



Trial Description

Title

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

Trial Acronym

WMR-C

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, cardiologic, 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.



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 \geq 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

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10704 Berlin
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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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E-mail: [---]*

URL: [---]*

Status

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

Trial Publications, Results and other documents

- Abstract **Schwarz, B., Wienert, J., & Bethge, M. (2015). Implementierungsstudien als notwendige Bedingung aussagekräftiger RCTs. Kongress der DGSM, DGMS und ÖGD. Regensburg, Germany.**
- Abstract **Schwarz, B., Wienert, J., & Bethge, M. (2016). RCTs vorgeschaltete Implementierungsstudien: Wie sie helfen können, den failure of implementation zu minimieren. 25. Rehabilitationswissenschaftliches Kolloquium. Aachen, Germany.**
- Paper **Wienert, J., Schwarz, B., & Bethge, M. (2016). Effectiveness of work-related medical rehabilitation in cancer patients: study protocol of a cluster-randomized multicenter trial. BMC Cancer, 16:544. doi: 10.1186/s12885-016-2563-z**



- Abstract <style fontName='DejaVu Sans' isBold='true'>Schwarz, B., Wienert, J., & Bethge, M. (2016). Development and implementation of work-related medical rehabilitation in cancer patients using organisational ethnography and action research methodology. Work Disability Prevention & Integration. Amsterdam, Netherlands.</style>
- Abstract <style fontName='DejaVu Sans' isBold='true'>Wienert, J., Schwarz, B., & Bethge, M. (2016). Medizinisch-beruflich orientierte Rehabilitation in der Onkologie: Zwischenergebnisse einer clusterrandomisierten Multicenterstudie. 15. Jahrestagung der Arbeitsgemeinschaft für Psychoonkologie in der Deutschen Krebsgesellschaft. Hannover, Germany.</style>
- Abstract <style fontName='DejaVu Sans' isBold='true'>Wienert, J., Schwarz, B., & Bethge, M. (2017). Patientenpräferenzen und Wartebereitschaft für eine medizinisch-beruflich orientierte Rehabilitation bei an Krebs erkrankten Patienten: ein Discrete Choice Experiment. 3. Interdisziplinären Kongress "Quality of Cancer Care". Berlin, Germany.</style>
- Abstract <style fontName='DejaVu Sans' isBold='true'>Wienert J., Schwarz B. & Bethge M. (2017). Medizinisch-beruflich orientierte Rehabilitation für onkologische Rehabilitanden – kurzfristige Ergebnisse einer clusterrandomisierten Multicenterstudie. 26. Rehabilitationswissenschaftliches Kolloquium, Frankfurt am Main, Germany.</style>
- Abstract <style fontName='DejaVu Sans' isBold='true'>Fauser D., Wienert J. & Bethge M. (2018). Patientenpräferenzen und Wartebereitschaft für eine medizinisch-beruflich orientierte Rehabilitation bei onkologischen Patienten: ein Discrete Choice Experiment. 27. Rehabilitationswissenschaftliches Kolloquium, München, Germany.</style>
- Abstract <style fontName='DejaVu Sans' isBold='true'>Fauser D., Wienert J. & Bethge M. (2018). Medizinisch-beruflich orientierte Rehabilitation für onkologische Rehabilitanden – mittelfristige Ergebnisse einer clusterrandomisierten Multicenterstudie. 27. Rehabilitationswissenschaftliches Kolloquium, München, Germany.</style>
- Abstract <style fontName='DejaVu Sans' isBold='true'>Fauser D., Bethge M., Wienert J., Beinert T., Biester I., Krüger H-U. & Schmielau J. (2018). Effectiveness and implementation of work-related medical rehabilitation in cancer patients: results from a cluster randomized multicenter trial. ISPRM World Congress, Paris, France.</style>
- Paper **Wienert, J., Bethge, M. (2018). Medizinisch-beruflich orientierte Rehabilitation für onkologische Rehabilitanden - kurzfristige Ergebnisse einer clusterrandomisierten Multicenterstudie. Rehabilitation, doi: 10.1055/a-0604-0157**
- Paper **Schwarz, B., Wienert, J., Bethge, M. (2019) Development and implementation of work-related medical rehabilitation in cancer patients using organizational ethnography and action research methodology. Int J Occup Med Environ Health, 32:217-28**
- Paper **Fauser, D., Wienert, J., Beinert, T., Biester, I., Krüger, H.-U., Presl, A., Schmielau, J., Bethge, M. (2019). Work-related medical rehabilitation in cancer patients - post rehabilitation results from a cluster-randomized multicenter-trial. Cancer, doi: 10.1002/cncr.32131**

* 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.