PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Evaluation of a training pogramm for patients with coronary heart disease

Trial Acronym

KHK-Schulung

URL of the trial

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Brief Summary in Lay Language

This study is conducted to look whether a training program for patients with coronary heart disease is effective. This training program is an advanced training for patients with coronary heart disease. This training is hold by special skilled medical qualified persons and after a standardized program. The aim of this training program is to inform patients better about her disease on 3 appointments. Thereby should be achieved that patients to get along better with there disease that lead to an improvement of the physical activity and quality of life. Such programs already exist for diabetics, hypertension and chronic respiratory disorder. There effectiveness was proved by studies. For the training program for patients with coronary heart disease effectiveness is not yet proved. After informed consent is given by the patient by lot will be determined whether the patient will be part of the trained group or to the group which will not train. This is necessary to compare the results of both groups later. In both groups patients have to complete five pseudonymized questionnaires about current medical level of knowledge, about the quality of training and self-assessment of their state of health. These questionnaires will be completed by patients before training, short after training and six months later. Furthermore patients will be asked six months after enclose in the study for call on family physician for an assessment of progress. In the case the patient is part of the non- trained group the patient will be asked in the same way to visit the family physician for an assessment. But these patients have also the possibility to attend for free the training program after the observation period is over.

Brief Summary in Scientific Language

In the Federal Republic of Germany, cardiovascular diseases are 45%, still in first place in the cause of death statistics. The diagnosis of ischemic heart disease, heart attack and heart failure were, according to Federal statistical in 2004, responsible for 194 083 deaths. As a complication of coronary artery disease is the myocardial infarction, acute life threatening heart attack threat after surviving a disability caused by heart failure and underperformance by angina pectoris. There is an increased risk for recurrent myocardial infarction and other cardiovascular complications. The hospital mortality of acute myocardial infarction was reduced

in the course of 30 years from now about 30% to 6-9% - the number of patients who die before reaching the hospital, but is still high. Of the patients who survive a first ST elevation myocardial infarction die in the following year depending on the risk constellation 3-25%. In patients with non-ST-elevation myocardial infarction, these are 5-14%. In 2006 in Germany according to § 73 a SGB V, the structured treatment program (disease management program, DMP) Coronary heart disease (CHD) is implemented. While other disease management programs, such as diabetes mellitus and bronchial asthma evaluated training programs exist, such a disease specific training in the DMP CHD is not being offered. In this context, the Education of patients in a small group to improve the disease-related quality of results has proved effective.
A CHD training might therefore ensure, inter alia, the long-term success after cardiac rehabilitation, complement and promote the participation in an outpatient heart group and to strengthen the emergency skills of patients and improve adherence to drug therapies and non-drug therapy, such as an increase in physical activity. Physical activity results in patients with CHD and / or stable chronic heart failure to improve exercise capacity, a reduction in symptoms and quality of life. In the secondary prevention means regular exercise an important, factor influencing the prognosis.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00000394**
- Date of Registration in DRKS: **2010/05/18**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **FF106/2008 , Ethikkommission der Landesärztekammer Hessen**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1114-6884**
- Sponsor-ID: **KHK-Schulung**

Health condition or Problem studied

- Free text: **coronary heart disease**
- ICD10: **I25 - Chronic ischaemic heart disease**

ICD10: **I25 - Chronic ischaemic heart disease**

Interventions/Observational Groups

- Arm 1: **Patients take part in the training program. The intervention includes in line with other recognized training in disease management programs, the following measures:**
  • Patients attending a training course. The course consists of three at intervals of about 7 days to be held units.
  • The contents of the training were created by the cardiologist, Dr. M. Dürsch from the Cardiology group practice in Frankfurt am Main - Sachsenhausen, the psychologist Ms U. Didjugeit and the team of Diem in Cologne. The teaching materials consist of a brochure for patients, including movement diary, teaching cards, a curriculum and the poster set. Each patient receives a patient brochure for self-study and a physical activity diary in which he can record their daily physical activity.
  • The training is conducted on the premises of schooling practices, and it will take a maximum of eight patients in a course. It is being held by a training force, which was prepared in a coach seminar on this activity. Most are medical professionals who already have experience in other training programs.
- Arm 2: **Patients do not participate in training program**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **Open (masking not used)**
- Who is blinded: **[---]***
- Control: **No treatment**
- Purpose: **Other**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

It will be tested two primary endpoints:

1st Improving physical activity daily 6 months after patients include in the study. Here, the intervention effect is expected from at least two hours per week times more activity (17% improvement in the Freiburg activity questionnaire).
2nd Improvement of disease-related quality of life 6 months after patients include in the study. Here, the intervention effect is expected by at least 0.5 points (10%) improvement in MacNew questionnaire.

Secondary Outcome

1st Improve awareness of risk factors. Here is a significant improvement in Bochum assessment questionnaire expected.
2nd Improve the ergometric performance (a minute longer at the maximum level).
3rd Improvement of risk factors (self-report)
4th Improve emergency skills (self report)
5th report reduction in the number of cardiovascular endpoints (MI, bypass op, percutaneous coronary intervention, hospitalization because of CHD> 2 days) (self report)
6th Increasing the number of heart group participants (self report)
7th Reduction in body weight

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2010/02/03**
- Target Sample Size: **406**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **90 Years**

Additional Inclusion Criteria

1. Age between 18-90 years
2. Patients with with coronary heart disease (in accordance with RSAV)
3. Ergometry within last 12 weeks
4. Ergometry in accordance with quality standards of the German society for research of cardiovascular diseases
5. ergometric achived power level of minimal 2 minutes 75 watt
6.Willingness and possibility to attend the training

Exclusion criteria

1. Patients, which are not able to answer questions of the questionnaires independently
2. Severe disease at final stage
3. Life expectancy under 6 months
4. Psychosis , severe dementia, nonexistence of contractual capability
5. Alcohol, drug and medication abuse
6. Participation on other studies

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

- **Private sponsorship (foundations, study societies, etc.)**

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  URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*