

Trial Description

Title

OutCaRe - clinical evaluation of potential outcome indicators in cardiac rehabilitation

Trial Acronym

OutCaRe

URL of the trial

<http://www.uni-potsdam.de/rehawiss/forschung/projekte/outcare-outcome-der-kardiologischen-rehabilitation-eine-methodenevaluierung-bei-berufsaehigen-patienten-zur-quantifizierung-des-rehabilitationserfolges.html>

Brief Summary in Lay Language

Cardiac rehabilitation is a multimodal, interdisciplinary intensive measure for patients with chronic cardiovascular disease or after an acute cardiac event such as a myocardial infarction. Medical care, physical training, patient training, nutrition and lifestyle counseling as well as social-medical and psychological care are the core components of cardiac rehabilitation. Thereby functional factors such as physical performance, personal factors such as the reduction of a depressive mood and social aspects such as the return to work should be affected simultaneously.

Due to the high complexity, taking all the involved therapeutic components into account, the success of a cardiac rehabilitation has not been possibly determined through a procedure. In the current study, various parameters of the categories of physical performance, cardiovascular risk factors, social medicine and psychology are to be examined for changes by rehabilitation and their predictive power for return to work after rehabilitation.

Brief Summary in Scientific Language

Against the background of the social-law obligation to safeguard and develop the quality of medical rehabilitation (§ 20 SGB IX), methods of outcome measurement become increasingly important. In the quality assurance programs of the paying authorities, the dimensions of process and structural quality are currently being examined. The outcome, on the other hand, appears underrepresented and is essentially operationalized by patient and physician consultations at the end or after the rehabilitation procedure.

The outcome is based on the health condition of a patient resulting from a health care measure. Cardiac rehabilitation, however, is a highly complex, interdisciplinary, patient-specific, holistic and intensive medical-therapeutic measure and it's success couldn't be defined in general terms. It therefore seems appropriate to identify indicators that show the success of the various core components of cardiac rehabilitation and reflect in their totality the outcome of cardiac rehabilitation. In the course of this evaluation study, the previous Delphi expert survey questioned the importance of performance measures as part of quality assurance by chief physicians, leading sports/physiotherapists and psychologists of cardiac rehabilitation. At the same time, the participants met a



selection of potential outcome indicators. The aim of the study is to identify and evaluate performance measures of cardiac rehabilitation for patients under 65 years of age with regard to their suitability and practicability, and to investigate their predictive power for their return to work and health-related quality of life.

Organizational Data

- DRKS-ID: **DRKS00011418**
- Date of Registration in DRKS: **2017/03/16**
- 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.: **S 4(a)/2017 , Ethik-Kommission der Landesärztekammer Brandenburg**

Secondary IDs

Health condition or Problem studied

- Free text: **all indication through a cardiac rehabilitation (ICD 10, chapter IX)**
- ICD10: **I00-I99 - Diseases of the circulatory system**

Interventions/Observational Groups

- Arm 1: **Observational group: Patients in cardiac rehabilitation are studied at the beginning and end of rehabilitation as well as 6 months thereafter on the basis of functional, physical, social-medical and subjective parameters regarding rehabilitation success. This is done using questionnaires as well as clinical documentation.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Uncontrolled/Single arm**
- Purpose: **Health care system**



Study Type: **Non-interventional**

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Blinding: [---]*

Who is blinded: [---]*

Control: **Uncontrolled/Single arm**

Purpose: **Health care system**

- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

state of return to work 6 months after rehabilitation (through questionnaire).

Secondary Outcome

Health-related quality of life 6 months after rehabilitation (through questionnaire).

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Klinik am See - Rehabilitationszentrum für Innere Medizin, Rüdersdorf b. Berlin**
- Medical Center **Paracelsus-Harz-Klinik Bad Suderode, Quedlinburg**
- Medical Center **Reha-Zentrum Seehof , Teltow**
- Medical Center **Klinik Höhenried der DRV Bayern Süd , Bernried**
- Medical Center **Frankenklinik , Bad Neustadt/Saale**
- other **Zentrum für ambulante Rehabilitation, Stuttgart**
- Medical Center **Klinik Möhnensee , Möhnensee**
- Medical Center **SEGBERGER KLINIKEN GMBH Herzzentrum , Bad Segeberg**
- Medical Center **Brandenburg Klinik, Bernau b. Berlin**



- Medical Center **MediClin Reha-Zentrum Spreewald** , Burg
- Medical Center **Caspar Heinrich Klinik, Bad Driburg**
- Medical Center **MediClin-Fachklinik Rhein/Ruhr** , Essen

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/05/24**
- Target Sample Size: **2000**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **65 Years**

Additional Inclusion Criteria

cardiac rehabilitation payed by any of the German statutory pension insurancy

Exclusion criteria

Inadequate knowledge of German and not given consent, early permanent retirement

Addresses

■ Primary Sponsor

**Universität Potsdam, Professur für Rehabilitationswissenschaften
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■ Contact for Scientific Queries

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Contact for Scientific Queries

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■ **Collaborator, Other Address**

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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.)**

Deutsche Rentenversicherung Bund

10704 Berlin

Germany

Telephone: [---]*



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■ **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2019/01/31**

Trial Publications, Results and other documents

- Paper **Ergebnisse der ersten OutCaRe-Projektphase (Delphi-Expertenbefragung), die der klinischen Evaluation vorangegangen ist**

* 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.