new model of home-based telemonitored cardiac rehabilitation in patients with heart failure: effectiveness, quality of life, and adherence.

Piotrowicz E, et al. *Eur J Heart Fail* 2010;12:164-171

Table 3 Comparison of outcomes before and after cardiac rehabilitation

	HTCR group n=75		SCR group n=56		P ₁ -value	P ₂ -value
	Before	After	Before	After		
NYHA class	2.5 ± 0.5	2.1 ± 0.5	2.5 ± 0.5	2.3 ± 0.5	0.0001	0.0070
Six-minute walking test						
Distance (m)	418 ± 92	462 ± 91	399 ± 91	462 ± 92	0.0001	0.0469
Borg RPE post-test	11.2 ± 2.5	10.6 ± 2.2	10.7 ± 3.1	10.3 ± 2.5	0.0028	ns
Cardiopulmonary exercise test						
Exercise time (s)	411 ± 140	479 ± 161	424 ± 136	477 ± 136	0.0001	ns
Peak VO ₂ (mL/kg/min)	17.8 ± 4.1	19.7 ± 5.2	17.9 ± 4.4	19.0 ± 4.6	0.0001	ns
% predicted peak VO ₂	60.0 ± 12.8	67.1 ± 17.0	61.9 ± 17.5	66.3 ± 17.2	0.0001	ns
Peak RER	1.00 ± 0.07	0.99 ± 0.06	1.02 ± 0.07	1.02 ± 0.07	ns	ns
Health-related quality of life						
SF-36 (score)	79.3 ± 25.6	70.5 ± 25.4	81.6 ± 27.3	69.2 ± 26.4	0.0001	ns

Data are presented as mean values ± SD; P₁—significance level for the hypothesis of no time effect; P₂—significance level for the hypothesis of no time × group effect (between group differences in improvement of outcomes). HTCR, home-based telemonitored cardiac rehabilitation; SCR, standard cardiac rehabilitation; ns, non-significant; NYHA, New York Heart Association; RPE, rating of perceived exertion; VO₂, oxygen consumption; RER, respiratory exchange ratio; SF-36, Medical Outcome Survey Short Form 36 questionnaire.

1 ICD patients are “trainable” and to a large extent, these are CHF patients with a “surplus”



2 Exercise training “seems” safe in ICD patients



3 The growing number of patients calls for alternatives



4 Sufficiently powered randomized trials are necessary