Trial Description

**Title**

Rehabilitation access and effectiveness cohort study for persons with back pain

**Trial Acronym**

REHAB-BP

**URL of the trial**

http://www.rehab-bp.de/de/

**Brief Summary in Lay Language**

The German Pension Insurance provides medical rehabilitation services with the aim of improving or restoring work ability. Musculoskeletal disorders, especially back pain, are the main reasons for medical rehabilitation. Evidence on access barriers to rehabilitation and the effectiveness of medical rehabilitation in patients with back pain is unclear. Therefore the aim of the study is two-fold: first to analyse access barriers to medical rehabilitation services, and second, to examine the effectiveness of medical rehabilitation services in Germany. To answer these questions, persons, who are registered in the German Pension Insurance, will be surveyed in 2017 and 2019. Survey data will be linked to administrative data on utilised rehabilitation services. The sample includes employed persons aged 45 to 59 years.

**Brief Summary in Scientific Language**

In cases of limited work ability or when work ability is at risk, people can apply for medical rehabilitation services. The German Pension Insurance provides these services with the aim of improving or restoring the work ability. Musculoskeletal diseases, especially back pain, are the main reasons for medical rehabilitation. The appropriate access to rehabilitation according to the actual needs of patients is currently an issue that is critically discussed. Frequently, the need for rehabilitation does not lead to a rehabilitation request. Despite the maxim “rehabilitation before pension”, every second person who receives a disability pension did not participate in rehabilitation services before the pension was granted. However, there are no up-to-date studies that have examined rehabilitation barriers. Moreover, randomised controlled trials that compared persons with and without rehabilitation participation have generated contradictory findings regarding the effects of medical rehabilitation. However, the setting of these studies was restricted to single centres or particular regions. There is currently no evidence on the effectiveness of rehabilitation services under routine conditions.

Therefore the study analyses firstly the access barriers to medical rehabilitation services. Secondly, the study examines the effectiveness of German medical rehabilitation services. The cohort study will identify persons with back pain and then compare back pain patients who completed a medical rehabilitation with back pain patients without utilising a medical rehabilitation program. The primary outcome is pain disability in important life domains (work, daily living and leisure time). To analyse the
effectiveness of medical rehabilitation services, participants and non-participants will be matched by the probability of treatment, i.e. to participate in a medical rehabilitation program (propensity score matching). The samples will be drawn from the registers of two pension insurance agencies (German Pension Insurance North: n = 22,500; German Pension Insurance Central Germany: n = 22,500). We will include employed people aged 45 to 59 years. Persons who requested or utilised medical rehabilitation services during the past four years and persons with requested or approved disability pensions will be excluded. Data are assessed by written surveys in 2017 and 2019. Additionally, administrative date will be extracted.

Organizational Data

- **DRKS-ID:** DRKS00011554
- **Date of Registration in DRKS:** 2017/01/26
- **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.:** 15-144, Ethik-Kommission Universität zu Lübeck Medizinische Fakultät des Universitätsklinikums Schleswig-Holstein

Secondary IDs

- **Universal Trial Number (UTN):** U1111-1162-7501

Health condition or Problem studied

- **ICD10:** M40-M54 - Dorsopathies

Interventions/Observational Groups

- **Arm 1:** Medical rehabilitation services (utilisation as derived from the German Pension Insurance accounts)
- **Arm 2:** No medical rehabilitation

Characteristics

- **Study Type:** Non-interventional
- **Study Type Non-Interventional:** Observational study
- **Allocation:** Non-randomized controlled trial
- **Blinding:** [---]*
- **Who is blinded:** [---]*
Study Type: **Non-interventional**  
Study Type Non-Interventional: **Observational study**  
Allocation: **Non-randomized controlled trial**  
Blinding: [--]*  
Who is blinded: [--]*  
Control: **Control group receives no treatment**  
Purpose: **Treatment**  
Assignment: **Parallel**  
Phase: **IV**  
Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

**Primary Outcome**

Pain disability: 3 items assess the impairments in everyday life, leisure time and at work with values ranging from 0 to 100. Higher values indicate higher impairments. The primary outcome will be assessed by questionnaire at baseline (2017) and follow-up (2019).

**Secondary Outcome**

The following secondary outcomes will be assessed by questionnaire at baseline and follow-up:  
- pain intensity (0 to 100 points) and disability days: German version of the Chronic Pain Grade (Klasen et al. 2004)  
- pain self-efficacy (10 to 60 points): German adaption of the Pain Self-efficacy Questionnaire (FESS) (Mangels et al. 2009)  
- fear avoidance beliefs: adapted version of two subscales (physical activity, 0 to 18 points; work as cause of pain, 0 to 18 points) of the German version of the Fear Avoidance Belief Questionnaire (FABQ) (Pfingsten et al. 1997)  
- self-rated health (0 to 10 points): adapted version of the single index value for health status of the EQ-5D (Rabin and de Charro 2001)  
- depressive symptoms (0 to 24 points): 8-item depression module of the Patient Health Questionnaire (PHQ-8) (Gräfe et al. 2004)  
- self-rated work ability (0 to 10 points): Work Ability Score (WAS) (Ilmarinen 2007)  
- self-rated prognosis of employability (0 to 3 points): 3 item scale (Mittag and Raspe 2003)  
- healthcare utilisation: use of pharmaceuticals, visits to physicians, outpatient therapy (e.g. physiotherapy), days of hospitalisation, and days of sick leave

The following secondary outcomes will be extracted from the pension insurance accounts for 2016 and 2018:  
- days in receipt of sickness absence benefits  
- days in regular employment  
- disability pensions

For estimating the propensity scores, additional measures will be assessed only at baseline:
- comorbidity (0 to 15 points): adapted version of the German version of the Self-Administered Comorbidity Questionnaire (SCQ-D) (Streibelt et al. 2012)
- health behaviour: physical exercise, smoking, and body mass index
- socio-demographic data: migration, educational level, job position, net income, partnership, number of household members, number of children (<14 years), family members with a special need of care, strain due to home and family work (2 items with values ranging from 0 to 10) (Worringen and Benecke 2001)
- work environment: occupation, profession, fixed-term job contracts, shift work, size of enterprise,
- physical job demands (0 to 15 points) (Slesina 1987)
- measures of the Copenhagen Psychosocial Questionnaire (COPSOQ) (0 to 100 points): psychological job demands, support by supervisor and colleagues, atmosphere at work, job insecurity, overall job satisfaction (Nuebling and Hasselhorn 2010)
- mobbing (Institut für Arbeitsmarkt- und Berufsforschung 1999)

To assess cognitions about and experiences with rehabilitation services, additional variables will be assessed at baseline and follow-up (Spanier et al. 2016):
- former medical rehabilitation services
- subjective need for rehabilitation
- intention to apply for medical rehabilitation
- knowledge on rehabilitation application procedures
- outcome expectations
- social support by family/friends and physicians/therapists

### Countries of recruitment
- DE Germany

### Locations of Recruitment

### Recruitment
- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/03/23**
- Target Sample Size: **45000**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

### Inclusion Criteria
- Gender: **Both, male and female**
- Minimum Age: **45 Years**
- Maximum Age: **59 Years**
Gender: **Both, male and female**

Minimum Age: **45 Years**

Maximum Age: **59 Years**

### Additional Inclusion Criteria

Persons will be included if they are employed.

### Exclusion criteria

Persons who requested or utilised medical rehabilitation services during the past four years and persons with requested or approved disability pensions will be excluded.

### Addresses

#### Primary Sponsor

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Sources of Monetary or Material Support

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Status

- Recruitment Status: Recruiting complete, follow-up continuing
- 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.