**Title**

Effectiveness of work-related medical rehabilitation in cancer patients: a cluster randomized multicenter trial

**URL of the trial**

http://www.uksh.de/ike-luebeck/Forschung/FB+IV+Rehabilitationsforschung/MBOR+_Wirksamkeit+medizinisch_beruflich+orientierter+Rehabilitation+bei+onkologischen+Erkrankungen_eine+clusterrandomisierte+Multicenter_Studie-p-486.html

**Brief Summary in Lay Language**

Work-related medical rehabilitation is a strategy to improve work ability and to support return to work. Studies proofed that work-related medical rehabilitation for orthopedic, cardiology, neurologic, and psychosomatic rehabilitation patients increases return-to-work rates when compared to common medical rehabilitation. However, work-related medical rehabilitation is not well established for cancer patients. Furthermore, there is a lack of high quality studies that proof the additional benefit of work-related medical rehabilitation in work-related outcomes for cancer patients. Therefore, it is the aim of the current study to test the effectiveness of work-related medical rehabilitation in cancer patients with poor work ability.

**Brief Summary in Scientific Language**

In Germany, rehabilitation programs with a strong work-related focus in diagnostics and therapy were established during the last years. These programs are named work-related medical rehabilitation (WMR). There is evidence from randomized controlled trials that WMR programs are more effective in improving work-related outcomes as compared to common medical rehabilitation (MR) in patients with orthopedic, cardiac, neurological or psychosomatic diseases. However, there is no evidence from randomized controlled trials for the effectiveness these programs in cancer patients. Therefore, it is the aim of the current study to test the effectiveness of WMR in cancer patients. We examine if cancer patients with poor work ability participating in WMR have better work and daily living role functioning as compared to patients participating in standard MR. Clusters of cancer patients who applied for a rehabilitation measure will be randomly allocated either to WMR or MR. Participants will be surveyed by standardized questionnaires before and after rehabilitation as well as 3 and 12 months afterwards. Additional data will be collected from the standardized rehabilitation discharge letters. The study will be conducted in four outpatient rehabilitation centers.

**Do you plan to share individual participant data with other researchers?**
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[---]*

Description IPD sharing plan  
[---]*

Organizational Data

- **DRKS-ID:** DRKS00007770  
- **Date of Registration in DRKS:** 2015/05/13  
- **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.:** 14-289, Ethik-Kommission Universität zu Lübeck Medizinische Fakultät des Universitätsklinikums Schleswig-Holstein

Secondary IDs

- **Universal Trial Number (UTN):** U1111-1145-4678

Health condition or Problem studied

- **ICD10:** C00-D48 - Neoplasms

Interventions/Observational Groups

- **Arm 1:** Participants receive the standard rehabilitation program and the following treatments which focus specifically on return to work: social counseling, work-related psychological group treatments and work-related functional capacity training.

  The social counseling (min. 90 minutes, 30 minutes of these in a one-to-one setting) considers the following themes: occupational situation and perspective, sickness benefits, rights for severely disabled people, employer disability management, graded return-to-work, aids/services for participation in work life, and chances and risks of disability pensions.

  The work-related psychological group treatments (min. 240 minutes) have the following contents: coping with work-related stress, work-related social competences, and barriers and supportive factors for return to work.

  The work-related functional capacity training (min. 390 minutes, 30 minutes of these for initial individual functional capacity evaluation) includes: training of
typical work-related movements, cognitive training, compensatory exercises, ergonomics.

The work-related treatments are introduced and reasoned by a physician in an initial group session. All patients were seen by a psychologist at the beginning of the rehabilitation program. Multiprofessional case reviews are conducted at the beginning during, and at the end of the rehabilitation.

- Arm 2: Participants receive the usual medical rehabilitation program in accordance to the guidelines of the German Pension Insurance Agency.

### Characteristics

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

### Primary Outcome

Primary outcome is self-reported role functioning 12 months after Rehabilitation. The role functioning will be assessed at the beginning of cancer rehabilitation (T1), as well as 3 months (T3) and 12 months (T4) after the end of cancer rehabilitation with a questionnaire (EORTC QLQ-C30, Aaronson et al. 1993).

### Secondary Outcome

Secondary outcomes will be assessed at the beginning of cancer rehabilitation (T1), at the end of cancer rehabilitation (T2), as well as 3 months (T3) and 12 months (T4) after the end of cancer rehabilitation with a questionnaire: physical functioning (T1, T2, T3, T4, EORTC QLQ-C30, Aaronson et al. 1993); emotional functioning (T1, T2, T3, T4, EORTC QLQ-C30, Aaronson et al. 1993); social functioning (T1, T3, T4, EORTC QLQ-C30, Aaronson et al. 1993); pain (T1, T2, T3, T4, EORTC QLQ-C30, Aaronson et al. 1993); global health (T1, T2, T3, T4, EORTC QLQ-C30, Aaronson et al. 1993); fatigue (T1, T2, T3, T4, EORTC FA-13, Weis et al. 2013); work ability score (T1, T2, T3, T4, Ilmarinen 2007); disease coping (T1, T2, T3, T4, questionnaire on disease coping, Muthny 1989); employment status (T1, T3, T4); disability days (T1, T3, T4, von Korff et al. 1992); time of return to work (T3, T4); realization of work-related aims and therapy content (T2, Bethge et al. 2014); treatment satisfaction (T2, Schmidt et al. 1989); received therapeutic treatments (T2, discharge letter); social-medical capacity evaluation (T2; discharge letter).
Countries of recruitment

- DE Germany

Locations of Recruitment

- Medical Center Klinik Bavaria Freyung, Freyung
- Medical Center Paracelsusklinik am See Bad Gandersheim, Bad Gandersheim
- Medical Center MediClin Rose Horn-Bad Meinberg, Horn-Bad Meinberg
- Medical Center AMEOS Reha-Klinikum, Ratzeburg

Recruitment

- Planned/Actual: Actual
- (Anticipated or Actual) Date of First Enrollment: 2015/06/01
- Target Sample Size: 504
- Monocenter/Multicenter trial: Multicenter trial
- National/International: National

Inclusion Criteria

- Gender: Both, male and female
- Minimum Age: 18 Years
- Maximum Age: 60 Years

Additional Inclusion Criteria

poor work ability (positive rating at one of the three scales of the SIBAR (Screening-Instrument Beruf und Arbeit, Bürger und Deck 2009); Karnofsky Performance Status Scale ≥ 70 % (Karnofsky et al. 1948); positive social-medical prognosis (employability of min. 3 hours/day in no later than 6 months)

Exclusion criteria

None

Addresses

- Primary Sponsor
Primary Sponsor

Deutsche Rentenversicherung Bund
Ruhrstraße 2
10704 Berlin
Germany

Telephone: [---]*
Fax: [---]*
E-mail: [---]*
URL: [---]*

Contact for Scientific Queries

Universität zu Lübeck, Institut für Sozialmedizin und Epidemiologie, Sektion Rehabilitation und Arbeit
Mr. Prof. Dr. Matthias Bethge
Ratzeburger Allee 160
23562 Lübeck
Germany

Telephone: +4945150051280
Fax: +4945150051204
E-mail: matthias.bethge at uksh.de
URL: [---]*

Contact for Public Queries

Universität zu Lübeck, Institut für Sozialmedizin und Epidemiologie, Sektion Rehabilitation und Arbeit
Mr. David Fauser
Ratzeburger Allee 160
23562 Lübeck
Germany

Telephone: +4945150051233
Fax: +4945150051204
E-mail: davidpeter.fauser at uksh.de
URL: [---]*

Contact for Scientific Queries

Universität zu Lübeck, Institut für Sozialmedizin und Epidemiologie, Sektion Rehabilitation und Arbeit
Mr. David Fauser
Ratzeburger Allee 160
23562 Lübeck
Germany

Telephone: +4945150051233
Contact for Scientific Queries

Universität zu Lübeck, Institut für Sozialmedizin und Epidemiologie, Sektion Rehabilitation und Arbeit
Mr. David Fauser
Ratzeburger Allee 160
23562 Lübeck
Germany

Telephone: +4945150051233
Fax: +4945150051204
E-mail: davidpeter.fauser at uksh.de
URL: [---]*

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
Ruhrstraße 2
10704 Berlin
Germany

Telephone: [---]*
Fax: [---]*
E-mail: [---]*
URL: [---]*

Status

- Recruitment Status: Recruiting complete, follow-up complete
- Study Closing (LPLV): 2017/11/08

Trial Publications, Results and other documents


