ORIGINAL ARTICLE

Evaluating the Efficacy of an Education and Treatment Program for Patients with Coronary Heart Disease

A Randomized Controlled Trial

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SUMMARY

Background: Until now, there has not been any evaluated, disease-specific education and treatment program for patients with coronary heart disease (CHD) in Germany. It is thought that education can improve these patients' physical activity and quality of life and teach them how to lessen their risk factors, what to do in case of an emergency, and how to assess their own medical treatment.

Methods: A randomized controlled open intervention trial was carried out from February 2010 to September 2011. 196 patients were assigned to receive the intervention (patient education), while 199 were assigned to a control group. In an intention-to-treat analysis, baseline and follow-up data were compared after a mean interval of 220 days. The evaluative instruments included the Freiburg Questionnaire of Physical Activity, the MacNew Heart Disease Quality of Life Questionnaire, questionnaires regarding knowledge about CHD, ergometric performance ability, and the body-mass index.

Results: The patients in the intervention group reported having increased their physical activity by a mean of 9.3 MET/week (MET=metabolic equivalent of task), compared to 2.5 MET/week in the control group; the difference of 6.8 MET/week was statistically significant ($p = 0.015$). The patients in the intervention group also rated their quality of life higher than those in the control group (0.2 ± 0.56 vs. 0.09 ± 0.53 [mean $\pm$ standard deviation], $p = 0.056$). They were significantly better informed than patients in the control group about risk factors and about what to do in an emergency.

Conclusion: Persistently unhealthy lifestyle is a common problem of CHD patients; the education and treatment program presented here may be a suitable means of improving patients' lifestyle for secondary prevention. Further studies will be needed to document long-term efficacy and to determine whether occasional refresher courses will be needed as well.

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In 2011, coronary heart disease (CHD) was in first place in the causes of death statistic for the male population in Germany, at 8.2%. In second and third place, respectively, were lung and bronchial cancer (7.3%) and acute myocardial infarction (7.0%). In the female population, CHD is also the most commonly reported cause of death (8.3%), followed by heart failure (6.9%) and acute myocardial infarction (5.3%) (1). In 2010, almost 7% of women and 10% of men reported that they had been diagnosed with CHD (2).

In the past few years, notable progress has been made in treating CHD (3). In contrast, however, the trend towards unhealthy lifestyles persists, hampering medical progress (4). The German Cardiac Society (Deutsche Gesellschaft für Kardiologie, DGK) is calling for more preventive programs that promote a healthy lifestyle (5).

In 2006 the disease management program (DMP) “coronary heart disease” was implemented in Germany according to §73a of the social code (Sozialgesetzbuch). For other treatment programs that were evaluated—for example, for diabetes or asthma/COPD (chronic obstructive pulmonary disease)—disease-specific training programs exist, but this is not the case for the DMP for patients with CHD. A training program for CHD patients might:

- Ensure the long-term success of cardiac rehabilitation
- Promote participation in an outpatient heart group
- Strengthen patients' competence in a medical emergency (6)
- Improve adherence to drug and non-medication treatment—for example, by increasing physical activity (7).

In patients with CHD, physical activity (exercise) resulted in improved physical performance, reduced symptoms, and improved quality of life. In secondary prevention, regular training constitutes an important factor that positively affects the prognosis (8–11).

The present study investigates the effect of an education and treatment program for CHD patients on the following primary end points: increase in physical activity and improvement in quality of life.

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Methods

The study was designed as a randomized controlled and open intervention study and is quality controlled by the Interdisciplinary Center for Clinical Trials in Mainz (Interdisziplinäres Zentrum für Klinische Studien, IZKS), approved by the ethics committee at the Hesse State Medical Association (*eBox*), and registered with the German Clinical Trials Register (Deutsches Register Klinischer Studien, DRKS).

The primary end points were evaluated in an intention-to-treat analysis and the secondary end points were evaluated as per protocol. In the time period from February 2010 to September 2011, a total of 395 patients with CHD and aged 18–89 years were included in the study. The definition of CHD was taken from the requirements concerning structured treatment programs for coronary heart disease published in the *Federal Law Gazette* (12). Recruitment was undertaken by members of the physicians' network Frankfurt North Training Association. 13 primary care physicians and two cardiologists in private practice participated. They initiated the randomization—immediately after recruitment and anonymous completion of the baseline questionnaire by the patients—and reported the results (and the dates of the education program for those in the intervention group) to the patients within 3 days. None of the participating patients refused randomization. Each doctor and practice personnel knew which group their patients were randomized to. If practices were not able to train the participants in the intervention group themselves they referred them to practices that were suitably equipped to deliver the training.

The study center was located at the Bürgerhospital, Frankfurt am Main, and functioned as a central coordinating center (headed by Ms Kufleitner). She randomized patients dynamically and communicated to the study practices whether a patient had been allocated to the intervention group or the control group (*Table 1*) (13). Altogether, 202 patients were randomized to the intervention group and 205 patients to the control group. In the context of the intention-to-treat evaluation, 196 patients remained in the intervention group and 199 patients in the control group (*Figure 1*). In the context of the evaluation as per protocol, 21 patients were excluded from the intervention group (for example, because of missed training appointments), and 19 patients from the control group, so that a total of 181 patients remained in the intervention group and 186 patients in the control group. The study included patients with confirmed coronary heart disease in whom an ergometric assessment had been carried out in the 12 weeks preceding the starting date of the study, and who had achieved a level of at least 2 minutes at 75 watts. This was done to ensure that the conditions for the change in the primary end point “physical activity” were met. The ergometry test was to be conducted according to predefined standards (14). Full participation was defined as attendance of three appointments at time intervals of about 7 days.

TABLE 1

Demographic patient data (analysis by intention to treat)—equal distribution of groups by means of dynamic randomization

	Intervention group (n = 196)	Control group (n = 199)
Sex		
Male	155	158
Female	40	41
Age		
Mean	65.7 years	65.8 years
18–39 years	0	1
40–49 years	7	7
50–59 years	41	38
60–69 years	75	79
70–79 years	63	62
≥ 80	9	12
German mother tongue		
Yes	176	180
No	19	19
Highest school leaving certificate		
No leaving certificate	2	4
Second-level primary school	83	83
Intermediate school certificate (after 10 years)	51	55
Abitur (qualification enabling entry into tertiary education)	59	57
Weight		
Mean*	83.1 kg	84.4 kg
BMI* (kg/m ²)	27.9	28.5

* No randomization parameter; differences between groups non-significant.

The course content was developed by the working group of the German Institute for Evidence Based Medicine (Deutsches Institut für evidenzbasierte Medizin, DiEM). In analogy to other education and treatment programs, the lesson materials consisted of:

- A patient brochure
- Teaching cards
- A curriculum
- A poster/wall chart set.

The patient brochure was intended for patients' own independent study and for the purpose of repeating the previous module (*eTable*). Patients were able to enter comments and responses to questions, as in a workbook. Additionally, patients were given an exercise diary to enable them to document their daily physical activity. The education program was delivered in 5 practices that had gained prior experience with other programs. Physicians and medical assistants entrusted with delivering the training were familiarized with the

FIGURE 1

Course of study—list of important stages in the study

special challenges in a seminar taking half a working day. The patients in the control group continued to receive usual care from their primary care physicians/cardiologists.

The follow-up data collection and analysis was planned for six months after the start of the study. At this date, an ergometric assessment had to be available that dated back a maximum of 4 weeks.

Data collection instruments

In order to measure the primary outcome variables, the following data collection instruments were presented to participants at the start of the study as well as at the follow-up appointment.

The Freiburg Questionnaire of Physical Activity documents—independently of the target group—health-promoting activities within the preceding week on the basis of participants' anonymous self-reports (15). These were recorded as metabolic equivalents of task (MET) (1 MET corresponds to the energy consumed while sitting down, of 4.2 kJ [1 Kcal] per kg of body weight per hour) (16). The MacNew Heart Disease Quality of Life Questionnaire (MacNew) captures the emotional states of patients with CHD (17).

The following data collection instruments were employed to measure secondary outcome variables:

- The Bochum Evaluation Questionnaire for Cardiovascular Risk Factors captures awareness of risk factors as a prerequisite of a health-conscious lifestyle (18).
- The Knowledge Questionnaire was developed by members of the study group and related to the themes and topics covered during the education program.
- The “General Disease Course” questionnaire was also developed by members of the study group. This questionnaire documented the quality of blood glucose control, blood pressure control, and fat metabolism regulation, smoking behavior, participation in an outpatient cardiovascular exercise group, and emergency competence, but it also documented severe cardiovascular events that occurred during the observation period.

Participants were randomized by age, sex, mother tongue, highest school leaving certificate, and recruiting practice (Table 1).

Statistical analysis

We used the software package IBM SPSS Statistics (version 20.0) for our statistical evaluations. In evaluating the primary end points, we used the Bonferroni-Holm method, with a multiple significance level of $\alpha=5\%$. The secondary end points were evaluated

TABLE 2

Primary end points

Characteristic	Intervention group (n = 196)	Control group (n = 199)	p-value
Trend in physical activity			
Baseline in MET/week; MW (SD)* ¹	31.8 (25.0)	29.0 (23.9)	0.015* ²
Follow-up in MET/week; MW (SD)* ¹	41.1 (31.9)	31.5 (29.5)	
Difference; MW (SD)* ¹	9.3 (30.6)	2.5 (24.1)	
Trend in disease-related quality of life			
Mean rank* ⁴	211.6	184.6	0.019* ³
Rank sum* ⁴	41 469.5	36 740.5	
Baseline; MW (SD)* ⁴	5.55 (0.95)	5.65 (0.88)	0.056* ²
Follow-up; MW (SD)* ⁴	5.75 (0.87)	5.74 (0.83)	
Difference; MW (SD)* ⁴	0.20 (0.56)	0.09 (0.53)	

^{*1} Freiburg Questionnaire of Physical Activity

^{*2} t test for independent samples in two-tailed test

^{*3} Mann-Whitney U test

^{*4} MacNew Heart Disease Quality of Life Questionnaire (MacNew)

MET, metabolic equivalent of task; MW, arithmetic mean; SD, standard deviation; n, number

exploratively (significance level $\alpha=5\%$, but without the Bonferroni-Holm procedure). In order to determine the necessary number of cases we conducted a *t* test power analysis with the following parameters for the Freiburg Questionnaire of Physical Activity:

- Difference between control group and intervention group = 2 h activity
- Standard deviation 6.4
- Power 0.8
- Significance level $\alpha=5\%$
- Result: 162 subjects per group.

Results

The follow-up data collection was done 220 ± 52 days after the baseline survey. In this study, the authors used the primary and secondary end points as variables for the proof of efficacy at follow-up.

Primary end points

The primary end points were evaluated on the basis of an intention-to-treat analysis according to the LOCF (last observation carried forward) principle (Table 2).

The trend in physical everyday activities is one of the primary end points. In the intervention group, an increase of 9.3 MET per week was observed. The group was therefore 29% more active than before the intervention program. In contrast, the control group increased its activity by only 2.5 MET per week (11% increase). In the comparison between the groups, the intervention group therefore showed a 18% higher increase in physical activity. The difference, of 6.8 MET/week, reached significance at the 95% level ($t[370]: -2.452$; $p=0.015$ in the two-tailed test; effect size $d=0.25$) (Figure 2).

The trend in disease-related quality of life—another primary end point—showed a significant difference in self-assessed quality of life in the MacNew questionnaire: patients who had participated in the intervention program perceived an improvement in their disease-related quality of life more clearly than patients in the control group (Table 2). As far as the mean values are concerned, the intervention group showed an increase of 0.2 points on the scale, compared with the control group, which showed only 0.09 points ($p=0.056$).

Secondary end points

The secondary end points were analyzed as per protocol. Patients in the intervention group were able to keep their knowledge of cardiovascular risk factors present notably longer than patients in the control group. On average, intervention group participants' knowledge—as measured by the Bochum Evaluation Questionnaire on Cardiovascular Risk Factors—deteriorated less than the control group's (Table 3). The intervention showed a clear effect in the responses given to the multiple choice “knowledge questions” devised by the study group. The intervention group improved its test results more than the control group (Table 3).

On the basis of the questionnaire “General Disease Course,” patients in the intervention group were found

Trend in physical activity—the intervention group included $n=196$ patients and the control group $n=199$ patients

MET = metabolic equivalent of task

to deal with emergencies in a more assured way. The confidence to act correctly in case of chest pain was captured by using a scale from 1 (“very confident”) to 7 (“very unconfident”). The intervention group displayed greater self confidence than before the intervention, whereas only slightly increased self confidence was noted in the control group (Table 3). Subjects in the intervention group therefore assessed themselves as significantly more confident of doing the right thing in case of chest pain than those in the control group. The assessment of the inhibition threshold at which participants were prepared to call out the emergency doctor was captured on a scale from 1 (“relatively low”) to 7 (“relatively high”). The intervention group assessed their threshold as notably lower than before the intervention, whereas the threshold in the control group remained relatively high. The threshold for calling out the emergency doctor therefore fell to a significantly greater extent in the intervention group (Table 3).

In all other general questions pertaining to the disease course, no systematic differences were seen between the two groups. Patients in the intervention group did not smoke significantly less after six months than patients in the control group ($z=-0.511$; $p<0.61$; rank sums of 33039.5 for the intervention group and 34488.5 for the control group). Similarly, no significant differences were seen for recorded data on diabetes, hypertension, lipid metabolism disorders with raised LDL cholesterol, inpatient treatment for CHD, bypass surgery, balloon dilatation, myocardial infarction, and membership in an outpatient cardiac group. More new patients in the intervention group joined a cardiac group ($n=17$ new members; 10.6% of the intervention group) compared to those in the control group ($n=9$ new members; 5.4% of the control group). The result did not reach the 95% significance level ($p=0.069$).

TABLE 3

Secondary end points

Characteristic	Intervention group (n = 181)	Control group (n = 186)	p-value
Deterioration of knowledge/awareness of cardiovascular risk factors			
Difference of follow-up and baseline questionnaires; MW (SD)* ¹	2.18 (1.26)	2.51 (1.40)	0.019* ²
Improvement of disease-related knowledge/awareness			
Evaluation of questionnaire; MW (SD)* ³	1.5 (2.2)	0.33 (2.0)	<0.001* ²
(Self-) Confidence in dealing with chest pain			
Baseline evaluation (scale from 1 = "very confident" to 7 = "very un-confident"); MW (SD)* ⁴	3.2 (1.7)	3.1 (1.6)	0.001* ²
Follow-up evaluation (scale from 1 = "very confident" to 7 = "very un-confident"); MW (SD)* ⁴	2.5 (1.2)	2.9 (1.6)	
Difference; MW (SD)* ⁴	0.7 (1.5)	0.2 (1.4)	
Inhibition threshold for calling the emergency doctor in case of chest pain			
Baseline evaluation (scale from 1 = "relatively low" to 7 = "relatively high"); MW (SD)* ⁴	3.4 (2.0)	3.2 (1.9)	0.014* ²
Follow-up (scale from 1 = "relatively low" to 7 = "relatively high"); MW (SD)* ⁴	2.7 (1.7)	2.9 (1.7)	
Difference MW (SD)* ⁴	0.7 (1.8)	0.3 (1.6)	

*¹ Bochum Evaluation Questionnaire for Cardiovascular Risk Factors

*² t test for independent samples in two-tailed tests

*³ Disease-related knowledge questionnaire

*⁴ Questionnaire "General Disease Course"

MW, arithmetic mean; SD, standard deviation; n, number

Furthermore, a comparison between the development of ergometric performance and body mass index (BMI) did not show any significant differences.

Discussion

The working group of the German Institute for Evidence Based Medicine (DIeM) showed that in patients with diabetes, arterial hypertension, and those who need long-term anticoagulation treatment, an education and treatment program reduces morbidity and mortality (19–21). According to a Cochrane analysis, the evidence level is high for the effectiveness of education programs in diabetes (22). An evaluated modular outpatient education program is also available for patients with asthma (23). International scientific medical societies consider education programs as an effective measure for lifestyle modifications in patients with CHD (24, 25). Brown et al., in a meta-analysis, did not find any hard evidence for a reduction in cardiovascular end points as a result of education programs for patients, but they did find evidence for an effective improvement in quality of life and cost reduction (26). The international EUROACTION study—which Germany is not participating in—describes a concept that is very similar to the education program devised by the authors of this article and confirms a positive effect of the intervention on subjects' cardiovascular risk profile (27). Sufficiently evaluated and publicized education and treatment programs for patients with CHD in Germany are so far lacking.

In contrast to mere patient information, an education and treatment program represents a substantially more comprehensive, therapeutic/educational approach. Patients are included in determining treatment measures and actively face up to their disease.

The programs that are accredited for the disease management have to meet certain quality criteria that are defined by the German Federal (Social) Insurance Office (Bundesversicherungsamt) (28). The authors took these into consideration for the purposes of this study. The patient education programs on arterial hypertension and self-management of long-term anticoagulation that are currently on offer in the DMP "coronary heart disease" do not relate directly to the management of CHD.

The German Federal (Social) Insurance Office has ascertained a positive benefit for the DMP for diabetes mellitus for the medical end points blood pressure control, smoking status, and blood glucose control (29), but no such benefit has been ascertained so far for the DMP for coronary heart disease. One possible reason for this is that a disease-specific education program is so far lacking, and any successes are therefore difficult to prove. The German Federal (Social) Insurance Office thinks that the DMPs require further optimization.

With the help of the education and treatment program investigated in this study (Figure 3), participants in the intervention group increased the amount of physical activity by an average of 9.3 MET/week, whereas those in the control group increased theirs by

Figure 3: Cover of the wall chart/poster set—

graphical representation of the topics of the three education sessions (with permission from Dorothee Wolters, illustrations, Ulrike Didjurgeit, coauthor, and Jürgen Wauch, Dr. Senckenberg Foundation)

only 2.5 MET/week. To give an example, 10 MET means an increase in activity corresponding to 1.5 hours of jogging (7 km/h) per week. This level of physical activity meets the required level for which a positive influence on total mortality and life expectancy has been confirmed (25, 30).

The second primary end point—perceived quality of life—was also improved to a relevant extent. Health-related quality of life is an important aspect in the evaluation of medical therapies. A still outstanding detailed evaluation of the answers to the MacNew Heart Disease Quality of Life Questionnaire will show whether the education and treatment program had a greater effect on physical, emotional, or social factors, and whether these effects depend on age, for example.

It should be emphasized that the large scientific medical societies are not only calling for instructions on how to modify one's lifestyle, but they also express a desire for comprehensive information provided by the treating team to affected patients, regarding the causes and typical symptoms of their disease (6). A high degree of knowledge about and awareness of one's own disease and treatment is regarded as an important factor in promoting adherence (7).

Another objective of the study was to review whether the patients were able to detect acute symptoms more quickly and whether the prehospital phase of a myocardial infarction could thus be shortened. Germany's current delays of more than 120 minutes could be improved by a better awareness of threatening chest symptoms and a run-through of the process in the acute scenario (31). The evaluation of the questions regarding competence in a medical emergency implies that this can be improved successfully by using the intervention program in this study.

Our study was not intended to prove efficacy of the CHD education and treatment program by using hard end points, as this would have exceeded the time frame and organizational scope. A positive correlation of physical activity as well as of quality of life and cardiovascular events has been shown several times (8–11, 24, 25). The fact that physical activity was determined according to subjective reports is a limitation of this study. A significantly weak association between subjective assessment of total activity and objectively determined energy consumption has been shown elsewhere (32). Any kind of self-assessment entails a risk of misjudgment on the basis of social desirability. By their very nature, the end points "physical activity" or "quality of life" are difficult to define objectively. Most of the reported epidemiological data on cardiovascular risk factors are based on such subjective reports.

In order to measure changes in activity behavior, patients with an ergometric performance <75W were excluded from the study. In our view, however, positive effects of the education program can be generalized to all patients with CHD. Even in case of impaired mobility, patients will, for example, benefit from improved knowledge/awareness and from the resulting improved adherence.

KEY MESSAGES

- In a randomized controlled intervention study, a newly developed education and treatment program for patients with coronary heart disease (CHD) was found to yield a significant increase in the primary end points "physical activity" and "quality of life" in the intervention group after a mean observation period of 220 days.
- Physical activity among participants in the education and treatment program was improved by 18% (+6.8 MET/week) compared with the control group. Participants in the intervention group exercised on average at a moderate level of intensity about 1.25 hours longer per week (this corresponds to jogging at 7 km/h) than before the education program.
- Participants in the intervention group were able to significantly more clearly perceive an improvement in their disease-related quality of life than controls.
- The intervention group also showed superior results for the secondary end points "knowledge/awareness of cardiovascular risk factors," "emergency competence," and "assessment of medical treatment process."
- The CHD education and treatment program should be made available to large numbers of patients in secondary prevention.

We were not able to formulate any conclusions on the long-term effects of participating in the education and treatment program. The experiences of the physicians who looked after study participants beyond the end of the study do, however, give rise to the assumption that a refresher program should be provided after a period of 2–3 years. For patients with diabetes there are data that speak in favor of a repeat education program after 3 years (33). Long-term data on the effectiveness of such a continuing education program are so far lacking.

The results of the present intervention study confirm the efficacy of a CHD education and treatment program. The findings seem to confirm that an important approach has been developed to do better justice to the obviously difficult to implement requirements for improvements in the lifestyle of CHD patients. The widespread utilization of this program in secondary prevention is highly desirable.

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Conflict of interest statement

The authors declare that no conflict of interest exists.

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ORIGINAL ARTICLE

Evaluating the Efficacy of an Education and Treatment Program for Patients with Coronary Heart Disease

A Randomized Controlled Trial

Richard J. Melamed*, Alexander Tillmann*, Heidrun-Eva Kufleitner, Uwe Thürmer, Martin Dürsch

eTABLE

Table of contents of the patient brochure—overview of topics

Chapter 1	Chapter 2	Chapter 3
Facts regarding coronary heart disease	Exercise and nutrition	Dealing with the disease
How does the heart work?	Risk factors that cannot be influenced	Medication therapy for coronary heart disease
What is coronary heart disease?	Risk factors that can be influenced	Platelet inhibitors
Arteriosclerosis	Avoidable risk factors	Beta blockers
Stable and unstable plaques	Mediterranean diet	Angiotensin-converting enzyme (ACE) inhibitors
Other disorders triggered by arteriosclerosis	Menu ideas	Statins
Possible sequelae	Alcohol	Nitrates
Symptoms of coronary heart disease	Lack of physical activity	Table: Medication overview
Typical angina pectoris, stable and unstable angina pectoris, non-anginal chest pain	Motivation, ideas for motivation	General facts about taking heart medications
Symptoms of myocardial infarction	Extent of physical activity	Cardiac catheterization with balloon angioplasty and/or stent implantation in coronary vessels
Symptoms and sequelae	Basal metabolic rate	Heart bypass surgery
Risk factors for coronary heart disease	Ideas for increasing everyday physical activities	Emergency management
Table: Classification of risk factors	What you need to know before starting regular exercise	The “golden hour”
Risk profile—my personal risk factors	Training plan	When do I call the emergency doctor?
Diagnostic methods	Selecting the right kind of exercise	What do I say when telephoning the emergency services?
First diagnosis of CHD	Aims of different kinds of exercise	What can I do until the emergency doctor arrives?
Blood tests	Pulse meter, pedometer	How can relatives help?
ECG, exercise stress test	Safety precautions	When should nitrates be given as emergency medication?
Further diagnostic evaluation	Table: Risk factors and agreed aims	How do I use nitroglycerine spray?
Further diagnostic work-up		What happens after the emergency doctor arrives?
		What happens in hospital?
		What happens from the emergency telephone call until arrival at the hospital in suspected acute myocardial infarction?
		What happens after a myocardial infarction, or, more specifically, after surgery?

CHD, coronary heart disease; ECG, electrocardiogram

*R. J. Melamed and A. Tillmann have equally contributed to the article

eBOX**Quality assurance and ethics committee**

The Interdisciplinary Center for Clinical Trials in Mainz (IZKS) undertook quality assurance and checking of the study documentation by monitoring in accordance with good clinical practice. The study was conducted in accordance with the Professional Code for Physicians and on the basis of the World Medical Association's Declaration of Helsinki. It was approved by the ethics committee of the Hesse State Medical Association and registered with the German Clinical Trials Register (DRKS 00000394).