

Developing the evidence base for cardiac rehabilitation: a 30 year & 6 cities journey

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Professor of Health Services Research
& Director of Exeter Clinical Trials Unit

University of Exeter Medical School. Exeter, UK

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June 9th 2017, REHPA, Nyborg, Denmark.





“The treatment itself has no side effects - but the number of statisticians needed to prove its value may cause dizziness and nausea”



Running heart research

© Volunteers are being sought for a unique investigation into coronary illness. STEWART McINTOSH explains how the Scottish People's Marathon will help study the problem.

HEART ATTACKS are a major risk for men aged between 35 and 50. But thanks to a unusual initiative involving doctors, scientists, and the Glasgow Herald, a major study is to be carried out on 40 participants in this year's Scott's Porage Marathon measuring the effects of marathon training — does it reduce body fat? How does it change the level of fitness? What is the effect on the heart?

Male volunteers between 25 and 50 who intend to run in the marathon on September 30 are being urged to take part in the experiment. The only condition is that they should have little or no running experience. Those who are physically fit need not apply. The object is to measure the effect of training on unfit people.

Volunteers should immediately contact Rod Taylor at the Institute of Physiology, Glasgow University, (telephone 041 339 8850, ext. 487 or 612, or 041 637 1321 in the evenings).

Despite the impact of the marathon boom, research on the physical effects of constant training on unfit people has been limited. The study which will be carried out by Glasgow University scientists and the Western Infirmary's cardiac unit will provide one of the most extensive studies so far.

The volunteers will be subjected to a rigorous battery of tests, including measurement of exercise bikes to measure the effects of training on the ability of the lungs to consume and process oxygen. Doctors from the cardiac unit will be monitoring changes in the strength of the subjects' hearts as their training builds up. Meanwhile, scientists from the University's physiology department will carry out a wide range of physical measurements to ascertain any changes in height, weight, limb circumference, bone diameter, and body fat.

The high incidence of cardiac problems in areas like the West of Scotland is sometimes put down to the levels of cholesterol (which comes from dairy foods and animal fats) in the bloodstream. The Herald volunteers will have their cholesterol levels monitored to find out whether increased fitness reduces the cholesterol level.

Volunteers motivated to finish the marathon and prepared to turn up on occasions between now and September 30 for the various tests.

Stan Grant, department of physical education, believes the experiment will be of his kind. "This study requires a level of co-operation between doctors and which will provide us with a better picture of the physical fitness than previously."

How an ex-British Lion had his body reborn and his feet rebuilt

By BARCLAY MURFIN

STRET Gordon Brown, the former agent body and rebuilt running shoe close to 10. Big Brown from Texas, former British Lion back forward, regarded as a world-class 1000 metres and thought he was fit to go before he started training for the Scottish People's Marathon.

Now Big Brown is doing "superly well" in his quest to run the first marathon a week on Sunday, according to exercise physiologist Rod Taylor.

"His heart rate is lower than it was before and his blood pressure is down because he has lost so much weight," Mr Taylor said after conducting the final set of health tests at Glasgow University yesterday.

Brown was an ideal candidate for Mr Taylor and his heart specialist colleagues at Glasgow's Western Infirmary who are undertaking an extensive study into the effects of marathon training in Glasgow, a city with the highest rate of coronary deaths in the world.

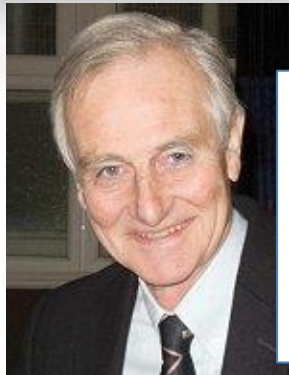
"They wanted to find out whether jogging is good or whether it's hard on the heart as they used the group with the highest coronary risk profile — males aged between 40 and 50 who had been any success for two years or run a marathon — at their own expense. At 40, it is a job which is about as physically demanding as trying a pair of rugby boots, and he totally motivates for two years, Mr Brown, the building society manager, fired the ball perfectly.

He was overweight, "I was brought home to me how far I was getting when my own health study programme is getting smaller," he said yesterday.

"I wanted to get fit and rebuild my feet."



1980-1984



Br. J. Nutr. (1974), 34, 77

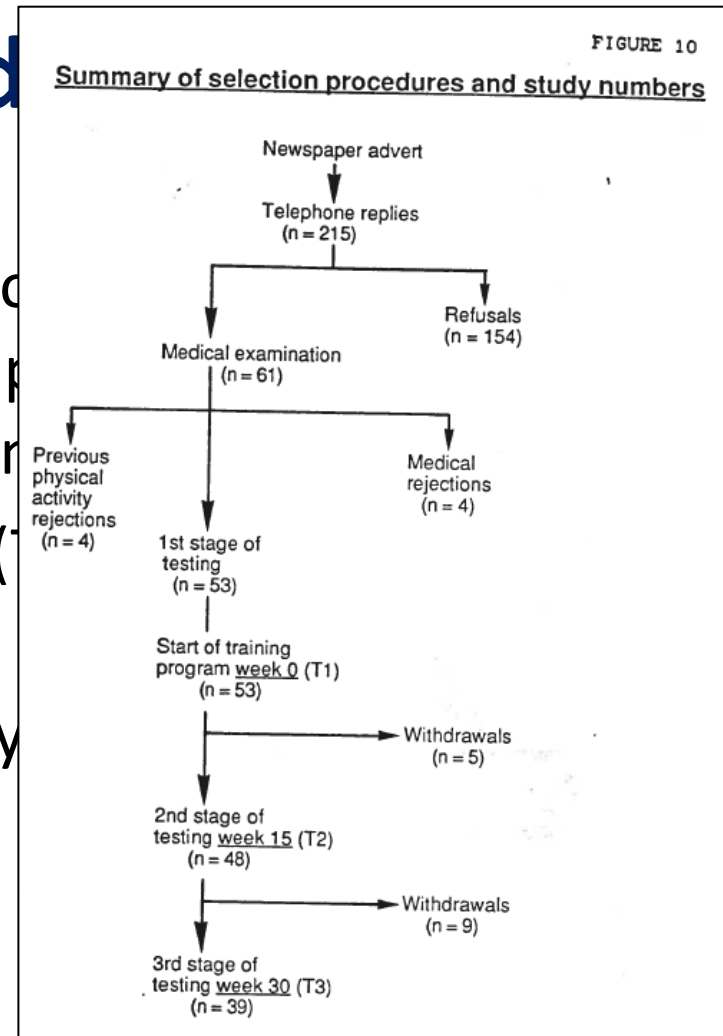
Body fat assessed from total body density and its estimation from skinfold thickness: measurements on 481 men and women aged from 16 to 72 years

BY J. V. G. A. DURNIN AND J. WOMERSLEY
Institute of Physiology, The University, Glasgow G12 8QQ

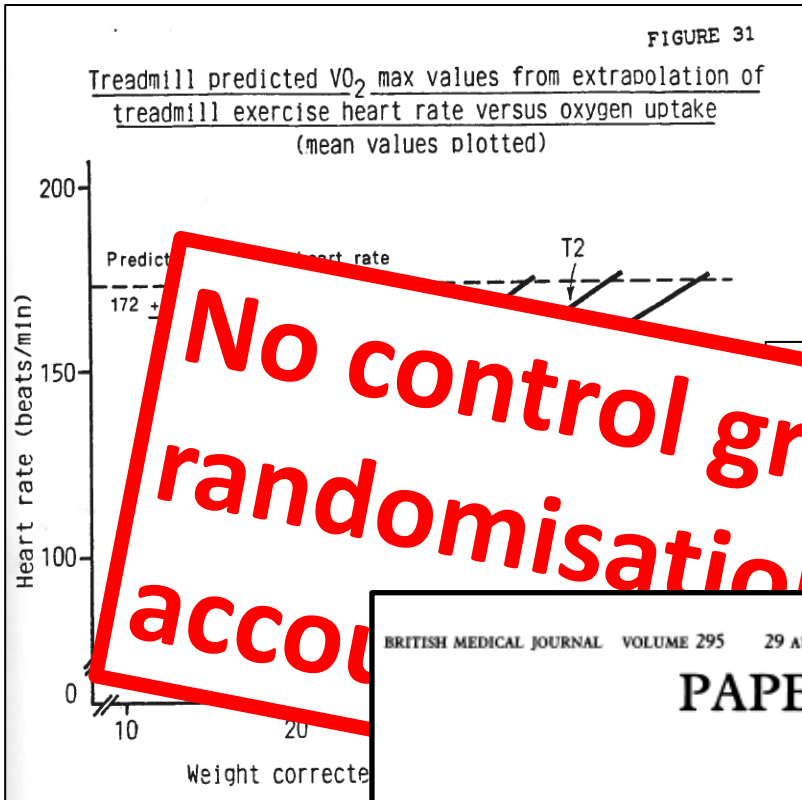
1985-1997

PhD - “Physical Training in Middle Aged

- Examine the physiological effect of a strenuous program of strenuous physical training in group of middle aged men
- Assessments at prior to training (T0) and 30 wks (T3) training
- 53 sedentary males; aged 35-50 y



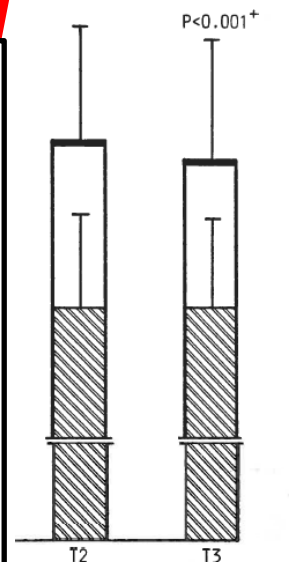
Results



No control group, no randomisation, no account

FIGURE 27
Maximal oxygen output and arterio-venous oxygen difference with training

FIGURE 26
Changes in body composition with training (mean values and SD's plotted)



BRITISH MEDICAL JOURNAL VOLUME 295 29 AUGUST 1987 521

PAPERS AND SHORT REPORTS

Cardiovascular effects of training for a marathon run in unfit middle aged men

IAIN N FINDLAY, RODNEY S TAYLOR, HENRY J DARGIE, STANLEY GRANT, ALAN R PETTIGREW, JOHN T WILSON, THOMAS AITCHISON, JOHN G F CLELAND, ALEX T ELLIOTT, B MILES FISHER, GERARD GILLEN, ANDREW MANZIE, ALAN G RUMLEY, JOHN V G A DURNIN

Legend:
 - Fat free mass (hatched)
 - Fat mass (white)
 - Total body weight (black)



Cardiac Rehabilitation After Myocardial Infarction

JAMA 1988;260: 945-50.

Combined Experience of Randomized Clinical Trials

Neil B. Oldridge, PhD; Gordon H. Guyatt, MD; Mary E. Fischer, MS; Alfred A. Rimm, PhD

Circulation

JOURNAL OF THE AMERICAN HEART ASSOCIATION



American Heart Association®

An overview of randomized trials of rehabilitation with infarction.

G T O'Connor, J E Buring, S Yusuf, S Z Goldhaber, E M Olmstead, H Hennekens

Circulation. 1989;80:234-244



1985-1997

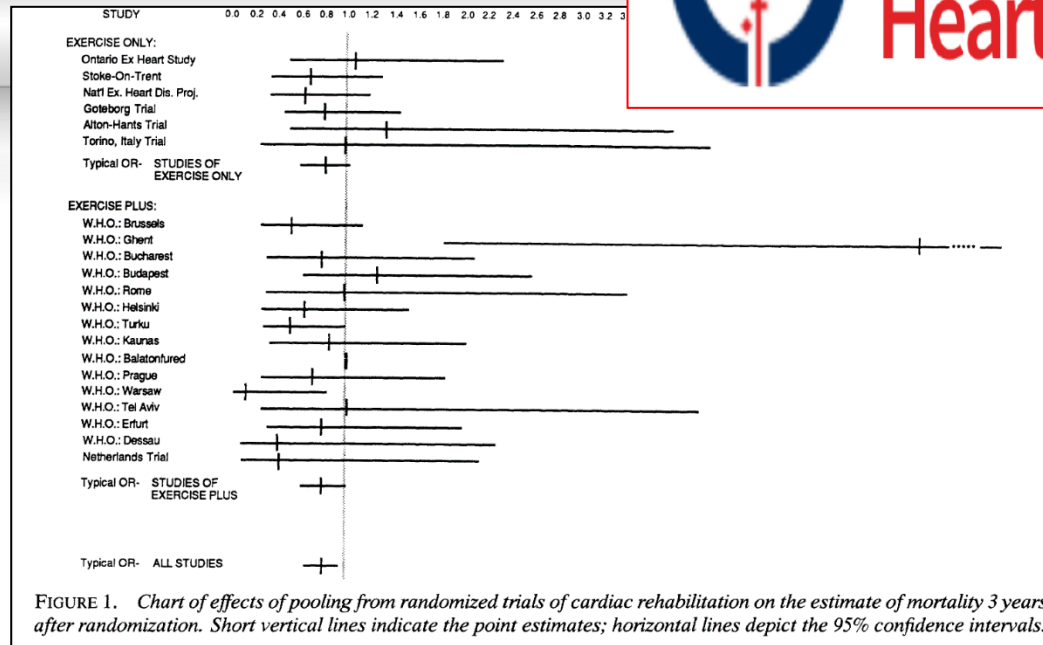


FIGURE 1. Chart of effects of pooling from randomized trials of cardiac rehabilitation on the estimate of mortality 3 years after randomization. Short vertical lines indicate the point estimates; horizontal lines depict the 95% confidence intervals.

Exercise-Based CR for CHD

- 36 RCTs in 8440 post MI and revascularisation patients
- Compared to control, CR reduced risk of all cause death by 19% (Odds Ratio: 0.81, 95% 0.72, 0.91)
- Improvements in lipids, and BP
- Limited data on HRQoL
- Quality of reporting poor

Exercise-based rehabilitation for coronary heart disease (Review)

Jolliffe J, Rees K, Taylor RRS, Thompson DR, Oldridge N, Ebrahim S










**THE COCHRANE
COLLABORATION®**

This is a reprint of a Cochrane review, prepared and maintained by The Cochrane Collaboration and published in *The Cochrane Library* 2001, Issue 1

<http://www.thecochranelibrary.com>

Cochrane CR 'Portfolio'

Title	Version	Publication status
Exercise based rehabilitation for...		
CHD [9811] 	v3	Jan 2016
Stable angina [1612] 	v1	Ongoing (Q2 2017)
Heart failure [0025] 	v3	Ongoing (Q4 2017)
Atrial fibrillation [1401] 	v1	Feb 2017
Post valve surgery [1301] 	v1	Mar 2016
Implantable cardiac defibrillators [1409] 	v1	Ongoing (Q3 2017)
Cardiac transplantation [1506] 	v1	Apr 2017

Psychological interventions for CHD

Educational interventions for CHD

Home vs centre based interventions

Interventions to increase uptake
[0422] 

JOURNAL OF THE AMERICAN COLLEGE OF CARDIOLOGY
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VOL. 67, NO. 1, 2016
ISSN 0735-1097/\$36.00
<http://dx.doi.org/10.1016/j.jacc.2015.10.044>

ORIGINAL INVESTIGATIONS

Exercise-Based Cardiac Rehabilitation for Coronary Heart Disease

Cochrane Systematic Review and Meta-Analysis

Lindsey Anderson, PhD,* Neil Oldridge, PhD,† David R. Thompson, PhD,‡ Ann-Dorthe Zwisler, MD,§
Karen Rees, PhD,|| Nicole Martin, MA,¶ Rod S. Taylor, PhD*



ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012

The Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure 2012 of the European Society of Cardiology. Developed in collaboration with the Heart Failure Association of the European Society of Cardiology



European Heart Journal (2012) 33, 1635–1701
doi:10.1093/eurheartj/ehs092

JOINT ESC GUIDELINES

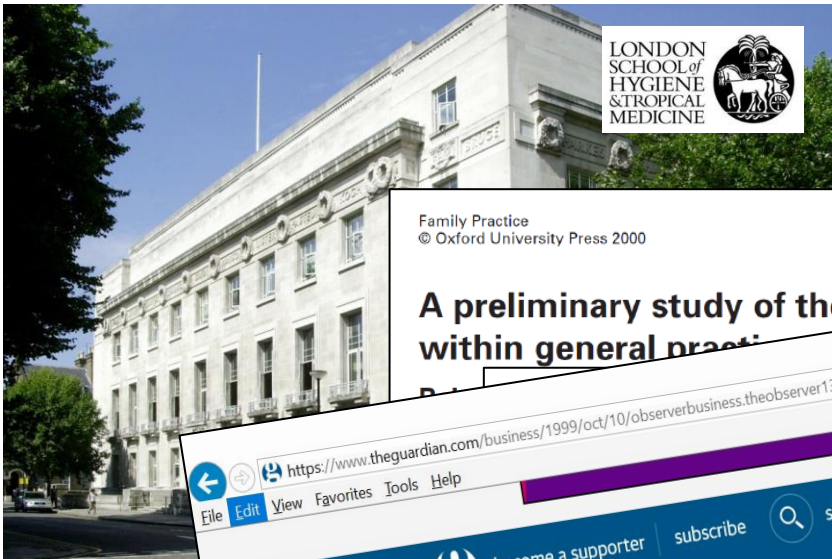
European Guidelines on cardiovascular disease prevention in clinical practice (version 2012)

The Fifth Joint Task Force of the European Society of Cardiology and Other Societies on Cardiovascular Disease Prevention in Clinical Practice (constituted by representatives of nine societies and by invited experts)

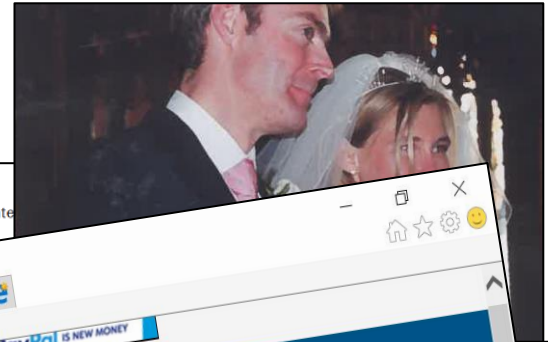
Recommendations for exercise prescription and multidisciplinary management

	Class ^a	Level ^b	Ref ^c
Regular exercise to reduce morbidity and mortality in patients	I	A	262, 263

Recommendations	Class ^a	Level ^b	GRADE	Ref ^c
Patients with previous acute myocardial infarction, CABG, PCI, stable angina pectoris, or stable chronic heart failure should undergo moderate-to-vigorous intensity aerobic exercise training ≥ 3 times a week and 30 min per session. Sedentary patients should be strongly encouraged to start light-intensity exercise programmes after adequate exercise-related risk stratification.	I	A	Strong	309, 310



LONDON SCHOOL of HYGIENE & TROPICAL MEDICINE



Family Practice
© Oxford University Press 2000

A preliminary study of the decision within general practice

https://www.theguardian.com/business/1999/oct/10/observerbusiness.theobserver13

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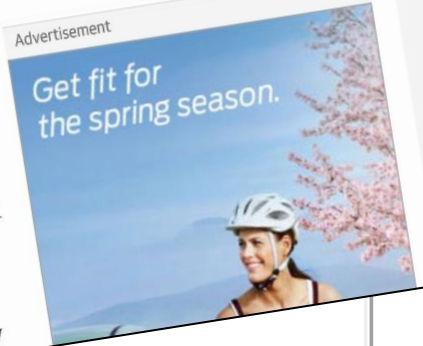


A sniffle, perhaps, but not the flu for Glaxo

Oliver Morgan on a disingenuous attempt to thwart the regulators
As usual, the small print contradicted the headlines. A glance at the latter last week would have left the impression that the British pharmaceuticals industry was about to go down the tubes.

In stating that Glaxo's flu treatment, Relenza, would not be paid for by the National Health Service, the government-appointed National Institute for Clinical Excellence (Nice) was destroying the market for the flagship product of one of Britain's flagship companies.

Glaxo's chairman, Sir Richard Sykes, fired off an angry letter to Health Secretary



Sunday 10 October 1999
03.01 BST

new treatments quickly across that there may be occasions
for children, the NHS," he said. "It will help when NICE guidelines would



UNIVERSITY OF
BIRMINGHAM



2000-2005



Health Technology Assessment 2007; Vol. 11: No. 35

The Birmingham Rehabilitation Uptake Maximisation Study (BRUM). Home-based compared with hospital-based cardiac rehabilitation in a multi-ethnic population: cost-effectiveness and patient adherence

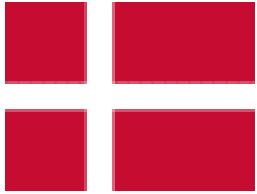
K Jolly, R Taylor, GYH Lip, S Greenfield, J Raftery, J Mant, D Lane, M Jones, KW Lee and A Stevens



European Journal of Heart Failure (2009) 11, 205-213
doi:10.1093/eurjhf/hfn029

A randomized trial of the addition of home-based exercise to specialist heart failure nurse care: the Birmingham Rehabilitation Uptake Maximisation study for patients with Congestive Heart Failure (BRUM-CHF) study

Kate Jolly^{1*}, Rod S. Taylor², Gregory Y.H. Lip³, Mick Davies⁴, Russell Davis⁵, Jonathan Mant⁶, Sally Singh⁷, Sheila Greenfield⁶, Jackie Ingram⁶, Jane Stubbley⁵, Stirling Bryan⁸, and Andrew Stevens¹



Cardiac Rehabilitation The Evidence Implications for

Rod Taylor FRCGS
Dept of Public Health & Epidemiology
University of Birmingham

Bispebjerg Hospital, Copenhagen
11th & 12th December



Cardiac Rehabilitation: The Evidence from the Cochrane Reviews

Rod Taylor, MSc PhD
Dept of Public Health & Epidemiology,
University of Birmingham

Center for Evidence-Based Medicine
Bispebjerg Hospital, Copenhagen,
28th October 2004

I met Ann-Dorthe Zwisler and then....



Table 2
Mean changes in primary outcomes from baseline to 9 months for patients randomized to hospital-based or home-based cardiac rehabilitation

Outcome characteristic	Hospital-based group (n=44) ^a			Home-based group (n=60) ^a			95% confidence interval for difference in means between home and hospital groups	p Value for analysis of covariance ^b
	Baseline	Mean (SD) value at 9 months	Mean change within group	Baseline	Mean (SD) value at 9 months	Mean change within group		
HADS								
Anxiety	5.67 (3.83)	4.74 (4.01)	-0.93 (-1.78 to -0.08)	7.27 (4.39)	6.27 (4.34)	-1.00 (-2.07 to 0.071)	-0.07 (-1.42 to 1.28)	0.50
Depression	2.84 (2.25)	2.61 (2.29)	-0.23 (-0.89 to 0.43)	4.05 (3.41)	3.82 (3.5)	-0.23 (-1.16 to 0.69)	0 (-1.12 to 1.12)	0.26
MacNew								
Emotional	5.14 (1.29)	5.78 (1.05)	0.64 (0.36 to 0.93)	4.77 (1.11)	5.48 (1.22)	0.71 (0.37 to 1.04)	0.07 (-0.37 to 0.50)	0.63
Physical	4.68 (1.33)	5.46 (1.22)	0.79 (0.43 to 1.14)	4.58 (1.08)	5.54 (1.12)	0.96 (0.59 to 1.32)	0.17 (-0.33 to 0.67)	0.68
Social	4.79 (1.45)	5.77 (1.23)	0.98 (0.60 to 1.36)	4.63 (1.21)	5.78 (1.14)	1.15 (0.77 to 1.54)	0.17 (-0.36 to 0.71)	0.79
Global	4.87 (1.30)	5.67 (1.12)	0.80 (0.48 to 1.12)	4.66 (1.06)	5.60 (1.12)	0.94 (0.60 to 1.28)	0.14 (-0.35 to 0.62)	0.94
Total	5.38 (1.22)	4.45 (1.01)	-0.93 (-1.26 to -0.61)	5.72 (1.24)	4.60 (1.12)	-1.11 (-1.42 to -0.80)	-0.18 (-0.62 to 0.27)	0.66
cholesterol (mmol/l)								



Hospital (n=44)
Completed 9-month
assessment (n=34)

Home based (n=60)
Completed 9-month
assessment (n=50)

Hospital (n=54)

Home based (n=72)

Exercise based rehabilitation for heart failure (Review)

Davies EJ, Moxham T, Rees K, Singh S, Coats AJS, Ebrahim S, Lough F, Taylor RS

Rehabilitation

NICE C

7. Offer a supervised group exercise-based rehabilitation programme with heart failure.

- Ensure the patient is stable and does not have a condition that preclude an exercise-based rehabilitation programme.
- Include a psychological and educational component in the programme.
- The programme may be incorporated within an existing cardiac rehabilitation programme [new 2010]

BMJ
open
accessible medical research

Why do so few patients with heart failure from Ireland

Hasnain M
Corrina Pe

	Number (%) or Median (range)
Exercise-only CR	10 (30%)
Centre-based	27 (85%)
Sample size	53 (19 to 2331)
Gender (% male)	61 (0 to 100)
Age (years)	60.5 (51 to 81)
LVEF(%)	29 (21 to 41)
Included NYHA IV	6 (18%)



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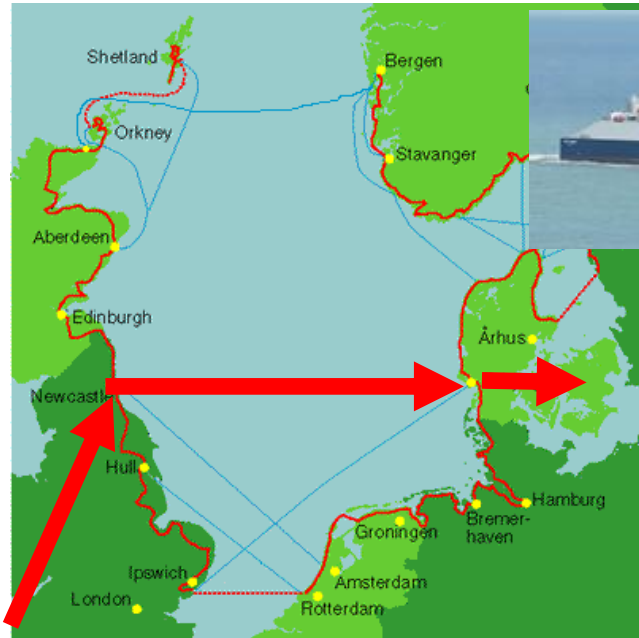
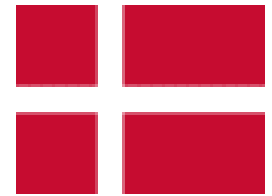
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- Manage your project
- Log in to the CCF RMS
- Download programme flyer

Details important and significant changes



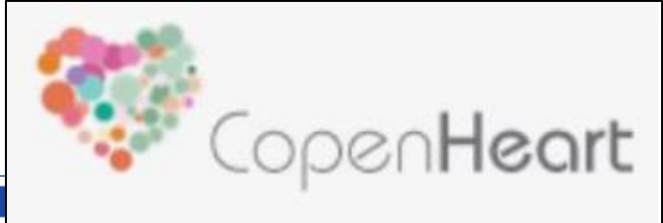
28th July 2014!



ORIGINAL ARTICLE

Cardiac rehabilitation increases physical capacity but not mental health after heart valve surgery: a randomised clinical trial

Kirstine L Sibilitz,^{1,2} Selina K Berg,^{1,3} Trine B Rasmussen,^{1,3} Signe Stelling Risom,¹ Lau C Thygesen,² Lars Tang,^{1,5,6} Tina B Hansen,^{1,7} Pernille Palm Johansen,^{1,8} Christian Gluud,⁹ Jane Lindschou,⁹ Jean Paul Schmid,¹⁰ Christian Hassager,¹ Lars Køber,¹ Rod S Taylor,^{2,11} Ann-Dorthe Zwisler^{1,2,12,13}



Open Access



A randomised clinical trial of comprehensive cardiac rehabilitation versus usual care for patients treated for infective endocarditis – the CopenHeart_{IE} trial protocol

Trine Bernholdt Rasmussen,^{1,2} Ann-Dorthe Zwisler,^{1,3} Kirstine Lærums Sibilitz,¹ Signe Stelling Risom,¹ Henning Bundgaard,¹ Christian Gluud,⁴ Philip Moons,^{1,5} Lau Caspar Thygesen,³ Jane Lindschou Hansen,⁴ Trine Norekvål,^{6,7} Selina Kikkenborg Berg,^{1,2} the CopenHeart_{IE} Group⁸

Open Access

Protocol

BMJ Open The CopenHeartSF trial – comprehensive sexual rehabilitation programme for male patients with implantable cardioverter defibrillator or ischaemic heart disease and impaired sexual function: protocol of a randomised clinical trial

Pernille Palm Johansen,^{1,2} Ann-Dorthe Zwisler,^{2,3} Jesper Hastrup Svendsen,⁴ Marianne Frederiksen,¹ Jane Lindschou,⁵ Per Winkel,⁵ Christian Gluud,⁶ Annamaria Giraldi,⁶ Elaine Steinke,⁷ Tinus Jaarsma,⁸ Selina Kikkenborg Berg,⁹ Lars Køber,¹⁰ the CopenHeart_{SF} Group¹¹



Original Article - Journal Club

Comprehensive cardiac rehabilitation improves outcome for patients with implantable cardioverter defibrillator. Findings from the COPE-ICD randomised clinical trial

European Journal of Cardiovascular Nursing 2015, Vol. 14(1) 34–44
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sagepub.co.uk/journalsPermissions.nav
DOI: 10.1177/1474515114521920
cnu.sagepub.com
SAGE



Cardiac rehabilitation versus usual care for patients treated with catheter ablation for atrial fibrillation: Results of the randomised CopenHeart_{RFA} trial

Signe S. Risom, RN, PhD,^{a,b,c} Ann-Dorthe Zwisler, MD, PhD,^{a,d,c} Trine B. Rasmussen, PhD,^{a,b,c} Kirstine Lærums Sibilitz, MD, PhD,^{a,b} Trine L. S. Madsen, RN, MScN,^c Jesper Hastrup Svendsen, MD, DMSc,^h Christian Gluud, MD, DMSc,^h Jane Lindschou, MSc,^h Per Winkel, MD, DMSc,^h and Selina Kikkenborg Berg, RN, MScN, PhD^{a,b,c} *Copenhagen, Odense C, Hellerup, and Copenhagen Hospital, Denmark*

Open Access

Protocol



A randomised clinical trial of comprehensive cardiac rehabilitation versus usual care for patients treated for infective endocarditis – the CopenHeart_{IE} trial protocol

Trine Bernholdt Rasmussen,^{1,2} Ann-Dorthe Zwisler,^{1,3} Kirstine Lærums Sibilitz,¹ Signe Stelling Risom,¹ Henning Bundgaard,¹ Christian Gluud,⁴ Philip Moons,^{1,5}

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MEMORANDUM OF UNDERSTANDING

FOR JOINT COLEBORATION AND SUPPORT IN ENHANCING KNOWLEDE & SKILLS IN THE FIELD OF CARDIAC PREVENTATION & REHABILITATION.

BETWEEN

Professor Ann-Dorthe Zwisler from Danish Knowledge Center for Rehabilitation for Palliative Care (REHPA), Clinical Institute, University of Southern Denmark, DENMARK

----- 1st Party.

AND

Professor Rod Taylor, Chair of Health Service Research, from University Of Exeter Medical School, Exeter, UNITED KINGDOM

----- 2nd Party.

AND

Professor Dr. Fazila-Tun-Nesa-Malik, Director-Academic affairs, from National Heart Foundation Hospital & Research Institute (NHF&RI), Dhaka, BANGLADESH.

----- 3rd Party.

BETWEEN

1st & 2nd Party (REHPA & UNIVERSITY OF EXETER)

AND

3rd Party (National Heart Foundation Hospital & Research Institute)

REACH HF

- Funded by NIHR Programme Grant, 2012-7
- Programme consists of linked work packages to:
 - develop, a **home based, self-help CR programme** ('the HF Manual') for people with HF and their caregivers
 - **pilot trial** assess feasibility of definitive trial of the HF Manual in HFPEF
 - **multi-centre RCT** to assess effectiveness and cost effectiveness of HF Manual vs. usual care in people with **HFREF** and their caregivers
 - evidence synthesis/modelling of the effectiveness and cost effectiveness of the **HF Manual vs. centre-based CR** in HFREF and HFPEF

REACH-HF contributors



● Truro

Dr H Dalal

Dr Jenny Wingham

Dr Robin Van Lingen

Kevin Paul (PPI)

● Birmingham

Professor Kate Jolly

Dr Russell Davis

● Gwent

Dr Jackie Austin

● Edinburgh

Heart Manual office

● Exeter

Professor Charles
Abraham

Professor Nicky Britten

Dr Colin Greaves

Dr Colin Green

Professor Rod Taylor

● York

Professor Patrick Doherty

● Dundee

Prof Chim Lang

Dr Karen Smith



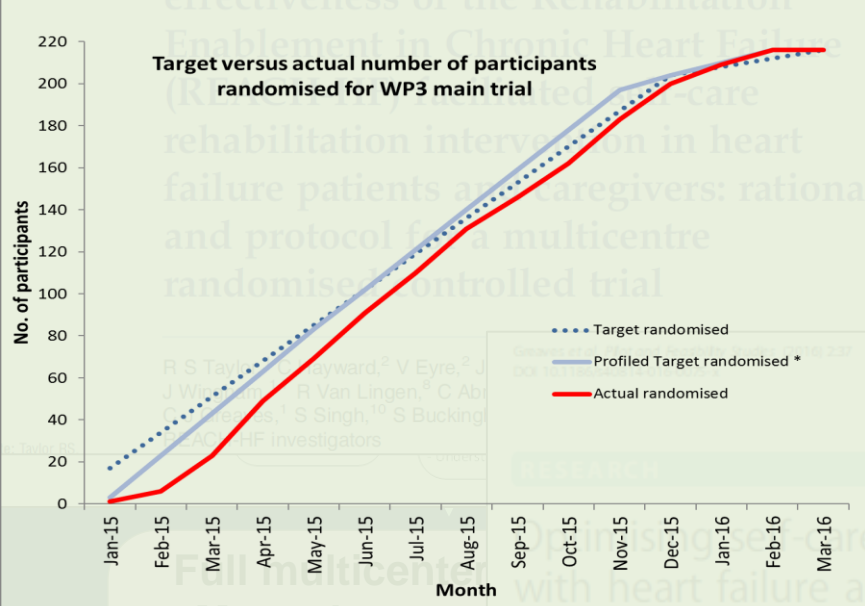
REACH HF PROGRAMME



Development of home-based

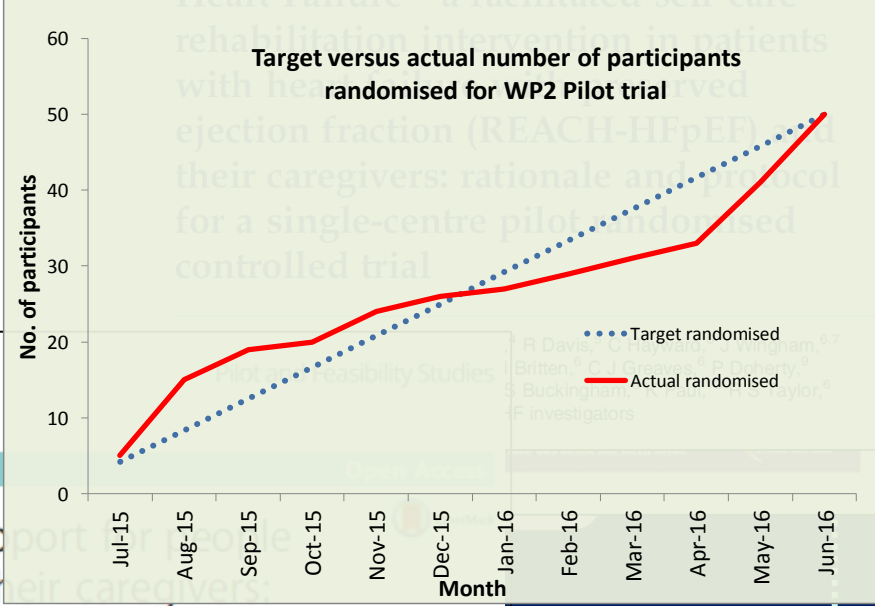
Open Access Protocol

BMJ Open Clinical effectiveness and cost-effectiveness of the Rehabilitation Enablement in Chronic Heart Failure (REACH-HF) intervention in heart failure patients and their caregivers: rationale and protocol for a multicentre randomised controlled trial



Open Access Protocol

BMJ Open Rehabilitation Enablement in Chronic Heart Failure: a facilitated self-care



Manual versus with parallel economic ev in HF

development of the Rehabilitation Enablement in Chronic Heart Failure (REACH-HF) intervention using intervention mapping

analytic modelling

Colin J. Greaves^{1*}, Jennifer Wingham^{1,2}, Carolyn Deighan³, Patrick Doherty⁴, Jennifer Elliott³, Wendy Armitage^{3,5}, Michelle Clark³, Jackie Austin⁶, Charles Abraham¹, Julia Frost¹, Sally Singh⁷, Kate Jolly⁸, Kevin Paul⁹, Louise Taylor³, Sarah Buckingham², Russell Davis¹⁰, Hasnain Dalal¹¹, Rod S. Taylor¹, on behalf of the REACH-HF investigators

The researches of many commentators have already thrown much darkness on this subject, and it is probable that if they continue, we shall soon know nothing at all about it.

Mark Twain

And the next (last) 5 yrs...

- **Danish Heart Foundation**



- Review of reviews [Sept!]

- **UK MRC Global Challenges**



- Implementing cost-effective CR in Bangladesh & Malaysia [Q1 2018]

- **REACH-HFpEF**



*National Institute for
Health Research*

- Full trial application to NIHR HTA [Q3 2017]

- **REACH-AF**



*National Institute for
Health Research*

- UK NIHR Programme Grant Application [Q3 2017]



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THIS WAY