

Trial Description

Title

Individualized patient information following patient's illness beliefs and treatment beliefs in the context of rehabilitation

Trial Acronym

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URL of the trial

[---]*

Brief Summary in Lay Language

Patient information is a central element of rehabilitation care. However, patients are often dissatisfied with received information. Therefore, the aim of this study was to develop an intervention to tailor patient information to the individual needs of patients considering their illness beliefs and treatment beliefs as well as their satisfaction with information about illness and treatment. The intervention took an individual approach in which the content of each patient's intervention was based on an individual assessment of the patient's illness and treatment perceptions and information needs. The tailored information was delivered during rehabilitation care. As a guide for tailoring the information, physicians and psychologists of the rehab centres received a "feedback form" that provided information about the patients' illness and treatment beliefs and information needs. The intervention was implemented and evaluated in nine cooperating inpatient rehabilitation centres for musculoskeletal diseases and psychosomatics.

Brief Summary in Scientific Language

Patient information is a central element of rehabilitation care. However, patients are often dissatisfied with received information. Therefore, the aim of this study was to develop an intervention to tailor patient information to the individual needs of patients considering their illness beliefs and treatment beliefs as well as their satisfaction with information about illness and treatment. The intervention took an individual approach in which the content of each patient's intervention was based on an individual assessment of the patient's illness and treatment perceptions and information needs. The tailored information was delivered during rehabilitation care. As a guide for tailoring the information, physicians and psychologists of the rehab centres received a "feedback form" that provided information about the patients' illness and treatment beliefs and information needs. The intervention was implemented in nine cooperating inpatient rehabilitation centres for musculoskeletal diseases and psychosomatics. The evaluation followed a prospective study design with three measurement points.

Organizational Data

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DRKS-ID: **DRKS00001901**

Date of Registration in DRKS: **2011/11/16**

Date of Registration in Partner Registry or other Primary Registry:
2008/03/20

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- Date of Registration in DRKS: **2011/11/16**
- Date of Registration in Partner Registry or other Primary Registry: **2008/03/20**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **033/08** , **Ethik-Kommission der Albert-Ludwig-Universität Freiburg**

Secondary IDs

- Partner Registry-ID: **UKF001463 (Register klinischer Studien des Universitätsklinikums Freiburg)**

Health condition or Problem studied

- ICD10: **F32 - Depressive episode**
- ICD10: **M40-M54 - Dorsopathies**
- ICD10: **F33 - Recurrent depressive disorder**
- ICD10: **F34.1 - Dysthymia**

Interventions/Observational Groups

- Arm 1: **Intervention group: Individualized patient information following patient's illness beliefs and treatment beliefs**
- Arm 2: **control group (care as usual)**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Non-randomized controlled trial**
- Blinding: **Open (masking not used)**
- Who is blinded: **[---]***
- Control: **Active control**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

health status/quality of life; functioning

Operationalization: SF-36; Oswestry disability index; Allgemeine Depressionsskala

measurement point: start of rehabilitation, end of rehabilitation, 6-months-follow up

Secondary Outcome

satisfaction with information about medicine, illness and rehabilitation; perceived involvement; adherence

Countries of recruitment

- DE **Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2008/03/02**
- Target Sample Size: **400**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

age > 18 years; informed consent; German speaking; adequate cognitive and physical functioning; ICD-10 F32, F33, F34.1; ICD-10 M40-M54

Exclusion criteria

Generic: on-going early retirement proceedings; Depressive disorders: bipolar disorder, acute suicidal tendency, addiction, disorientation; Chronic Back Pain: disc surgery within the last 6 months, indication of an inflammatory or neoplastic origin, orientation disorders and psychiatric illnesses.

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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10709 Berlin
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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2011/04/30**

Trial Publications, Results and other documents

- Paper **Glattacker M, Heyduck K, Meffert C. Illness beliefs, treatment beliefs and information needs as starting points for patient information - evaluation of an intervention for patients with chronic back pain. Patient Education and Counseling. Epub ahead of print (DOI 10.1016/j.pec.2011.05.028).**
- Paper **Glattacker, M Heyduck K, Meffert C (2009). Entwicklung eines Fragebogens zur Erfassung des subjektiven Behandlungskonzepts von Rehabilitanden. Rehabilitation, 48, 345-353.**
- Paper **Glattacker, Heyduck, Meffert: Entwicklung, Implementierung und Umsetzung einer Intervention zur bedarfsgerechten Patienteninformation für Rehabilitandinnen und Rehabilitanden. Rehabilitation, 2010, 49, 292 - 300**
- Paper **Heyduck K, Glattacker M, Meffert C: Rehabilitation aus Patientensicht - Eine qualitative Analyse der subjektiven Behandlungskonzepte von Patienten in der stationären orthopädischen und psychosomatischen Rehabilitation Rehabilitation, 2011; 50 (4): 232-243**

* 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.