Effectiveness of programmes as part of primary prevention demonstrated on the example of cardiovascular diseases and the metabolic syndrome
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Health political background
The HTA-report (HTA = Health Technology Assessment) deals with the primary prevention of cardiovascular diseases and diabetes mellitus type 2. In 2009 approximately 356,000 people died in Germany due to cardiovascular diseases. According to estimations about 6.3 million people are suffering from diabetes mellitus type 2. The compulsory health insurance (GKV) defined as a goal for primary prevention the reduction of cardiovascular diseases as this disease has the highest epidemiological importance regarding morbidity, mortality and costs. Within the national health targets the reduction of the occurrence of the metabolic syndrome and the incidence of diabetes mellitus type 2 in the field of primary prevention is formulated as national health target. Due to the importance of cardiovascular diseases and the metabolic syndrome the HTA-report focus on the analysis of effectiveness of primary prevention interventions for the prevention of these two diseases.

Scientific background
In industrial countries mainly seven risk factors are responsible for the majority of cardiovascular diseases and the metabolic syndrome: high blood pressure, smoking, alcohol, high cholesterol level, overweight, too little fruit and vegetables consumption as well as too little exercise. The main prevention target is the reduction of these factors by a change of lifestyle. The interventions which are subsidized by the public health insurance are mainly focused on physical activities, healthy nutrition, stress management and the reduction of the consumption of addictive drugs and luxury food.

Medical research questions
• Which lifestyle-related interventions and/or programmes for primary prevention of cardiovascular diseases and/or of the metabolic syndrome are effective?
• To what extent will the health status be improved by these offers?
• To what extent will existing health resources and skills be strengthened by these offers?
• Are there any differences regarding the effectiveness among the interventions with respect to different settings or subgroups?
Economic research questions

- Which lifestyle-related measures and/or programmes for primary prevention of cardiovascular diseases and of the metabolic syndrome are sustainable and cost-effective?
- Which outcome parameters are in the view of the contributors decisive for the evaluation of the effectiveness?
- In the view of the contributor are there different values between the outcome parameters?
- In the view of the payers and other actors are there different values between the outcome parameters?

Ethical and juridical research questions

- Which ethical and juridical factors have to be considered?
- Which social and/or socio-economic parameters influence the use of the services and effectiveness?

Methods

A systematic literature research is done by the German Institute for Medical Documentation and Information (DIMDI). Additionally, the authors look for related studies and literature. HTA-reports, systematic reviews/meta-analysis, randomized controlled trials (RCT), observational studies, intervention studies, cost studies, cost minimization studies, cost-benefit-analyses and cost-effectiveness studies are included which report on primary prevention programmes regarding cardiovascular diseases or the metabolic syndrome from 2005 to 2010. With respect to the outcomes the studies have to deliver results about effectiveness, benefit and efficacy. The scientifically based classification according to the evidence levels of the Oxford Centre of Evidence-based Medicine of 2006 is used for a critical evaluation of the available literature.

Medical results

A total of 27 medical studies meet the inclusion criteria. These studies prove the efficacy of lifestyle interventions regarding cardiovascular diseases and the reduction of multiple metabolic deviances. In particular the affected persons can reduce their weight, the body mass-index (BMI), fat intake, the blood pressure, blood lipids and smoking. Furthermore, the mortality and morbidity rate, the quality of life, the prevalence of the metabolic syndrome, the cost-effectiveness can be improved and the physical activity and fitness can be increased.

The evaluation of the medical research results shows that the activity programmes have a stronger effect than the nutrition programmes. The efficacy also applies for psychological programmes, if they contain cognitive behaviour therapy. Strengthening the health resources with educative input leads in the sense of a comprehensive rehabilitation to a positive outcome of the risk factors such as blood lipid or blood pressure and thus towards a necessary lifestyle intervention.
Economic results
Seven economical studies are included in the HTA-report. Despite the enormous effects of cardiovascular diseases on the health system, there is a lack of economical studies in Germany.
So far only a few results exist regarding the cost-effectiveness of lifestyle related interventions. The identified studies however show that mainly programmes for prevention of hypertension, hypercholesterolaemia and diabetes turn out as cost-effective. Interventions that focus on the general population prove to be particularly cost-effective and sustainable. These include initiatives to reduce the salt content in bread or media campaigns.

Ethical and juridical results
Ten ethical studies meet the including criteria – but ethical and juridical aspects are not taken into account. The identified studies deal basically with primary prevention interventions which should neutralize social inequality and allow a better access to health care. The studies prove the effectiveness of psychological treatments. They show positive effects on the quality of life and depression. Furthermore, lifestyle programmes can counteract smoking. The level of education, distance, age and gender are identified as factors regarding the influence on the use of prevention programmes.

Discussion
The identified studies prove the effectiveness of primary prevention programmes. There is a wide range of lifestyle-related interventions and/or programmes for primary prevention of cardiovascular diseases and the metabolic syndrome. Interventions to change the lifestyle include mainly guidelines, training courses, movement training, cognitive behaviour therapy, nutrition interventions, information campaigns, and focus groups.
Compared to a normal diet nutritional advice has only small effects on weight loss which further reduce in the course of time. As a result, cognitive behaviour therapy can have an influence on nutrition and physical activity and this can result in permanent loss in weight. The outcomes and results are consistent with the recommendations of the two identified evidence-based guidelines regarding the recommendations on lifestyle and healthy nutrition. Every three identified cost-effectiveness-analyses prove the cost-effectiveness of the analyzed programmes. The number of identified studies in German-speaking countries is low. The transferability of the foreign results to the German situation has to be critically assessed. The surveys are often conducted on the basis of few or very short follow-up periods. The research process is often not adequately described in the identified reviews and guidelines. Based on the studies it cannot be concluded to what extent there is an empowerment of the participants by the interventions.

Conclusion
On the whole a comprehensive, structured setting approach with educative, medical, psychosocial and activity therapeutic components is recommended. Due to the evidence the catalogue of interventions comprises controlled intake of salt, endurance training, BMI < 25 kg/m², nicotine abstinence and limited alcohol consumption. Furthermore, nutrition with few saturated fatty acids and
less cholesterol, especially fruit, vegetables as well as fiber-rich, low fat nutrition, whole grain products and proteins of vegetable origin turn out to be useful. A cognitive behaviour therapy combined with stress management can also be included in the catalogue. The sustainability of a prevention measure must be ensured from programme to programme. Long-term studies are necessary to make valid statements regarding the sustainable effectiveness. In the current practiced evaluation of the use of primary prevention services by the health insurance there is an essential deficit regarding the evaluation of the prescribed preventive intervention. With regard to the ethical, social and economical evaluation the research situation is deficient. Primarily, evaluation studies about the success of primary prevention measures for socially deprived are needed.