Randomised Evaluation of Secondary Prevention by Outpatient Nurse SpEcialists.

On behalf of the RESPONSE studygroup:

Ron JG Peters, MD

Academic Medical Center

University of Amstedam

Amsterdam

The Netherlands

Background

- Secondary prevention may effectively prevent recurrent cardiovascular events.
- Guidelines have been issued by ESC, AHA/ACC
- A gap exists between these guidelines and clinical practice
- New, practical initiatives are needed to reduce this gap

Study design

Study goal:

- To quantify the impact of a nurse coordinated prevention program on risk factor levels in patients with a recent coronary event

Population:

- Patients 18-80 years
- ACS within 8 weeks before inclusion

Main outcome:

- SCORE 10 year risk of mortality at 12 months after index event

Study design

- Multicenter (n=11) randomised clinical trial in The Netherlands

Participating centers

Breda	Amphia Ziekenhuis	Marco Alings, MD
Enschede	Medisch Spectrum Twente	Clemens von Birgelen, MD
Goes	Oosterscheldeziekenhuizen	Anho Liem, MD
Deventer	Deventer Ziekenhuis	Dirk Lok, MD
Endihoven	Catharina Ziekenhuis	Jan-Melle van Dantzig, MD
Heerlen	Atrium Medisch Centrum	Hans Kragten, MD
Nieuwegein	St. Antonius Ziekenhuis	Wybren Jaarsma, MD
Leeuwarden	Medisch Centrum Leeuwarden	Kees-Jan de Vries, MD
Hilversum	Tergooiziekenhuizen	Paul de Milliano, MD
Delft	Reinier de Graaf Gasthuis	Adrie Withagen, MD

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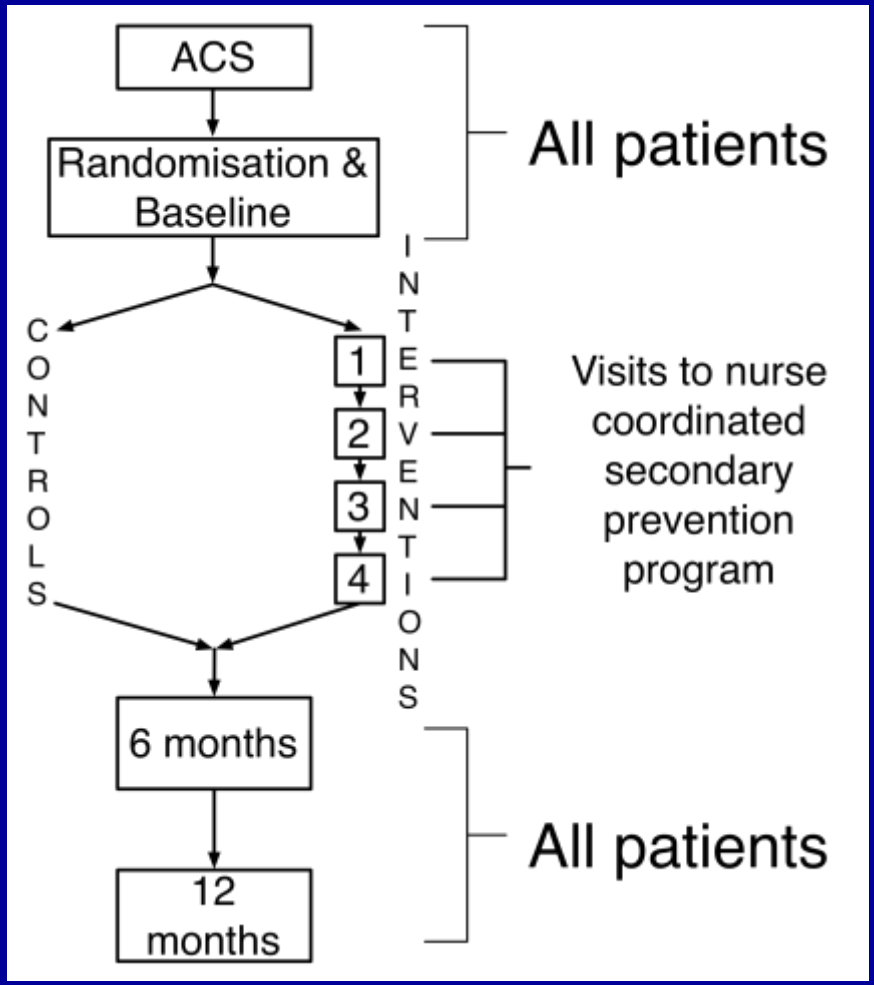
Study design

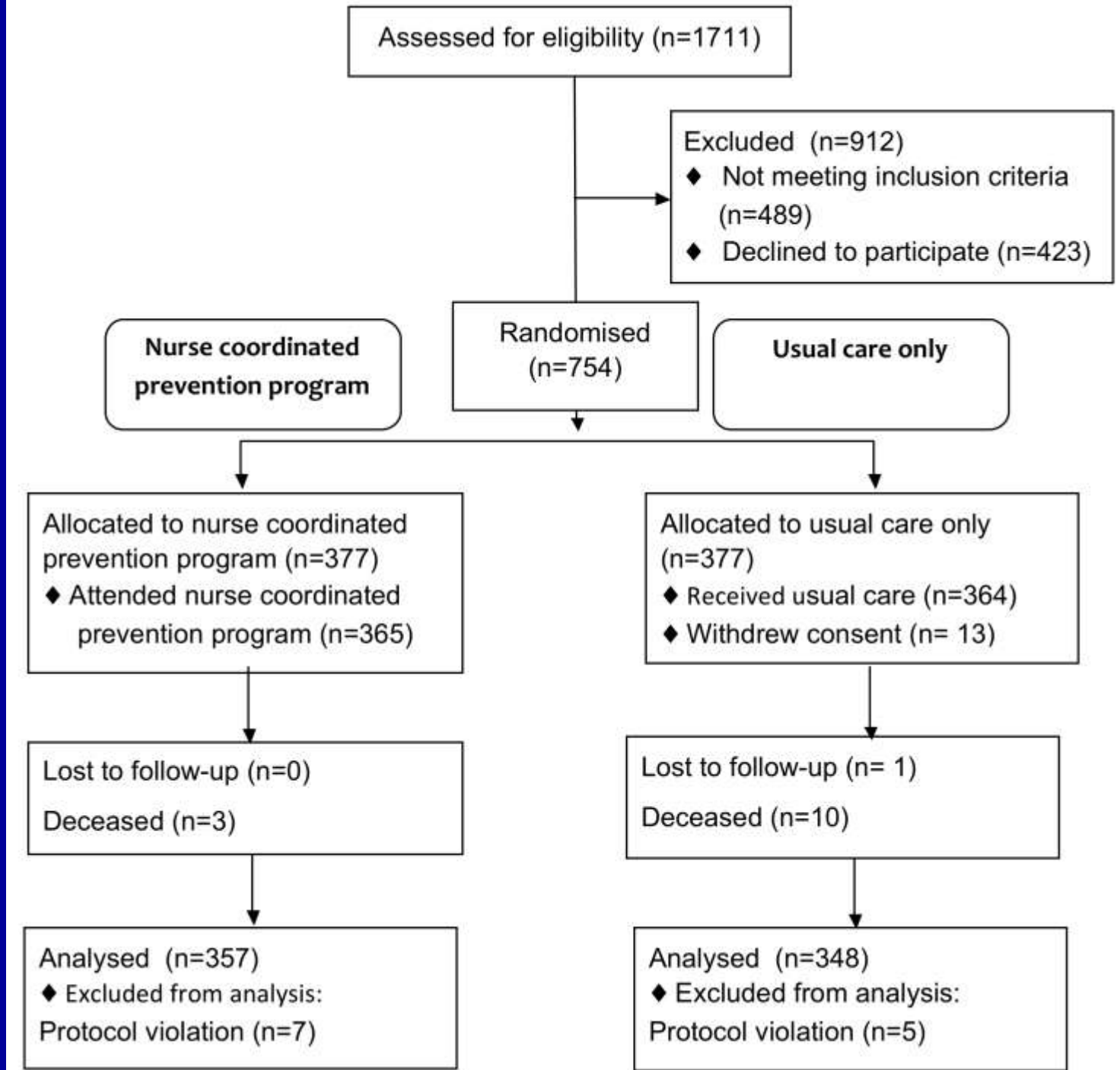
Data collection

Data collection

Data collection



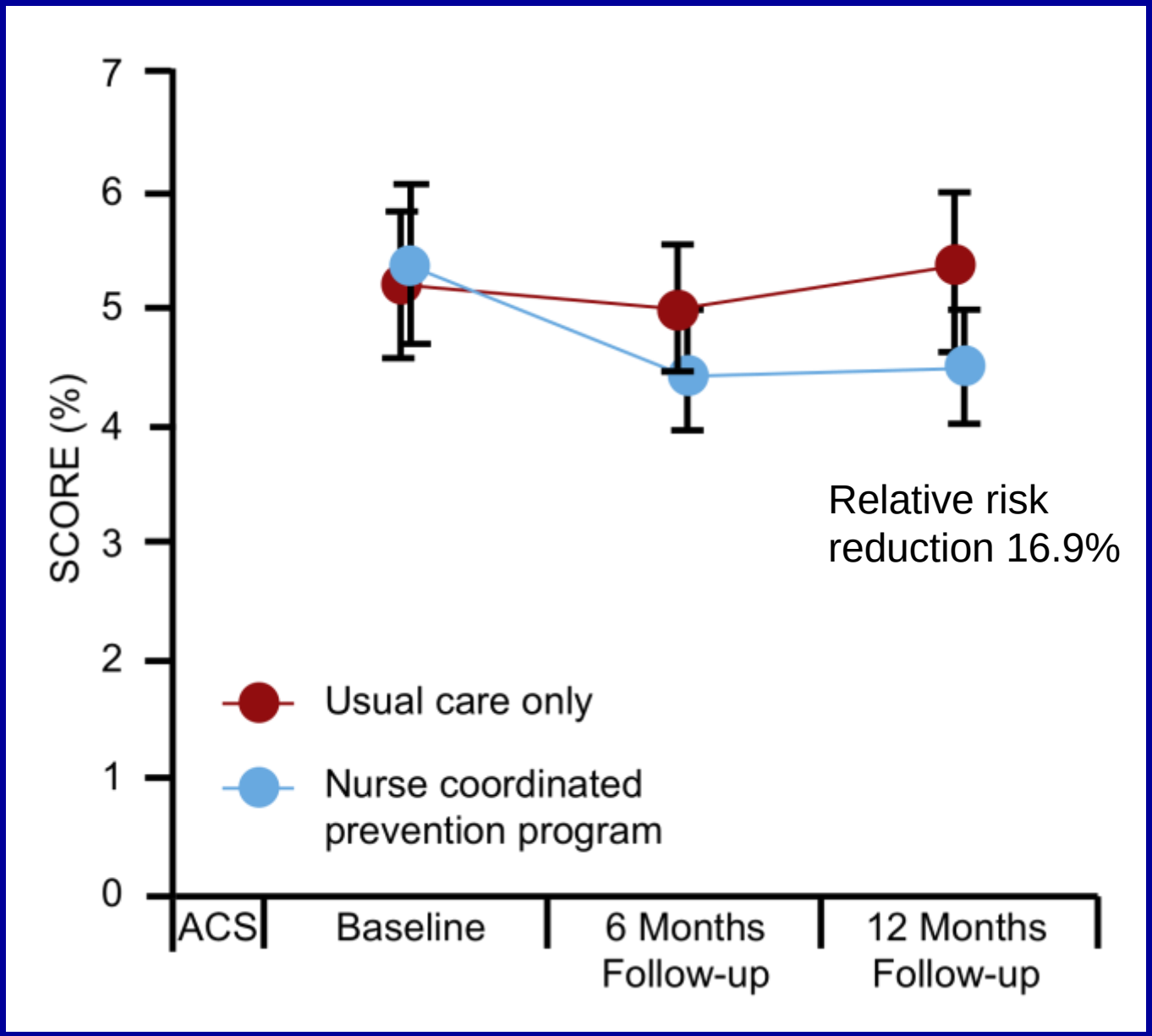
93.3% attendance


Assessed for eligibility (n=1711)
Excluded (n=912)
♦ Not meeting inclusion criteria (n=489)
♦ Declined to participate (n=423)
Nurse coordinated prevention program
Randomised (n=754)
Usual care only
Allocated to nurse coordinated prevention program (n=377)
♦ Attended nurse coordinated prevention program (n=365)
Allocated to usual care only (n=377)
♦ Received usual care (n=364)
♦ Withdrew consent (n= 13)
Lost to follow-up (n=0)
Deceased (n=3)
Lost to follow-up (n= 1)
Deceased (n=10)
Analysed (n=357)
♦ Excluded from analysis:
Protocol violation (n=7)
Analysed (n=348)
♦ Excluded from analysis:
Protocol violation (n=5)

Baseline characteristics

	Randomised treatment	
	Intervention (N=357)	Control (N=348)
Age, years	57·5	57·7
Female	20%	21%
Diagnostic category at index event		
ST-segment elevation myocardial infarction	50%	48%
Non ST-segment elevation myocardial infarction	33%	33%
Unstable Angina Pectoris	17%	19%
Previous vascular disease (prior to index event)	26%	27%
History of cardiovascular risk factors		
Positive family history	59%	60%
History of diagnosed diabetes mellitus	14%	14%
History of dyslipidemia	69%	71%
Current smoking	47%	43%
Ex-smoker	36%	39%
History of hypertension	38%	35%

Calculated 10 year mortality



On target analysis

targets	Baseline			12 months		
	Intervention (n=357)	Control (n=348)	p value	Intervention (n=357)	Control (n=348)	p value
Nurse targeted parameters						
Body mass index ≤25 kg/m2	23%	28%	0·121	20%	27%	0·048
Waist circumference men ≤94 cm, women ≤80 cm	20%	26%	0·049	22%	24%	0·47
Systolic blood pressure ≤140 mmHg	68%	73%	0·138	74%	61%	<0·001
LDL-cholesterol ≤2.5 mmol/L	67%	68%	0·871	73%	64%	0·013
Current smoker	47%	53%	0·289	23%	24%	0·859
Physical activity ≥30 min, ≥5 times per week	50%	51%	0·763	67%	54%	0·001
Alcohol consumption men ≤3 units per day, women ≤2 units per day	95%	93%	0·213	98%	96%	0·178
Vegetables ≥200 g per day	71%	66%	0·193	81%	71%	0·002
Fruit ≥2 pieces per day	80%	83%	0·248	94%	85%	<0·001

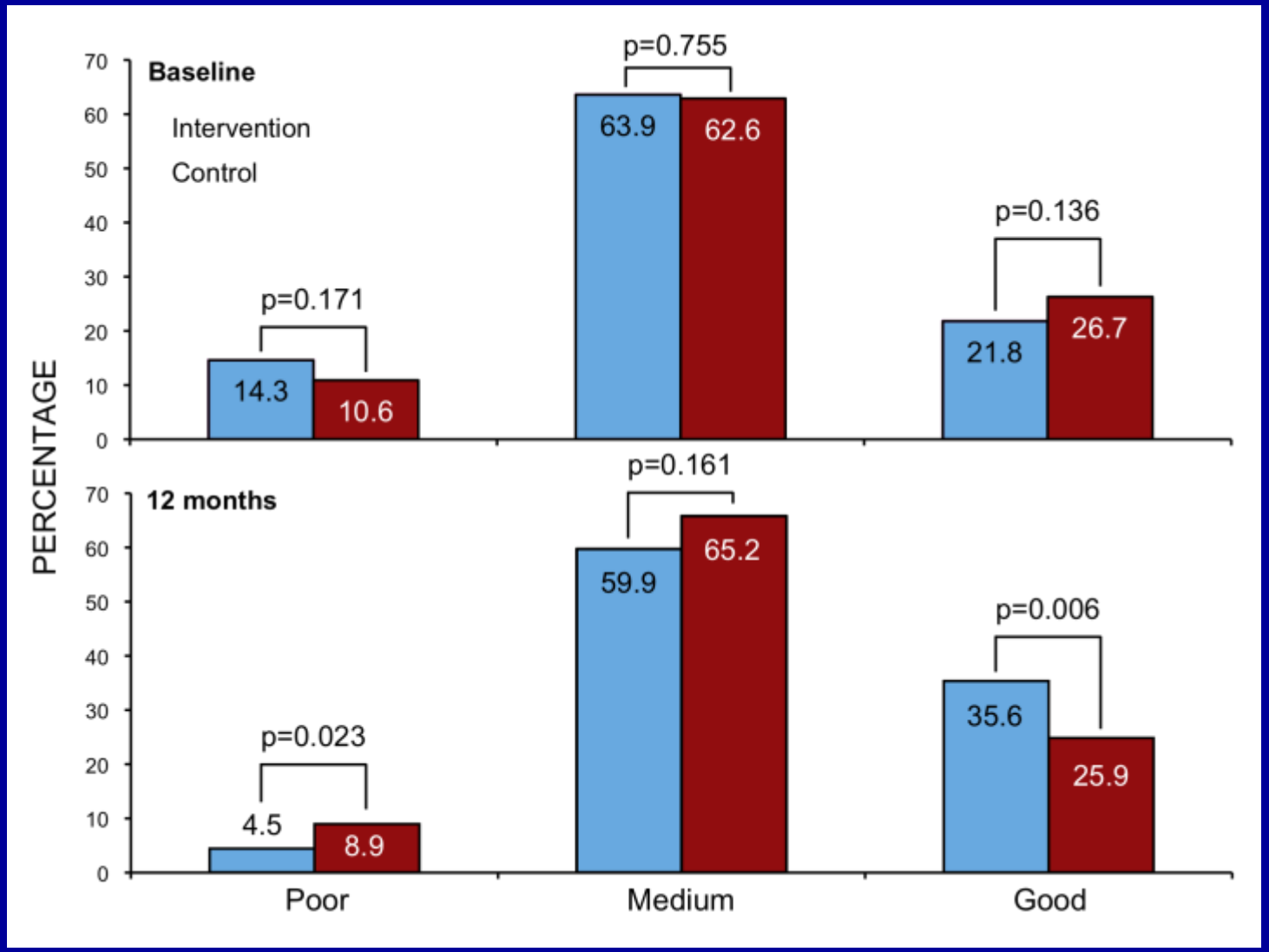
*Number of patients currently smoking, data presented at baseline measurements represents smoking status prior to index event.

Medication use

	Baseline			12 months		
	Intervention (N=357)	Control (N=346)	p value	Intervention (N=352)	Control (N=345)	p value
Any antithrombotic agent	99%	100%	0·624	98%	99%	0·773
Any lipidlowering agent	96%	97%	0·565	93%	94%	0·642
Beta blockers	90%	90%	1.000	76%	79%	0·470
Calcium channel blocker	17%	18%	0·921	22%	19%	0·345
Diuretics	14%	14%	1.000	22%	15%	0·030
Angiotensin-converting enzyme inhibitors	55%	48%	0·083	57%	46%	0·008
Angiotensin II receptor blockers	10%	8%	0·515	17%	16%	0·837
Alfa blockers	0%	1%	0·120	0%	1%	0·059

Antithrombotic agents are asprinie, clopidogrel, dipyridamol or any oral anticoagulant.
Lipidlowering agents are statins or non-statin lipidlowering agents.

Risk factor control



Poor:	0-3 factors on target
Medium:	4-6 factors on target
Good:	7-9 factors on target

Conclusions

- A nurse coordinated hospital based prevention program with up to 4 outpatient clinic visits in addition to usual care results in sustained lowering of cardiovascular risk in patients with coronary disease.
- The program was well attended, practical and can be readily implemented into daily practice.