

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

Trial Description

Title

Effectiveness of a self-management patient education program "Curriculum Heart Failure" for inpatient cardiac rehabilitation.

Trial Acronym

[---]*

URL of the trial

http://www.psychotherapie.uni-wuerzburg.de/forschung/projekte-koop_20.html

Brief Summary in Lay Language

Patient education is an essential part of the medical rehabilitation of patients with chronic heart failure targeting self-management behavior and subsequent illness progress. For inpatient cardiac rehabilitation, no evaluated educational group program for patients with heart failure is so far available for routine use. The aim of the study is to evaluate a self-management patient education program for heart failure in medical rehabilitation. The main research question is the short-, intermediate and long-term effects of the educational program on self-management competence as compared with a usual care program for patients with heart failure receiving inpatient medical rehabilitation.

Participants are 540 rehabilitants with heart failure, who participate in a patient education program. 270 patients will receive the new patient education group program and 270 patients one lecture of basic medical education by a physician. The participants are randomly assigned to one program. Data will be assessed with questionnaires at admission and discharge of rehabilitation as well as after 6- and 12-months.

Brief Summary in Scientific Language

The aim of the study is to evaluate a self-management patient education program for heart failure in medical rehabilitation. The main question is the short-, intermediate and long-term effects of the patient-oriented educational program as compared with a usual care program for HF-patients receiving inpatient medical rehabilitation. Moreover, moderator effects of gender, age, education, and type of rehabilitation (cardiac rehabilitation within 14 days after an acute cardiac index event versus cardiac rehabilitation during the chronic course of disease without recent acute index event) will be explored. The study is a multicenter cluster randomized controlled trial in four cardiac rehabilitation clinics. Clusters are patient education groups that comprise HF-patients which start inpatient medical rehabilitation within certain time periods of about 2 weeks. A cluster randomization was chosen for practical reasons, i.e. the number of eligible patients to join the educational groups. Furthermore, to prevent contamination by interaction of patients with different group allocation during rehabilitation.

Rehabilitants with chronic systolic heart failure (n = 540) will be consecutively recruited for the study at the beginning of inpatient rehabilitation. Data will be assessed at admission, at discharge and after 6- and 12-months with patient-reported questionnaires. In the intervention group (IG), patients receive the new patient-oriented self-management education program, whereas in the control group (CG), patients receive a basic educational program (usual care). The primary outcome is patients` subjective self-management competence. Secondary outcomes include behavioral determinants and self-management health behavior (symptom monitoring, physical activity, medication adherence), health-related quality of life, and treatment satisfaction. Outcomes are assessed by standardized measures. Treatment effects (between-group effects of IG and CG) will be evaluated separately for each follow-up time point using multilevel regression analysis, and adjusting for baseline values. Moderator analysis will be performed by including the moderator variable as additional fixed effect and examining interaction effects.

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

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Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00004841**
- Date of Registration in DRKS: **2013/04/05**
- 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.: **60/11 , Ethik-Kommission der Medizinischen Fakultät der Universität Würzburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **I50 - Heart failure**

Interventions/Observational Groups

- **Arm 1: Intervention condition is a new self-management educational program “Curriculum Heart Failure” that consists of 5 patient-oriented, interactive sessions of 60 or 75 minutes each, which are held in small groups of a closed format (15 participants or less). The program is manual-based and interdisciplinary with sessions led by a physician, a nurse, a psychologist and a physiotherapist, respectively. In each session, patients are actively involved in the educational process using a combination of didactic methods (short lectures, group discussion, practice, partner and individual work). Didactic materials included presentations, flipcharts, and two patient booklets (educational booklet with HF information and worksheets, symptom-monitoring diary for six months). Contents of the lessons include HF illness and treatment knowledge (e.g. aetiology, symptoms and signs, diagnostic, medical treatment options, medication) with regard to individual needs of the participants. Furthermore, there is a focus on self-management behaviors (e.g. dietary restrictions, attention to deterioration signs/symptoms, and daily weight and blood pressure monitoring) and medication adherence. To promote physical activity theory-based intervention techniques are applied (e.g. action and coping planning, self-monitoring). Additionally, signs of emotional distress according to HF and coping strategies are discussed.**
- **Arm 2: Control condition is treatment as usual. One lecture of basic medical education by a physician with duration of about 60 minutes. Information is mostly presented in a vertical manner. Contents included basic heart failure illness information on aetiology, symptoms and signs, pharmacological treatment, surgery, and self-management recommendations (e.g. symptom monitoring and health behavior). Patients get handouts which comprise main information, and worksheets.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: [---]*
- Allocation: **Randomized controlled trial**
- Blinding: [---]*
- Who is blinded: **patient/subject**
- Control: **Active control (effective treatment of control group)**
- Purpose: **Treatment**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

- 1) **Self-management competence; Health Education Impact Questionnaire HeiQ - Scales Self-monitoring and insight, Skill and technique acquisition (german version; Schuler et al., 2012); time frame: admission, discharge, after 6 months, after 12 months.**
- 2) **Self-efficacy; Kansas City Cardiomyopathy Questionnaire KCCQ (german version; Faller et al., 2005); time frame: admission, discharge, after 6 months, after 12 months.**

Secondary Outcome

1) Behavioral determinants: 1.1) Symptom control; adapted questionnaire for habit strength (Fleig et al., 2011); time frame: after 6 months, after 12 months. 1.2) Physical activity; HAPA-scales (Schwarzer et al., 2007; Sniehotta et al., 2005), modified version of Self-Report Habit Index SRHI (Fleig et al., 2011); time frame: admission, discharge, after 6 months, after 12 months. 1.3) Medication beliefs. Beliefs about Medicine Questionnaire BMQ-D (Horne & Weinman, 1999; german version, Opitz et al., 2008); time frame: admission, discharge, after 6 months, after 12 months.

2) Self-management behavior: 2.1) Symptom control; short questionnaire developed by our research group; time frame: admission, after 6 months, after 12 months. 2.2) Physical activity; Godin Leisure-Time Exercise Questionnaire, modified version (Godin et al., 1985); time frame: admission, after 6 months, after 12 months. 2.3) Medication adherence; Medication Adherence Report Scale MARS-D (german version; Mahler et al., 2010); time frame: admission, after 6 months, after 12 months. 2.4) Smoking; single items (www.gbe-bund.de); time frame: admission, discharge, after 6 months, after 12 months. 3) Health-related quality of life; Kansas City Cardiomyopathy Questionnaire KCCQ (german version; Faller et al., 2005); time frame: admission, discharge, after 6 months, after 12 months. 4) cardiac events; time frame: after 6 months, after 12 months. 5) treatment satisfaction; short questionnaire developed by our research group (Meng et al., 2009); time frame: discharge.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Reha-Zentrum Bad Nauheim, Klinik Wetterau, Bad Nauheim**
- Medical Center **Kirchbergklinik, Bad Lauterberg**
- Medical Center **Klinik Mönensee der Dr. Becker Klinikgesellschaft , Mönensee**
- Medical Center **Segeberger Kliniken, Bad Segeberg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/01/02**
- Target Sample Size: **540**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**

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- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Chronic systolic heart failure HF (ICD-10: I50), left ventricular ejection fraction LVEF of 40 or less, and New York Heart Association NYHA functional classification of class II or III.

Exclusion criteria

Acute events of decompensation, cognitive impairment, inadequate German language ability, and severe visual or hearing impairment.

Addresses

■ **Primary Sponsor**

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2014/12/31**

Trial Publications, Results and other documents

- Paper <style fontName='DejaVu Sans' isBold='true'>Meng, K., Musekamp, G., Seekatz, B., Glatz, J., Karger, G., Kiwus, U., Knoglinger, E., Schubmann, R., Westphal, R. & Faller, H.

(2013). Evaluation of a self-management patient education program for patients with chronic heart failure undergoing inpatient cardiac rehabilitation: Study protocol of a cluster randomized controlled trial. *BMC Cardiovascular Disorders*, 13:60. DOI: 10.1186/1471-2261-13-60 Meng, K., Musekamp, G., Schuler, M., Seekatz, B., Glatz, J., Karger, G., Kiwus, U., Knoglinger, E., Schubmann, R., Westphal, R. & Faller, H. (2016). The impact of a self-management patient education program for patients with chronic heart failure undergoing inpatient cardiac rehabilitation. *Patient Education and Counseling* DOI: <http://dx.doi.org/10.1016/j.pec.2016.02.010>

* *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.*