



# The telephone lifestyle intervention ‘Hartcoach’ has modest impact on coronary risk factors: A randomised multicentre trial

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## Abstract

**Background:** Unhealthy diets and inactivity are still common among patients with cardiovascular diseases. This study evaluates the effects of the telephonic lifestyle intervention ‘Hartcoach’ on risk factors and self-management in patients with recent coronary events.

**Design:** This was a randomised trial in five Dutch hospitals.

**Methods:** Patients (18–80 years), less than eight weeks after hospitalisation for acute myocardial infarction or (un)stable angina pectoris were randomised to the Hartcoach-group, who received telephonic coaching every four weeks for a period of six months (in addition to usual care), and a control group receiving usual care only. Simple random allocation was used (without relation to prior assignment). Measurements were taken by research nurses blinded for group allocation. Differences after six months of participation were compared using linear or logistic regression models with treatment-group and baseline score for the outcome under analysis as covariates, resulting in adjusted mean change (*b*).

**Results:** Altogether 374 patients were randomised (173 Hartcoach + usual care, 201 usual care only). Follow-up was obtained in 331 patients who still participated after six months. Hartcoach had significant favourable effects on body mass index (BMI) ( $b = -0.32$ ; 95% CI:  $(-0.63 - -0.003)$ ), waist circumference ( $b = -1.71$ ; 95% CI:  $(-2.73 - -0.70)$ ), physical activity ( $b = 15.08$  (score); 95% CI:  $(0.13, 30.04)$ ) daily intake of vegetables ( $b = 13.41$ ; 95% CI:  $(1.10 - 25.71)$ ), self-management ( $b = 0.11$ ; 95% CI:  $(0.00 - 0.23)$ ) and anxiety ( $b = -0.65$ ; 95% CI:  $(-1.25 - -0.06)$ ). Hartcoach slightly increased the total number of risk scores on target ( $b = 0.45$ ; 95% CI:  $(0.17 - 0.73)$ ).

**Conclusions:** Hartcoach has modest impact on BMI, waist circumference, physical activity, intake of vegetables, self-management and anxiety. Therefore, it may be a useful maintenance programme in addition to usual care, to support patients with recent coronary events to improve self-management and reduce risk factors.

## Keywords

Lifestyle, cardiovascular diseases, risk factors, self-care

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## Introduction

Fatality rates for cardiovascular diseases (CVDs) have been declining due to improvements in diagnosis and treatment, leaving a greater number of patients in need of secondary prevention.<sup>1</sup> In spite of comprehensive guidelines for the long-term management of patients with coronary diseases, persistent smoking, unhealthy diets and physical inactivity are still common,

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suggesting the need for more effective lifestyle interventions.<sup>2</sup> Research showed that lifestyle modification programmes that include goal setting, planning, self-monitoring and feedback, showed greater improvements in dietary and exercise behaviour than programmes without these components.<sup>3</sup> The Australian programme, Coaching Patients On Achieving Cardiovascular Health (COACH),<sup>4–7</sup> includes these four elements and provides a telephonic professional support for self-management.

Evaluation showed that patients who were coached showed a significantly greater reduction in body weight, dietary intake of fat and lower levels of cholesterol, compared to patients who received usual care only.<sup>7</sup> In addition, patients reported more regular walking, were less anxious and experienced better health and mood.<sup>7</sup> In the Netherlands, the health insurance company Zilveren Kruis has introduced the COACH programme in clinical practice. It is unclear, however, if the results that were obtained in Australia may also be expected in other countries with different health care systems. Therefore, a randomised trial was conducted to assess the effects of the program in the Netherlands. To avoid confusion with another Dutch coaching programme for patients with heart failure,<sup>8</sup> the Dutch version of the COACH programme is renamed as ‘Hartcoach’.

The primary aim of this study was to investigate the effects of Hartcoach on cholesterol, body mass index (BMI), waist circumference, systolic blood pressure, physical activity and diet in patients with recent coronary events. The secondary aim was to see to what extent the Hartcoach programme affects glucose, smoking, medication adherence, self-management, anxiety, depression and quality of life.

## Methods

### Study design

A multicentre, randomised parallel-group study was performed in five Dutch hospitals between January 2012–August 2014. The experimental group received Hartcoach in addition to usual care, while the control group received usual care only. The study protocol, sample size calculation and intervention have been described in detail previously and are summarised here.<sup>9</sup>

The study was approved by the institutional committees on human research of all participating hospitals (Trial Registration Number: NTR2388).

### Population and randomisation

Patients fulfilled the inclusion criteria if they were 18–80 years old and had been hospitalised less than eight

weeks before due to an acute myocardial infarction: ST-segment elevation myocardial infarction (STEMI), non ST-segment elevation myocardial infarction (non-STEMI), unstable angina pectoris (UAP), or chronic angina pectoris (CAP). The exclusion criteria were planned surgery or other interventions; life-expectancy of less than two years according to judgment of the treating cardiologist; moderate to severe heart failure (NYHA class III or IV); previous or current similar lifestyle interventions (i.e. any intervention with multiple sessions focusing on changing patient’s lifestyle), while participation in traditional cardiac rehabilitation was allowed; no telephone; or communication disorders.

Between January 2012–December 2014, eligible patients were informed about the study by a research nurse or the treating cardiologist from the hospital, and provided with written information. After receiving the signed informed consent and the first measurement (performed within eight weeks after discharge from the hospital), each patient was allocated to ‘Hartcoach + usual care’ or to ‘usual care’ only, using a PHP RAND function. This function generates a random integer 0 or 1, (irrespective of prior assignment) after the research nurse logged in to a specific portal. The coordinating research centre (Netherlands Institute for Health Services Research (NIVEL)) provided written information to the patient about the randomisation. Research nurses and cardiologist were blinded to allocation.

### Intervention

Hartcoach consisted of a period of six months in which the coach contacted each patient every four to six weeks by telephone. The Dutch coaches were nurses who were working at the medical call centre of Zilveren Kruis, a medical insurance company in the Netherlands. These nurses were trained in Australia and additionally participated in a course on motivational interviewing.

Before starting the first coaching session, the baseline values for risk factors and medication use as recorded by the research assistant at the baseline measurement were sent to the coaches by the coordinating study centre.

In each coaching session, the following items were addressed: (a) information on individual risk factors and appropriate targets; (b) information and education on methods to reach the appropriate target on the risk factors; (c) negotiating a plan to reach those targets; (d) stimulating healthy dietary and exercise behaviour; (e) monitoring and feedback on progress; (f) stimulating the patient’s own responsibility; (g) stimulating assertiveness in relation to health care providers and the patient’s direct environment (e.g. asking for test results).

Each coaching session lasts about 20 min (up to a maximum of 30 min) and is concluded with a clear agreement regarding date and time of the next call.

### Usual care

Usual care in the Netherlands may include visits to the cardiologist, cardiac nurse, general practitioner, physical therapist, and dietician. Usual care may also include cardiac rehabilitation.

### Measurements and outcomes

All measurements (body length, weight, waist circumference, blood pressure, anamnesis and patients questionnaire) were performed at baseline and after six months by research nurses in the participating hospitals. Blood values were determined in the medical centre in which the patient was treated, according to local standard practice.

Gender, educational status, marital status, work status, the occurrence of life events in the past 12 months, ethnicity, cardiovascular history, treatment history, medication use and co morbidity were documented by the research assistant or nurse at baseline, using an electronic questionnaire and information from the medical record of the hospital. Smoking, alcohol consumption, illness perception, self-care strategies in relation to coronary diseases, medication adherence, physical activity, dietary behaviour, quality of life, anxiety and depression were measured through a (paper) patient questionnaire. Validated questionnaires were used for medication adherence, physical activity, dietary behaviour, quality of life, anxiety and depression (Table 1).<sup>10–17</sup> Questions to measure patients' smoking, understanding of the heart condition and self-management are presented in the Supplementary Material, Appendix 1. At six months, all measurements were repeated, supplemented with a question about received usual care.

In Table 1 definitions of primary and secondary outcome measures are presented, including ideal outcomes according to national guidelines where applicable.<sup>18</sup> Of note, the individualised targets that were set by nurse and patient in the coaching trajectory may not always fully correspond with the ideal outcomes. For example, a patient may decide to reduce the number of cigarettes instead of complete cessation of smoking.

### Statistical analysis

For comparisons between the study groups at baseline independent sample *t*-tests or Fisher's exact tests were used. Differences between baseline and six months follow-up were tested with paired sample *t*-tests and

McNemar tests. Differences in outcomes at follow-up between both groups were compared using linear or logistic regression models with treatment group and baseline score for the outcome under analysis as covariates. Residuals were tested for normality using the Shapiro–Wilk test and residuals plots were inspected. Age, gender, ethnicity, educational status and cardiovascular history were analysed as possible covariates.

The primary analysis was based on the 'intention to treat' principle, in which patients were analysed according to their random allocation. In addition, we performed an analysis 'according to protocol'. In this latter analysis, results were treated according to the actually received intervention (14 patients from the Hartcoach group were never reached by the coach, while four patients from the usual care group erroneously received Hartcoach), and data from patients from the Hartcoach group who received less than four coaching sessions ( $n = 34$ ) were excluded.

### Number of risk factors on target

Most of the outcome variables in this study are well known risk factors for cardiovascular diseases (e.g. low density lipoprotein (LDL) cholesterol, systolic blood pressure, BMI, waist circumference, physical activity, intake of vegetables, fruit, saturated fat and alcohol, smoking and glucose). In addition to the differences in mean scores of the outcome variables, we investigated whether the patient's risk factors were on target according to the national guidelines for coronary prevention.<sup>18,19</sup>

Differences in proportion of patients with individual risk factors on target between baseline and six months follow-up within groups were tested with McNemar test. The differences between both groups were analysed using logistic regression analysis with treatment group and baseline proportion for the variable under investigation as covariates. We also analysed the total number of individual risk scores on target (range 0–9).

Results were analysed using STATA statistical software (StataCorp, College Station, Texas, USA).

## Results

Between January 2012–December 2014, 374 patients were included in the study, 303 men and 71 women, with an average age of 60 years. Eighteen patients withdrew from the study after the first measurement (six from the Hartcoach and 12 from the usual care group), and 25 patients were lost to follow-up (nine from the Hartcoach and 16 from the usual care group) (Figure 1). As a result, follow-up was obtained in 331 patients (89%). There were no systematic

**Table 1.** Study outcomes, targets and measurements at T<sub>0</sub> and T<sub>1</sub>.

	Target	Measurement
Primary outcomes		
BMI	≤25 or at least 5% reduction of bodyweight	Height: measured without shoes, by nurse Weight: measured without coat and shoes, by nurse
Waist circumference	♀ ≤ 88 cm, ♂ ≤ 102 cm	Measured by nurse with a measuring tape halfway between the lowest rib and the top of the hipbone around the abdomen, under (or without) clothing.
Physical activity	≥30 min 5 times per week	Patient questionnaire: Physical Activity Scale for the Elderly (PASE) <sup>16</sup>
Systolic blood pressure	<140 mm Hg	Measured by nurse with an automatic sphygmomanometer. Patient is seated and both arms are measured. Measurement on the arm with the highest systolic blood pressure is repeated. The mean value of both measurements is registered
Total cholesterol	≤5.0 mmol/l	Laboratory
LDL cholesterol	≤2.5 mmol/l	Laboratory
HDL cholesterol	≥1.0 mmol/l	Laboratory
Diet	2 Ounces of vegetables, 2 pieces of fruit	Patient questionnaire: Maastricht Dietary questionnaire <sup>14,15</sup>
Secondary outcomes		
Blood glucose	Fasting glucose < 7 mmol/l	Laboratory
Smoking	Fully quit	Patient questionnaire: Self report, one question (see Supplementary Material, Appendix 1)
Self-management		Patient questionnaire: Self report, five questions (see Supplementary Material, Appendix 1)
Medication adherence	Full adherence	Patient questionnaire: Adapted Morisky Scale <sup>10</sup>
Quality of life		Patient questionnaire: MacNew Heart Disease Health-related Quality of Life Questionnaire <sup>11,12</sup>
Depression and anxiety		Patient questionnaire: Hospital Anxiety and Depression Scale (HADS) <sup>13,17</sup>

BMI: body mass index; HDL: high density lipoprotein; LDL: low density lipoprotein.

differences in characteristics or outcome variables at baseline between the dropouts from the Hartcoach group and the usual care group. The majority of patients was admitted to the hospital because of an acute myocardial infarction (STEMI and non-STEMI together 74%), followed by instable angina pectoris (17%). Sixty-three percent of the patients in both study groups had followed cardiac rehabilitation (Table 2).

Comparison of demographics and individual risk factors at baseline revealed no significant differences between both study groups. Patients in the Hartcoach group received on average 4.94 (1.07) telephone sessions, 107 patients (62%) received five or more sessions. Most people were very willing to be reached for the next appointment, but the coaches often had to call

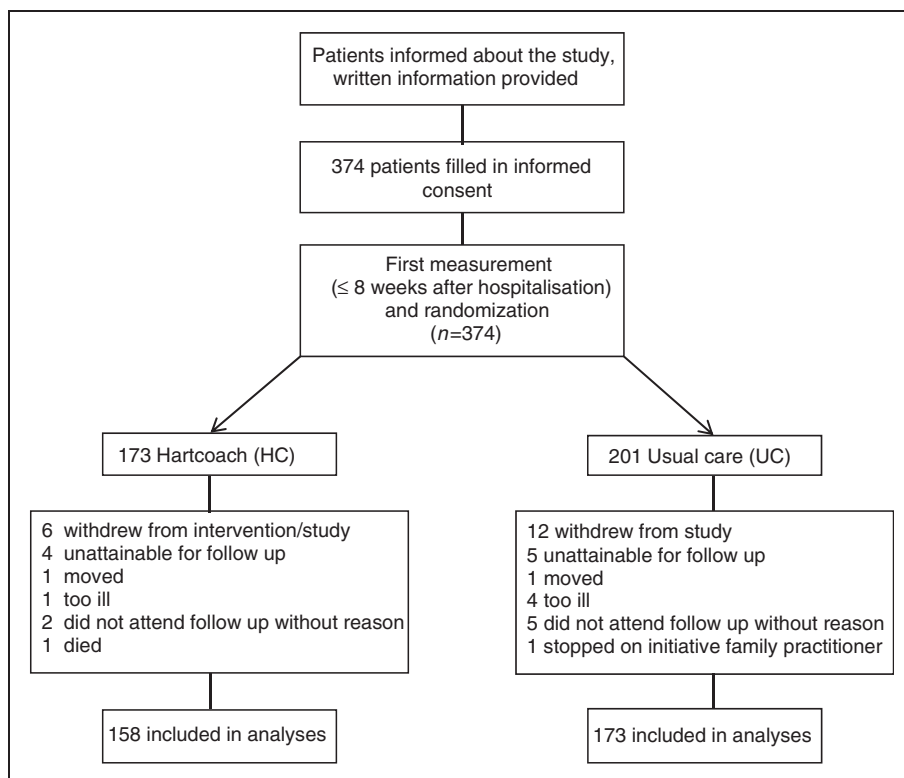
several times because participants had forgotten the exact date and time of the appointment.

### *Change in outcome between baseline and after six months participation*

Tables 3 and 4 present mean values and standard deviations of the primary and secondary outcomes at baseline and after six months participation (column 3: Hartcoach, column 5: usual care).

In both groups, systolic blood pressure significantly increased from baseline to six months. The intake of saturated fat decreased, and self-management and quality of life improved significantly.

In the Hartcoach group, waist circumference significantly decreased, while understanding of the heart



**Figure 1.** Randomisation and reasons for withdrawal.

condition increased and anxiety diminished. In the usual care group, a significant increase of total cholesterol and BMI was found between baseline and six months follow-up.

Since over 97% of the participants had an adequate score on the medication adherence questionnaire at baseline and the distribution of the residuals was strongly skewed, these results were not further analysed.

After six months participation in the study, more patients were on target for self-reported physical activity in the Hartcoach group compared to baseline. The total number of risk factors on target decreased in the usual care group from baseline to six months follow-up ( $<0.05$  on a one-tailed paired  $t$ -test) (Table 5, columns 3 and 5).

### Effects of Hartcoach

Tables 3 and 4 also present the adjusted mean change (baseline value as covariate) in outcomes from baseline to six months between Hartcoach and usual care (column 6). Significant favourable effects of Hartcoach were found for the primary outcomes BMI, waist circumference, physical activity and intake of vegetables. In the Hartcoach group, BMI was unchanged, waist circumference decreased, the intake of vegetables and physical activity increased.

Conversely, in the usual care group BMI increased, waist circumference remained unchanged, intake of vegetables and physical activity decreased. Furthermore, Hartcoach showed favourable effects on the secondary outcomes self-care and anxiety.

When results are analysed per protocol, the favourable effects of Hartcoach on physical activity and intake of vegetables were no longer statistically significant ( $p=0.36$ , resp.  $p=0.07$ ). On the other hand, a significant positive effect of Hartcoach was found on patient's understanding of the heart condition.

None of the covariates age, gender, ethnicity, educational status and cardiovascular history interacted with the results.

Hartcoach had no significant effect on the proportion of patients on target for individual risk factors, but did have a significant positive effect on the total number of risk scores on target. While the total number of risk factors on target slightly increased in the Hartcoach group, a significant decrease in total number of risk factors on target was seen in the usual care group.

### Discussion

In this multicentre randomised study we found that Hartcoach, telephonic coaching for patients with coronary heart diseases, leads to improvements in waist circumference, physical activity, vegetable

**Table 2.** Patient's characteristics.

	Hartcoach		Usual care		Total	
	<i>n</i>	(%)	<i>n</i>	(%)	<i>n</i>	(%)
Number of patients	173		201		374	
Mean age (SD)	61.0	(10.0)	60.0	(10.4)	60.4	(10.2)
Gender						
Male	136	(78.6)	167	(83.1)	303	(81.0)
Female	37	(21.4)	34	(16.9)	71	(19.0)
Education						
Lower/ average	107	(65.2)	133	(67.5)	240	(66.5)
Ethnicity						
Dutch	145	(83.8)	168	(83.6)	313	(83.2)
Working status						
Paid job	84	(48.6)	100	(49.8)	184	(49.2)
Retired	66	(38.2)	73	(36.3)	139	(37.2)
Volunteer work, housewife/man, other	31	(17.9)	38	(19.9)	69	(18.4)
Unemployed	17	(9.8)	24	(11.9)	41	(11.0)
Reason for admission						
Acute myocardial infarction - STEMI	79	(45.7)	92	(45.8)	171	(45.7)
Acute myocardial infarction – non-STEMI	47	(27.2)	58	(28.9)	105	(28.1)
Unstable angina pectoris (UAP)	31	(17.9)	34	(16.9)	65	(17.4)
Chronic angina pectoris (CAP)	9	(5.2)	9	(4.5)	18	(4.8)
Other/unknown	8	(4.6)	9	(4.5)	17	(4.6)
Treatment						
Coronary artery bypass graft surgery (CABG)	28	(16.2)	38	(18.9)	66	(17.7)
Percutaneous coronary intervention (PCI)	129	(74.6)	151	(75.1)	280	(74.9)
Medication	73	(42.2)	82	(40.8)	155	(41.4)
Other	15	(8.7)	14	(7.0)	29	(7.8)
Medical history						
Myocardial infarct	28	(16.2)	39	(19.4)	67	(17.9)
PCI	33	(19.1)	35	(17.4)	68	(18.2)
CABG	3	(1.7)	11	(5.5)	14	(3.7)
Stroke	7	(4.1)	8	(4.0)	15	(4.0)
Peripheral vascular disease	8	(4.6)	17	(8.5)	25	(6.7)
Hypertension	68	(39.3)	84	(41.8)	152	(40.6)
Heart failure	2	(1.2)	5	(2.5)	7	(1.9)
Kidney failure	5	(2.9)	5	(2.5)	10	(2.7)
Risk factors						
Positive family history <sup>a</sup>	91	(52.6)	103	(51.2)	194	(51.8)
Diabetes	33	(19.1)	40	(19.9)	73	(19.5)
Dyslipidaemia	63	(36.4)	80	(39.8)	143	(38.2)
Combination of these 3 risk factors	8	(4.6)	12	(6.0)	20	(5.6)
Smoking						
Never smoked	43	(25.4)	49	(24.8)	92	(25.1)
Smoker	16	(9.5)	23	(11.6)	39	(10.6)
Former smoker	110	(65.1)	126	(63.6)	236	(64.3)
≤3 months stopped	31	(28.4)	43	(34.4)	74	(20.1)
>3 months stopped	78	(71.6)	82	(65.6)	161	(43.9)

(continued)

**Table 2.** Continued

	Hartcoach		Usual care		Total	
Alcohol use (yes)	132	(67.0)	112	(67.5)	244	(67.2)
Cardiac rehabilitation (yes)	109	(63.0)	127	(63.2)	236	(63.1)

STEMI refers to acute myocardial infarction with elevation of ST-segment and raised troponin or creatinine kinase-MB (CK-MB); non-STEMI refers to acute myocardial infarction without elevation of ST-segment but with raised troponin or CK-MB;

UAP refers to patients with an acute coronary syndrome without raised troponin or CK-MB, with or without Electrocardiography (ECG) changes indicating ischaemic heart muscle (ST-segment depression or elevation etc.); chronic angina pectoris refers to patients without Acute Coronary Syndrome (ACS) but with symptoms of angina (chest pain etc.)

<sup>a</sup>Father, mother, brother or sister with heart disease at age <60 years.

**Table 3.** Adjusted mean change<sup>a</sup> in outcome from baseline to six months between the Hartcoach and usual care groups (primary outcomes).

Primary outcome	Hartcoach			Usual care			Adjusted mean change (95% CI)	p Value
	n <sup>b</sup>	Mean	(SD)	n	Mean	(SD)		
Total cholesterol (mmol/l)								
Baseline		4.00	(0.86)		3.95	(0.81)		
6 Months	151	4.10	(0.83)	169	4.17	(0.95) <sup>c</sup>	-0.12 (-0.29-0.04)	0.15
LDL cholesterol (mmol/l)								
Baseline		2.21	(0.69)		2.13	(0.67)		
6 Months	151	2.28	(1.04)	166	2.23	(0.78) <sup>c</sup>	-0.001 (-0.19-0.18)	0.99
HDL cholesterol (mmol/l)								
Baseline		1.29	(0.81)		1.18	(0.33)		
6 Months	151	1.29	(0.37)	169	1.24	(0.34) <sup>c</sup>	0.03 (-0.05-0.10)	0.47
Systolic blood pressure (mm Hg)								
Baseline		130	(17.16)		132	(19.29)		
6 Months	158	135	(18.00) <sup>c</sup>	173	137	(19.91) <sup>c</sup>	-0.92 (-4.38-2.54)	0.60
BMI								
Baseline		27.3	(3.71)		27.7	(4.20)		
6 Months	158	27.3	(3.54)	172	28.0	(4.34) <sup>c</sup>	-0.32 (-0.63- -0.003)	0.048
Waist circumference (cm)								
Baseline		100.5	(10.31)		101.1	(11.40)		
6 Months	158	99.3	(9.75) <sup>c</sup>	172	101.5	(11.88)	-1.71 (-2.73- -0.70)	0.001
Physical activity (PASE score)								
Baseline		144.29	(82.06)		136.81	(75.30)		
6 Months	148	153.26	(87.15)	169	133.54	(79.45)	15.08 (0.13-30.04)	0.048
Vegetables (g daily)								
Baseline		149.40	(79.84)		138.81	(62.96)		
6 Months	144	157.69	(84.87) <sup>d</sup>	164	136.93	(62.08)	13.41 (1.10-25.71)	0.033
Fruit (pieces daily)								
Baseline		1.72	(1.64)		1.49	(1.37)		
6 Months	138	1.81	(1.51) <sup>d</sup>	159	1.52	(1.36)	0.17 (-0.11-0.45)	0.23
Intake of fat								
Baseline		17.65	(5.59)		17.58	(5.50)		
6 Months	142	16.00	(5.73) <sup>c,d</sup>	166	16.14	(4.94) <sup>c</sup>	-0.17 (-1.08-0.74)	0.72

BMI: body mass index; CI: confidence interval; PASE: Physical Activity Scale for the Elderly; SD: standard deviation.

<sup>a</sup>Data are given as a mean (SD) change from baseline, adjusted for baseline levels as covariate.

<sup>b</sup>Sample size changes due to missing data.

<sup>c</sup>Significant change from baseline to six months ( $p < 0.05$ ).

<sup>d</sup>Score on Maastricht Dietary questionnaire.

**Table 4.** Adjusted mean change<sup>a</sup> in outcome from baseline to six months between the Hartcoach and usual care groups (secondary outcomes).

Secondary outcome	Hartcoach			Usual care			Adjusted mean change <sup>a</sup>	p Value
	n <sup>b</sup>	Mean	(SD)	n	Mean	(SD)		
Blood glucose (mmol/l)								
Baseline		5.8	(1.12)		6.0	(1.58)		
6 Months	150	5.9	(1.24)	169	6.16	(1.78)	-1.0 (-0.31-0.12)	0.37
HbA1c (mmol/mol)								
Baseline		47.97	(7.40)		48.06	(14.49)		
6 Months	31	48.77	(10.57)	32	50.47	(14.66)	-1.62 (-6.26-3.02)	0.49
Understanding heart condition								
Baseline		6.72	(1.55)		6.42	(1.69)		
6 Months	124	7.11	(1.66) <sup>c</sup>	141	6.64	(1.66)	0.31 (-0.04-0.66)	0.08
Self-management								
Baseline		3.48	(0.68)		3.43	(0.67)		
6 Months	145	3.73	(0.59) <sup>c</sup>	167	3.60	(0.61) <sup>c</sup>	0.11 (0.00-0.23)	0.049
Anxiety								
Baseline		4.67	(3.78)		5.05	(3.91)		
6 months	145	3.95	(3.59) <sup>c</sup>	167	4.88	(4.00)	-0.65 (-1.25- -0.06)	0.031
Depression								
Baseline		3.41	(3.29)		3.64	(3.61)		
6 Months	145	3.31	(3.71)	167	3.83	(3.64)	-0.35 (-0.93-0.24)	0.24
Quality of life								
Total score								
Baseline		5.24	(0.98)		5.15	(1.00)		
6 Months	143	5.65	(1.02) <sup>c</sup>	164	5.49	(1.05) <sup>c</sup>	0.09 (-0.07-0.25)	0.27
Physical								
Baseline		5.02	(1.15)		4.95	(1.16)		
6 Months	144	5.54	(1.21) <sup>c</sup>	164	5.36	(1.21) <sup>c</sup>	0.12 (-0.07-0.31)	0.23
Emotional								
Baseline		5.25	(1.08)		5.14	(1.13)		
6 Months	143	5.54	(1.06) <sup>c</sup>	165	5.29	(1.17) <sup>c</sup>	0.17 (-0.01-0.34)	0.06
Social								
Baseline		5.45	(1.03)		5.31	(1.11)		
6 Months	143	5.89	(1.09) <sup>c</sup>	165	5.86	(1.07) <sup>c</sup>	-0.06 (-0.25-0.13)	0.54

HbA1c: haemoglobin A1c; SD: standard deviation.

<sup>a</sup>Data are given as a mean (SD) change from baseline adjusted for baseline levels as covariate.

<sup>b</sup>Sample size varies due to missing data.

<sup>c</sup>Significant change from baseline to six months ( $p < 0.05$ ).

intake, self-management and anxiety and prevents deterioration of BMI. These positive results are consistent with results from the Australian study of Hartcoach and earlier reviews of lifestyle interventions.<sup>3,7,20,21</sup> As Hartcoach primes the patient towards self-management by making relevant behavioural changes, the intervention fits in today's policy to enhance self-management of patients as a means of secondary prevention.<sup>22,23</sup>

No overall effect of Hartcoach was found on cholesterol, in contrast to the COACH study in Australia.<sup>7</sup> This may be related to the fact that, contrary to the Australian situation, the initial cholesterol level in our

study was on target for almost 90% of the patients, with an average level of 3.99 mmol/l. This can be explained by the fact that, according to Dutch guidelines, 90% of the patients in this study used statins to control their cholesterol level.

No effects were found for glucose level, systolic blood pressure and haemoglobin A1c (HbA1c), which corresponds with the results in the review study by Angermayr and Melchart.<sup>20</sup> A relatively 'light' intervention such as telephone sessions may have no direct effect on blood values. Even if the intervention is effective, a time lag may exist between improved lifestyle and



**Table 5.** Odds of the number of patients with individual risk factors on target from baseline to six months between the Hartcoach and usual care groups.

Risk factors	Hartcoach			Usual care			OR <sup>a</sup> (95% CI)	p Value
	N	n	(%)	N	n	(%)		
LDL cholesterol ( $\leq 2.5$ mmol/l)								
Baseline		110	(72.9)		127	(76.5)		
6 Months	151	118	(78.2)	166	122	(73.5)	1.51 (0.85–2.68)	0.16
Systolic blood pressure ( $< 140$ mm Hg)								
Baseline		116	(73.4)		121	(69.9)		
6 Months	158	103	(65.2)	173	99	(57.2)	1.38 (0.85–2.24)	0.19
BMI ( $\leq 25.0$ )								
Baseline		48	(30.4)		41	(23.8)		
6 Months	158	46	(29.1)	173	38	(22.1)	1.31 (0.59–2.95)	0.51
Waist circumference ( $\text{♀} \leq 88$ cm, $\text{♂} \leq 102$ cm)								
Baseline		29	(18.4)		26	(15.1)		
6 Months	158	34	(21.5)	172	27	(15.7)	1.47 (0.74–2.93)	0.27
Physical activity ( $\geq 30$ min, 5 times per week)								
Baseline		117	(81.3)		133	(79.6)		
6 Months	144	129	(89.6) <sup>b</sup>	167	139	(83.2)	1.85 (0.88–3.88)	0.11
Vegetables ( $\geq 2$ ounces daily)								
Baseline		27	(18.8)		23	(14.0)		
6 Months	144	36	(25.0)	164	27	(16.5)	1.62 (0.86–3.02)	0.13
Fruit ( $\geq 2$ pieces daily)								
Baseline		54	(39.1)		51	(32.1)		
6 Months	138	60	(43.5)	164	51	(32.1)	1.55 (0.91–2.63)	0.10
Smoking (not)								
Baseline		155	(92.3)		131	(91.6)		
6 Months	168	152	(90.5)	143	131	(91.6)	1.55 (0.48–5.05)	0.46
Blood glucose (fasting glucose $< 7$ mmol/l)								
Baseline		120	(71.0)		104	(69.3)		
6 Months	169	110	(65.1)	150	107	(71.3)	1.58 (0.90–2.78)	0.11
Total number of risk factors on target (0–9)								
Baseline		Mean	(SD)		Mean	(SD)	Adjusted mean change (95% CI)	p value
Baseline		4.92	(1.46)		4.71	(1.38)		
6 Months	145	5.03	(1.57)	168	4.46	(1.43) <sup>c</sup>	0.45 (0.17–0.73)	0.002

BMI: body mass index; CI: confidence interval; LDL: low density lipoprotein; OR: odds ratio.

Number of patients varies due to missing data.

<sup>a</sup>OR adjusted for baseline levels as covariate.

<sup>b</sup>Significant difference between baseline and six months (test of proportions  $p < 0.05$ ).

<sup>c</sup>Significant difference between baseline and six months (paired t-test  $p < 0.05$ ).

subsequent changes in blood values. In addition, most people take medication to control their blood pressure and blood values and any additional effects of Hartcoach may be too small to detect.

Smoking is one of the most relevant risk factors for coronary disease. In this study however, the number of self-reported current smokers at baseline (baseline measurement was about eight weeks after the coronary event) was too low to study the effect of Hartcoach on smoking cessation. The majority of the former smokers

had stopped less than three months previously, probably on the occasion of their coronary event.

While self-management significantly improved, anxiety decreases and the risk factors of BMI, waist circumference, physical activity and intake of vegetables are positively influenced by Hartcoach, the effects we found are small. Furthermore, improvements for physical activity and intake of vegetables were no longer statistically significant when results were analysed per protocol. Therefore, it is difficult to access the clinical

relevance of these favourable effects. Sometimes the effect of Hartcoach is merely a prevention of deterioration rather than an improvement, as seen with BMI. A comparable effect was found by Jørstad et al. who found that a nurse coordinated prevention programme prevented deterioration in blood pressure.<sup>24</sup>

Hartcoach also revealed no effect on reaching the appropriate targets on individual risk factors when analysed separately. However, the total number of risk factors that reached target levels is positively influenced, although the difference in number of risk factors on target is very small (0.45).

Yet, Hartcoach is a 'light and cheap intervention' which is implemented in the Netherlands as an additional programme after cardiac rehabilitation and was never intended to substitute usual care. Patients have time to ask for information which they may find more difficult in a regular visit with their cardiologist or cardiac nurse. The regular telephone contacts not only offer the patient an opportunity to discuss health related issues, but may also provide the patient with emotional support, which is supported by the effect we found on anxiety. Furthermore, maintenance of lifestyle changes is difficult and cardiac patients relapse into old habits.<sup>2</sup> Hartcoach could therefore function as a "support" programme for people after cardiac rehabilitation.

### Limitations of the study

A limitation of the study is that two primary outcomes were self-reported: physical activity and dietary behaviour. Although this applies to patients from both study groups, patients who are coached may be more aware of the desired dietary and exercise behaviour and may be inclined to report this more positively.

With the food questionnaire used<sup>14,15</sup> the intake of saturated fat could not be measured separately from total fat intake, making it impossible to analyse whether patients reached the target score on this risk factor. Furthermore, over 97% of the participants had an adequate score on medication adherence questionnaire at baseline, and the distribution of scores was strongly skewed. Therefore, effect on medication adherence could not be analysed at all.

### Conclusions

Hartcoach was associated with positive effects on BMI, waist circumference, physical activity, intake of vegetables, self-management and anxiety. These effects were mild but consistent with results found in the literature on lifestyle interventions. Hartcoach may be a useful maintenance programme in addition to usual care to support patients with coronary diseases to achieve a

healthier lifestyle and improve their coronary risk factors.

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