The OPTImal CArdiac REhabilitation (OPTICARE) trial:

a randomized, controlled superiority trial of two extended educational and behavioral intervention programs

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No conflict of interests

Agenda

- Introduction
- Objectives
- Design and enrollment
- Results
- Summary

Background

- Currently, most patients with ACS undergo PCI in the acute phase and are under optimal medical treatment.
- As a result, the prognosis of ACS patients increased significantly.
- The favourable developments in ACS treatment have, however, an important downside → s***ee next***

What is that?

- *ACS patients have less time for reflection on the event they experienced* **&**
- *The contact time with healthcare professionals during the acute phase is limited, whereas in this period patients might be most open to accept (lifestyle) advice to avoid future cardiac events*.

In order to adapt and maintain a heart-healthy lifestyle, ACS patients therefore probably need more guidance in the subacute phase than is currently offered in CR programs.

Can CR help?

- Several cardiac rehabilitation (CR) programs have been developed since the 1980s for CAD patients, which offer a variety of interventions that aim to stimulate an active and healthy lifestyle.
- In meta-analyses it has been demonstrated that these programs effectively reduce the 1-year incidence of total mortality, cardiovascular mortality and nonfatal MI.
- However, these initial beneficial results **were not maintained during longer-term** follow-up.

"The lifestyle changes adopted during the rehabilitation period were probably not incorporated into daily routine".

The research question is….

Could CR programs followed by relatively brief maintenance programs and booster sessions, improve long-term adherence to lifestyle modifications?

Any data available???

- **GOSPEL:**
  - An extended CR program consisting of supervised 30 min aerobic exercise, comprehensive lifestyle and risk factor counselling sessions may even further benefit patients in the long term.
  - However, it should be realised that in this trial multiple (11 sessions in 3 years) and thus costly interventions were done.
- **COACH:**
  - In the COACH trial a limited number of telephone interventions also had beneficial effects. However, in that trial only approximately half of the patients underwent CR and the beneficial effect of the COACH intervention in the CR subgroup is unknown.

Objectives of the study

To determine the effects of two extended CR programs designed to stimulate permanent adaption of a heart-healthy lifestyle, compared with current standard CR, in ACS patients.

Neth Heart J (2013) 21:324–330
DOI 10.1007/s12471-013-0422-y

REVIEW ARTICLE

OPTImal CArdiac REhabilitation (OPTICARE) following Acute Coronary Syndromes: Rationale and design of a randomised, controlled trial to investigate the benefits of expanded educational and behavioural intervention programs

M. Sunamura · N. ter Hoeve · H. J. G. van den Berg-Emons · M. Haverkamp · K. Reddekop · M. L. Geleijnse · H. J. Stam · E. Boersma · R. T. van Domburg

Published online: 23 May 2013

Methods

The **OPTICARE** trial is a multicentre, open, multidisciplinary randomised controlled trial with a **12-**month follow-up. The PRospective Open, Blinded Endpoint (**PROBE**) design will be applied, and an independent Clinical Event Committee will verify all cardiac events.

Inclusion criteria

- Patients with a documented ACS who were referred for CR

The study was done in **Erasmus Medical Center and Capri Cardiac Rehabilitation Rotterdam**

Exclusion criteria

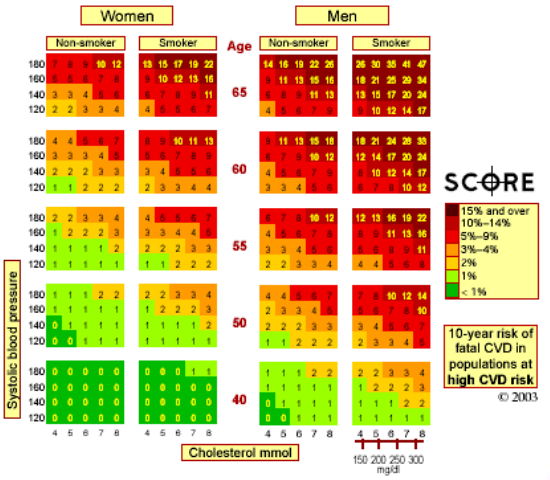
- Heart failure or LVEF<40%
- Psychological or cognitive impairments which may limit cardiac rehabilitation
- COPD
- Renal failure.

The study randomised 914 patients with ACS to 3 different CR programs:

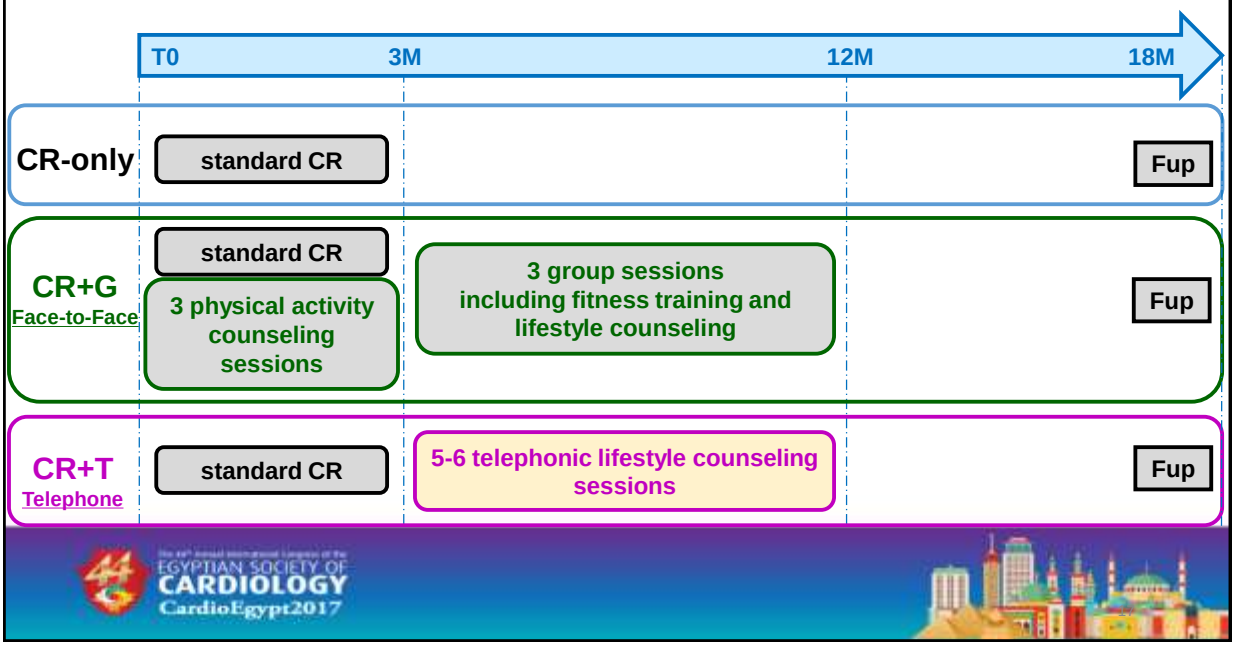
- Standard CR, which involved 3 months of bi-weekly supervised exercise and educational sessions (CR-only);
- Standard CR plus an additional 9 months of group sessions on lifestyle and fitness training (CR+G);
- Standard CR plus an additional 9 months of personal telephone coaching on lifestyle (CR+T).

Outcome parameters

- **Primary** → (SCORE) at 18 Months
- **Secondary**:
  - Individual parameters:
    - **Systolic blood pressure**
    - **Total cholesterol**
    - **Smoking behavior , BMI,...**
  - Quality of life
  - Anxiety
  - Daily physical activity



Treatment allocation



Baseline characteristics

	CR+G N=309	CR+T N=299	CR-only N=306
Age, years	57	57	57
Male, %	79	83	80
Intervention at baseline			
PCI, %	81	75	78
CABG, %	12	15	14
No revascularization, n (%)	7	10	8
Prior MI, %	7	10	9
Prior PCI, %	8	10	11
Prior CABG, %	1	1	2
Diabetes, %	14	11	14
Dyslipidemia, %	29	33	40
Current smoking (pre-ACS), %	45	43	42
Hypertension, %	44	40	39

Results

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In an intention-to-treat analysis, the study found NO difference between the groups for the SCORE outcomes ??????????

Why???

Most patients largely reached the target levels of the modifiable SCORE risk factors (Systolic BP, total cholesterol and smoking) already at randomization, which made it almost impossible to achieve an additional benefit ("ceiling effect").

However, since compliance to the enhanced programs was **lower** than for the standard program (61% and 57% in CR+G and CR+T, compared with 83% in CR-only), a **per-protocol analysis** was done that included only those participants who completed at least 75% of their CR program.

Randomization

OPTICARE trial
N=914

	CR+G Face-to-Face N=309	CR+T Telephone N=299	CR-only N=306
ITT analysis			
	262 completed standard CR (85.1%)	250 completed standard CR (83.6%)	306 completed standard CR (82.7%)
PP analysis	187 completed CR+G (60.5%)	170 completed CR+T (56.8%)	306 completed CR-only (82.7%)

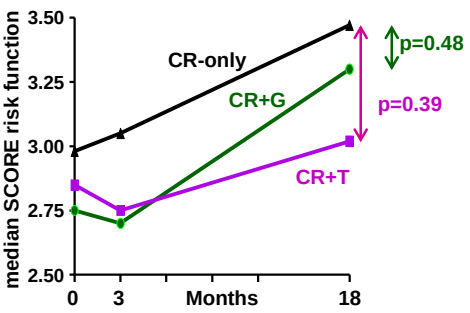
CR+G: standard CR extended with face-to-face group counseling sessions

CR+T: standard CR extended with telephone counseling sessions

CR-only: standard CR

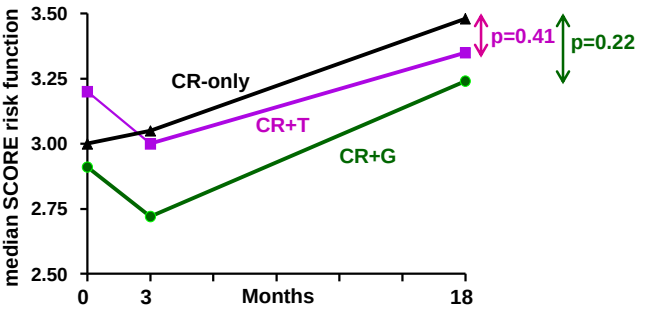
Primary outcome: Score risk function

Intention-to-Treat



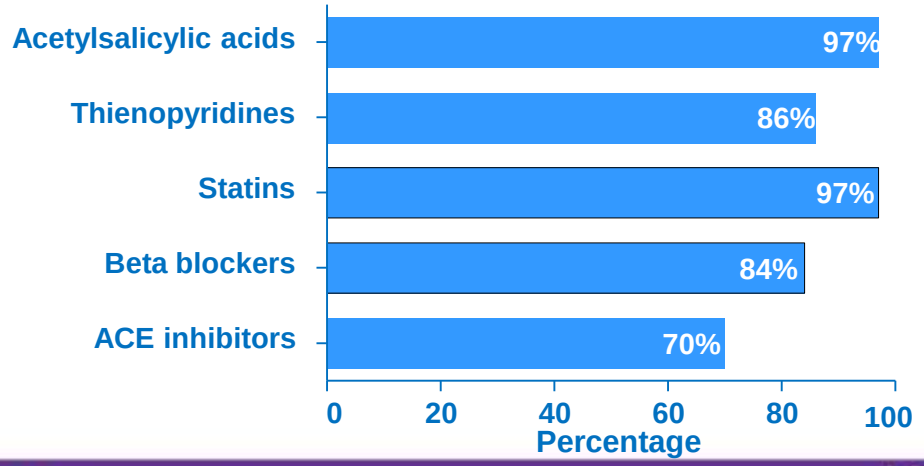
CR+G: standard CR, extended with group counseling sessions

Per-Protocol

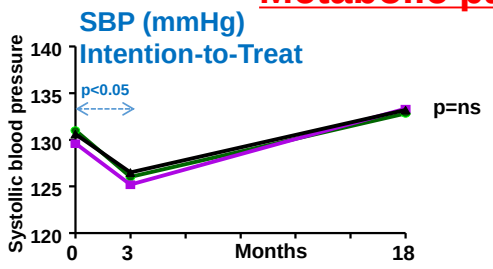


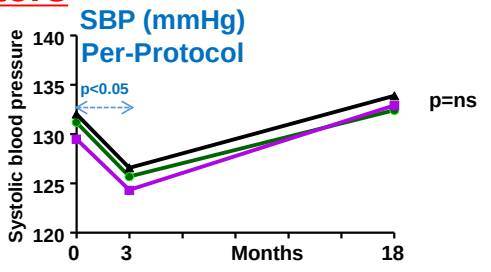
CR+T: standard CR, extended with telephone counseling sessions

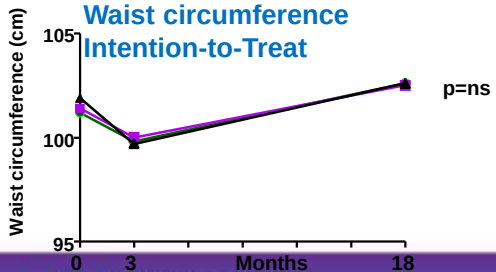
Cardiac medication at randomization (6 weeks post-ACS)

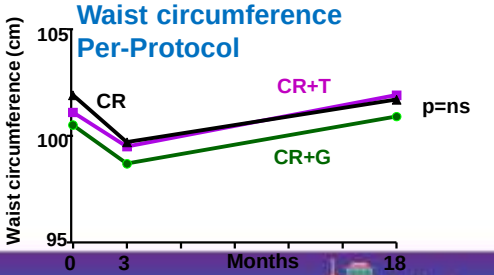


Metabolic parameters



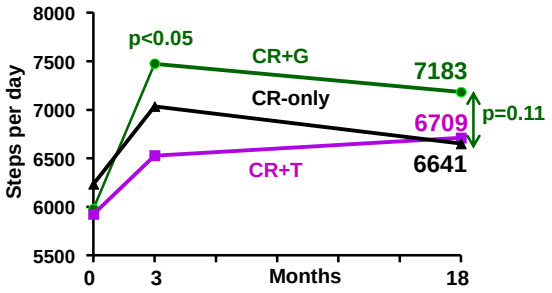




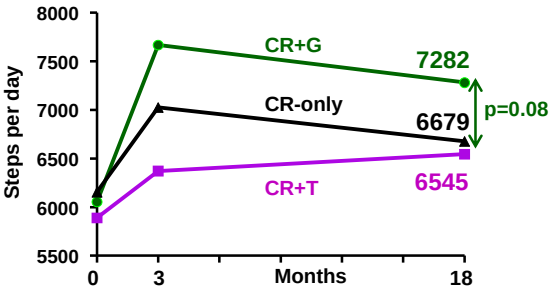


Number of steps per day

Intention-to-Treat



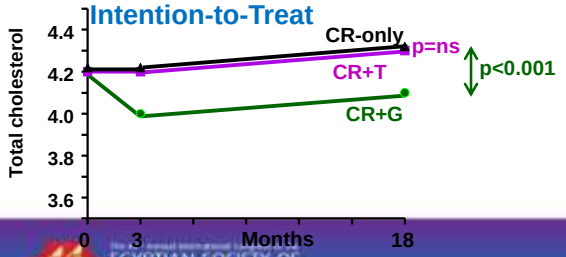
Per-Protocol



"Among these motivated individuals both smoking cessation and total cholesterol were significantly better in the CR+G compared with the CR-only group (13.4% vs 21.3%)" and to a lesser extent in CR+T

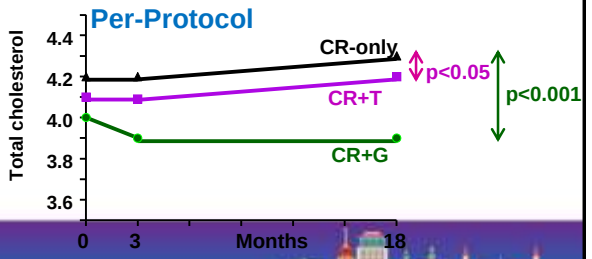
preACS 0 3 Months 18

Total cholesterol Intention-to-Treat

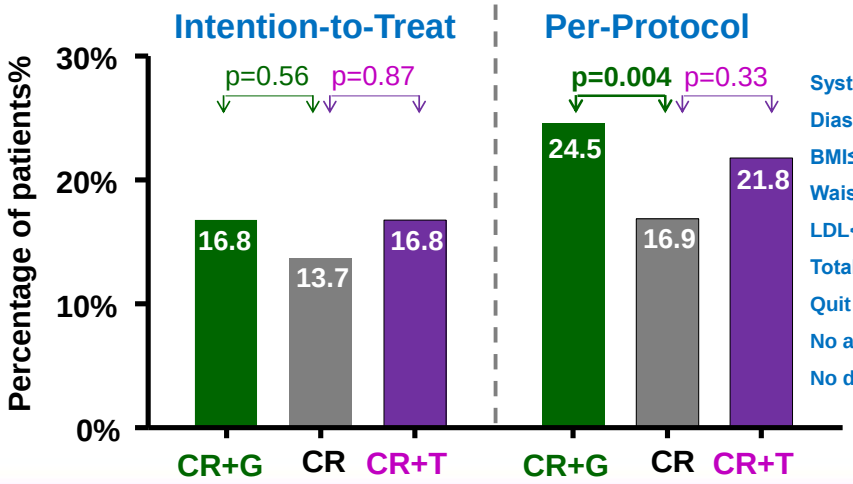


preACS 0 3 Months 18

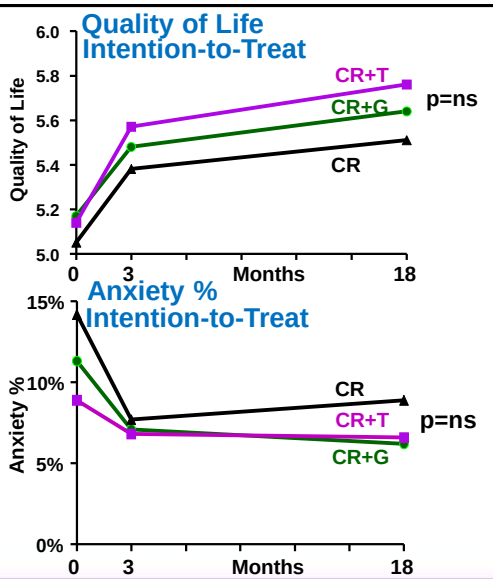
Total cholesterol Per-Protocol

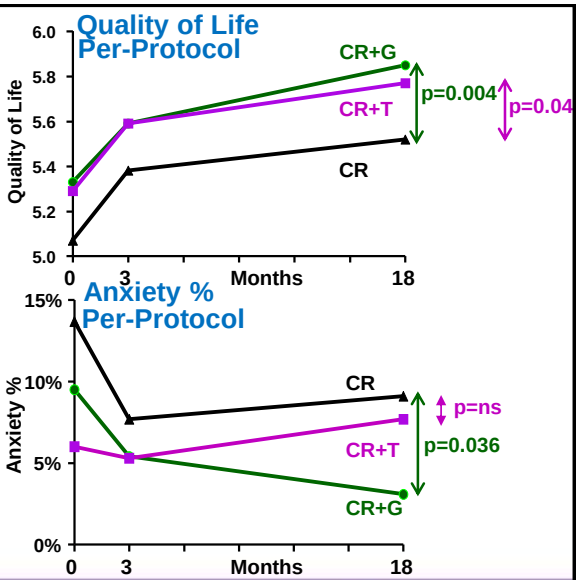


At least 6 of the 9 risk factors on target at 18M



- Systolic blood pressure≤140 mmHg
- Diastolic blood pressure≤90 mmHg
- BMI≤25
- Waist circumference (m≤94cm;f≤80cm
- LDL<1.8mmol/L
- Total cholesterol≤4.5 mmol/L
- Quit smoking
- No anxiety
- No depression





Cardiac events at 18 months

	CR+G N=309	CR+T N=299	CR-only N=306	Pvalue
Total number of events	83 (27%)	79 (26%)	70 (22%)	0.44
Mortality, n (%)	1 (0)	1 (0)	0 (0)	0.56
Readmissions for ACS				
STEMI, n (%)	1 (0)	5 (2)	2 (1)	0.24
NSTEMI, n (%)	5 (2)	3 (1)	3 (1)	0.98
Unstable angina, n (%)	4 (1)	3 (1)	2 (1)	0.64
Other CVD admissions				
Stable angina, n (%)	14 (4)	13 (4)	9 (3)	0.64
Chest pain, n (%)	16 (5)	12 (4)	11 (4)	0.53
Arrhythmias, n (%)	6 (2)	4 (1)	2 (1)	0.65
Interventions				
CAG, n (%)	8 (3)	5 (2)	7 (2)	0.59
PCI, n (%)	9 (3)	9 (3)	12 (3)	0.85
CABG, n (%)	1 (0)	0 (0)	2 (1)	0.16
Cardiac ER, n (%)	18 (6)	24 (8)	20 (7)	0.90

Conclusions

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Both extended CR programs (**face-to-face group and telephone counseling sessions on top of standard CR)** as compared with **standard CR-only**

- Were **NOT** beneficial with respect to the SCORE risk function.

[Most patients largely reached the target levels of the modifiable SCORE risk factors already at randomization ("ceiling effect")].

Extended CR with **telephone counseling sessions on top of standard CR** as compared with **standard CR-only** showed

- ❑ PP analyses (motivated patients)
  - Less smoking
  - Lower cholesterol level
  - Improved quality of life
- ❑ No benefit for the other end points in the ITT and PP analyses

Extended CR with **face-to-face group counseling sessions on top of standard CR** as compared with **standard CR-only** showed

- ITT analyses
  - *Lower cholesterol levels*
- PP analyses (motivated patients)
  - *Less smoking*
  - *More risk factors on target*
  - *Less anxiety*
  - *Lower cholesterol levels*
  - *Higher quality of life*
  - *Trend to more steps/day*

OPTICARE trial enhanced cardiac rehab programs help heart attack patients, but do not decrease cardiovascular risk

29 August 2016

Enhanced cardiac rehabilitation (CR) programs that include a year of group or personal lifestyle and fitness coaching *did not improve* cardiovascular risk scores more than a standard 3-month program in patients recovering from a heart attack.

But, findings from (OPTICARE) trial, presented in a Hot Line session at ESC Congress 2016, showed that motivated patients who stuck with the year-long protocol were "***happier, healthier and more active***," than those in the regular program, said investigator Ron van Domburg, PhD, from Erasmus Medical Center Rotterdam, the Netherlands.

"*Although we were not able to show any greater improvement in metabolic parameters, there were some initial indications that* ***a firm commitment to a year-long program might encourage more permanent lifestyle improvements***," said Professor van Domburg.

THANK YOU