

## HTA-Report | Summary

# Evaluation of medical and health economic effectiveness of non-pharmacological secondary prevention of coronary heart disease

Müller-Riemenschneider F, Damm K, Meinhard C, Bockelbrink A, Vauth C, Willich SN, Greiner W

### Health political background

Coronary heart disease (CHD) is in Germany, as in other industrialised countries an important disease with a substantial burden for individuals and society. Both, mortality statistics and hospital admission diagnoses statistics are dominated by CHD and as a result, disease related costs are substantial.

With this in mind, the relevance of effective prevention programs in the treatment of CHD becomes clear. An effective and cost-effective secondary prevention strategy is essential from a public health perspective.

In addition to drug therapies, non-pharmacological interventions are considered the basis for patients with CHD. These interventions include smoking cessation, exercise training, dietary programs or psychosocial interventions. In Germany they are offered as single or combined methods within rehabilitation clinics or in so called "heart groups".

A great number of studies and research is available, investigating the effectiveness of non-pharmacological interventions, but a systematic analysis, at least from a German perspective, is currently lacking, as are evaluations of their cost-effectiveness.

The present HTA (HTA = Health Technology Assessment) therefore aims to summarise current literature on non-pharmacological secondary prevention of CHD and to evaluate their effectiveness and efficiency. Areas with insufficient evidence should also be identified in order to guide future research.

### Scientific background

CHD is a common and potentially fatal disease with a lifetime prevalence of 20 %. Cardiovascular diseases (CVD) are responsible for most of the deaths in developing as well as in developed countries. In Germany 43 % of all deaths were attributable to CVD in 2006. Development of CHD is multi-causal and related to many cardiovascular lifestyle risk factors. Many relevant risk factors have been identified, which are potentially modifiable. In the German Monica-Augsburg study it has been shown, that 65 % of the myocardial infarctions can be attributed to smoking, hypertension and high blood lipids. In this context, interventions to change harmful lifestyle behaviour play an important role in the treatment of patients with CHD.

German Agency for HTA  
at DIMDI (DAHTA)  
Waisenhausgasse 36-38a  
50676 Köln  
Germany

Tel.: +49 221 4724-525  
Fax: +49 221 4724-444  
dahta@dimdi.de  
www.dimdi.de

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## Research questions

The aim of this HTA is to summarise current literature on secondary prevention interventions in patients with CHD and to evaluate their medical effectiveness/efficacy and cost-effectiveness as well as the ethical, social and legal implications of secondary prevention programs. In order to do so, the following research questions will be addressed from a medical standpoint:

1. What is the effectiveness of combined non-pharmaceutical secondary prevention interventions in the treatment of CHD?
2. What is the effectiveness of single non-pharmaceutical secondary prevention interventions in the treatment of CHD?
3. What is the effectiveness of combined/single non-pharmaceutical secondary prevention interventions in the treatment of CHD compared to each other?
4. What is the effectiveness of combined and single non-pharmaceutical secondary prevention interventions related to specific subgroups of patients, such as men or women, patients with stable CHD, acute myocardial infarction, or following revascularization, patients with comorbid conditions, or socially deprived patients etc.?
5. What is the effectiveness of combined/single non-pharmaceutical secondary prevention programs in comparison or in addition to alternative therapy options in the treatment of CHD?
6. How safe are combined/single non-pharmaceutical secondary prevention interventions in the treatment of CHD?

Considering that financial resources are limited, it is necessary to relate the benefits of non-pharmaceutical secondary prevention strategies to its costs and to compare the results with alternative options. Therefore the following questions result from an economic dimension:

1. To what extent can non-pharmacological secondary prevention strategies be classified as efficient?
2. How efficient are combined interventions? How efficient are single component interventions?
- 3.

Concerning social and ethical aspects, the following questions should be answered:

1. What are the reasons for patients not to participate in available non-pharmacological interventions?
2. Could specific interventions help to overcome underutilisation and distortions of demand?

## Methods

Relevant publications were identified by means of a structured search of databases accessed through the German Institute of Medical Documentation and Information (DIMDI). In addition a manual search of identified reference lists was conducted. The former included the following electronic resources:

DAHTA; INAHTA (NHS-CRD-HTA); NHSEED; CDAR94 (NHS-CRD-DARE); CDSR93 (Cochrane Library); ME00 (MEDLINE); EM00 (EMBASE); CB85 (AMED); BA90 (BIOSIS Previews); MK77 (MEDIKAT); CCTR93 (Cochrane Library – Central); GA03 (gms); SM 78 (SOMED); CV72 (CAB Abstracts); I178 (ISTPB + ISSHP); ED93 (ETHMED); AZ72 (GLOBAL Health); AR 96 (Deutsches Ärzteblatt); ME0A (Medline Alert); EA08 (Embase Alert); IS90 (SciSearch); CC00 (CCMed); IN73 (Social SciSearch); KR03 (Karger Pub-

lisher Database); KL97 (Kluwer Publisher Database); SP97 (Springer Publisher Database); SPPP (Springer Publisher Database PrePrint); TV01 (Thieme Publisher Database).

The present report includes German and English literature published between January 2003 and September 2008. The search parameters can be found in the appendix. The target population was adults with CHD. The methodological quality of included studies was assessed using standardised checklists and rated according to criteria recommended by the "Scottish Intercollegiate Guidelines Network Grading Review Group" (SIGN).

## Results

### Medical results

Among 4,798 publications, the selection process identifies 43 publications reporting the results of 27 primary studies and eight meta-analyses meeting the pre-specified inclusion criteria. These include 24 studies rated with good and high methodological quality. Multimodal secondary prevention programs are investigated in 14 studies, eleven studies investigate exercise based secondary prevention interventions, seven programs focus on psychosocial interventions while diet and smoking cessation interventions are each investigated in three studies. Among 35 included medical publications, only 18 report amongst others mortality as an outcome parameter, while the remaining studies report alternative outcomes. Duration of follow-up varies between twelve and 120 months. Although overall effectiveness of prevention programs shows considerable heterogeneity, there is evidence for the effectiveness of non-pharmaceutical secondary prevention interventions. Especially programs including exercise interventions report reductions in mortality, while psychosocial programs seem to improve quality of life in particular. Only a few of the included studies have a follow up with a duration of more than 60 months. Only two studies from Germany fulfill the methodological requirements and are included in this report.

### Health economic results

Out of 3,789 publications, 25 economic studies met the inclusion criteria. Seven of these publications are cost-utility-analyses, seven are cost-effectiveness-analyses, another three are reviews, three can be classified as "expert opinion", two as "guidelines" and one is a comparative cost-analysis. Two health technology assessments are also included.

In summary, both quantity and quality of publications examining combined interventions are higher compared with those investigating single interventions. However, there are difficulties in transferring the international results into the German health care system, because of its specific structure of the rehabilitation system. While international literature mostly shows a positive cost-effectiveness ratio of combined programs, almost without exception, studies investigate out-of hospital or home-based programs. The examination of publications evaluating the cost-effectiveness of single interventions merely shows a positive trend of exercise-based and smoking cessation programs. Due to a lack of appropriate studies, no conclusive evidence regarding psychosocial and dietary interventions is available.

### Social results

Altogether eleven publications concerned with ethical or social issues of non-pharmacological secondary prevention strategies are included. These publications are either based on surveys, data analyses or expert opinions. Studies confirm the assumption that patients with a lower socioeconomic background reflect a population at increased risk and therefore have specific needs to participate in rehabilitation programs. However, there currently remains uncertainty, whether these patients participate in rehabilitation more or less often. As barriers, which

deter patients from attending, aspects like a lack of motivation, family commitments or the distance between home and rehabilitation centres are identified. Psychological factors like anxiety, depression and uncertainty as well as physical constraints are also pointed out.

## **Discussion**

### **Discussion of medical aspects**

Non-pharmacological secondary prevention interventions in the treatment of CHD are effective to improve mortality, morbidity and quality of life. While there is considerable heterogeneity in study quality, follow-up duration and reported effect sizes, the overall quality of included studies is satisfactory. Because follow up duration is predominantly twelve to 24 months, conclusions about the sustainability of the interventions are limited. With regard to mortality exercise based interventions provided most conclusive evidence for effectiveness while psychosocial interventions particularly seem to improve quality of life effectively. Due the limited number of studies investigating diet or smoking cessation, reliable conclusions regarding the effectiveness of those components are limited. Although only two studies from Germany are included, the majority of studies are from industrialised countries and there is no evidence, that these findings are not applicable to the German context.

### **Discussion of economic aspects**

With regard to the cost-effectiveness of non-pharmaceutical interventions, overall, international studies show positive results. However, there are considerable limitations due to the qualitative and quantitative deficiencies of identified studies. The special characteristics of the German rehabilitation system with its primarily inpatient offers result in further difficulties, when trying to transfer international study results to the German health care system. Both, studies demonstrating the cost-effectiveness of inpatient programs and those investigating the cost-effectiveness of single interventions are currently not available. To examine the German rehabilitation programs concerning their efficiency and their potential for optimisation, there is a need for further research.

### **Discussion of social aspects**

Concerning social and ethical issues, a lack of studies addressing the structure of rehabilitation participants in Germany is striking. The same applies to studies examining the reasons for none participation in non-pharmaceutical secondary prevention programs. Evidence regarding these questions would provide an informative basis for optimising rehabilitation programs in Germany.

## **Conclusion/Recommendations**

Non-pharmacological secondary prevention programs in patients with CHD can be effective in the improvement of mortality, morbidity and quality of life. Especially multimodal programs and those including exercise based strategies seem advisable. Considering transferability to the German context, presented findings at present have to be considered best available evidence for the development of secondary prevention programs in Germany, as long as methodologically reliable studies of current prevention programs are unavailable.

Future research should aim to investigate the effectiveness of secondary prevention programs in specific subgroups of patients, such as women, patients with comorbidities, and socially deprived patients. Furthermore, the comparative effectiveness of different secondary prevention strategies needs to be investigated. In addition, factors should be identified, which can improve implementation and adoption of secondary prevention programs in everyday care.

There is on the one hand a lack of cost-effectiveness analyses of hospital based or inpatient rehabilitation programs, and on the other hand positive results of out of hospital or home-based interventions. This should facilitate the evaluation of non-pharmacological secondary prevention programs specific to the German health care system and provide better evidence regarding their efficiency and potential for optimisation. Effectiveness and cost-effectiveness should further be investigated for different patient subgroup. Concerning the evaluation of single component interventions, further research is also warranted.

While there is conclusive evidence that patients of lower socio-economic status are at increased overall risk in Germany and therefore have a special need for rehabilitation interventions, there remains uncertainty, whether these patients participate in rehabilitation more or less often. As barriers, which deter patients from attending, aspects like a lack of motivation, family commitments or the distance between home and rehabilitation centres are identified. These factors should be examined with a specific focus on the German health care system, in order to improve future non-pharmacological secondary prevention programs.