### Trial Description

**Title**

Improving self-regulation in patients with chronic disease

**Trial Acronym**

SELF

**URL of the trial**

[---]*

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**Brief Summary in Lay Language**

The aim of the study is to develop an intervention that tries to adjust information individually to patients’ beliefs about illness and treatment and thus meet individual information needs. New information should for example refer to already received input and should also consider patients’ beliefs about their illness and treatment and previous coping behavior. In the long run, this should lead to optimal assistance and support for patients dealing with their disease.

The first step of our project will be to develop a questionnaire to assess patients’ coping behavior and its appraisal. This questionnaire will then be tested on N=400 patients with chronic low back pain and depressive disorders. Based on these findings, the intervention will be developed in the second step of the project. Finally patients and professionals should evaluate the intervention.

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**Brief Summary in Scientific Language**

The aim of the study is to develop an intervention that tries to adjust information individually to patients’ beliefs about illness and treatment and thus meet individual information needs. This should lead to optimal assistance and support of patients’ self-regulation concerning their disease and its treatment. The development of the intervention refers to the Common-Sense Model of self-regulation, a theory that was developed by Howard Leventhal and colleagues.

Considering the central components of this model, the intervention in patient information to be developed should incorporate three aspects: (1.) patient’ perceptions of illness and treatment (i.e. What do patients think about their illness and treatment?), (2.) previous coping behavior/action plans (i.e. What have patients already tried to overcome their disease? Do they for example have experience with medication or with rehabilitative treatment?) and (3.) the appraisal of coping behavior/action plans (i.e. Was the coping behavior successful or not from the patients’ point of view?).

The first step of our project will be to develop a questionnaire based on the Common-Sense Model of self-regulation to assess coping behavior and its appraisal. This questionnaire will then be psychometrically tested on N=400 patients with chronic low back pain and depressive disorders. Based on these findings, the intervention will be developed in the second step of the project. This will take place in cooperation with physicians and psychologists from six rehabilitation centres, in which this concept will be implemented and formatively
evaluated. Here, qualitative as well as quantitative designs will be applied. Primary Outcomes will be acceptance on patients’ and professionals’ side and clinical feasibility. The project should result in an intervention that is seen as useful and beneficial from both patients’ and professionals’ view and which can be integrated into clinical procedures.

Organizational Data

- DRKS-ID: DRKS00003094
- Date of Registration in DRKS: 2011/06/09
- 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.: 122/11, Ethik-Kommission der Albert-Ludwigs-Universität Freiburg

Secondary IDs

- Universal Trial Number (UTN): U1111-1121-5502

Health condition or Problem studied

- ICD10: F32 - Depressive episode
- ICD10: F33 - Recurrent depressive disorder
- ICD10: F34.1 - Dysthymia
- ICD10: F38.1 - Other recurrent mood [affective] disorders
- ICD10: M42.1 - Adult osteochondrosis of spine
- ICD10: M42.9 - Spinal osteochondrosis, unspecified
- ICD10: M43.0 - Spondyloysis
- ICD10: M43.1 - Spondylolisthesis
- ICD10: M43.2 - Other fusion of spine
- ICD10: M43.5 - Other recurrent vertebral subluxation
- ICD10: M43.8 - Other specified deforming dorsopathies
- ICD10: M43.9 - Deforming dorsopathy, unspecified
- ICD10: M47.2 - Other spondylolysis with radiculopathy
- ICD10: M47.8 - Other spondylosis
- ICD10: M47.9 - Spondylosis, unspecified
- ICD10: M48.8 - Other specified spondylopathies
ICD10: M48.9 - Spondylopathy, unspecified
ICD10: M51.0 - Lumbar and other intervertebral disc disorders with myelopathy
ICD10: M51.1 - Lumbar and other intervertebral disc disorders with radiculopathy
ICD10: M51.2 - Other specified intervertebral disc displacement
ICD10: M51.3 - Other specified intervertebral disc degeneration
ICD10: M51.4 - Schmorl's nodes
ICD10: M53.8 - Other specified dorsopathies
ICD10: M53.9 - Dorsopathy, unspecified
ICD10: M54.1 - Radiculopathy
ICD10: M54.3 - Sciatica
ICD10: M54.4 - Lumbago with sciatica
ICD10: M54.5 - Low back pain
ICD10: M54.9 - Dorsalgia, unspecified
ICD10: M96.1 - Postlaminectomy syndrome, not elsewhere classified
ICD10: Z96.7 - Presence of other bone and tendon implants

Interventions/Observational Groups

Arm 1: tailored information on illness and treatment that consider patients’ beliefs about their illness and its treatment (During inpatient rehabilitation physicians and psychologists will inform patients about their illness and treatment at the beginning and at the end of rehabilitation. Altogether this will take about 1h.)

Characteristics

Study Type: Interventional
Study Type Non-Interventional: [---]*
Allocation: Single arm study
Blinding: [---]*
Who is blinded: [---]*
Control: Uncontrolled/Single arm
Purpose: Treatment
Assignment: Single (group)
Phase: N/A
Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): N/A
Primary Outcome

containing development of the intervention: acceptance on patients’ and professionals’ side and clinical feasibility; data collection after implementation of the intervention with internal developed questionnaires (patients) and interviews (patients and professionals) at the end of rehabilitation

Secondary Outcome

containing pretest: development and psychometric testing of a questionnaire assessing coping behavior and its appraisal (on patients’ side); data collection with the questionnaire to be developed and other validation instruments (i.e., Illness Perception Questionnaire Revised und Beliefs about Medicines Questionnaire) at the end of rehabilitation and 6 month after the rehabilitation

Countries of recruitment

- DE Germany

Locations of Recruitment

Recruitment

- Planned/Actual: Actual
- (Anticipated or Actual) Date of First Enrollment: 2011/07/01
- Target Sample Size: 560
- 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

rehabilitants with diagnosis chronic low back pain or depressive disorder

Exclusion criteria
chronic low back pain: disc surgery within the last 6 months, indication of an inflammatory or neoplastic origin, orientation disorders and psychiatric illnesses or ongoing early retirement proceedings; depressive disorder: bipolar disorder, suicidal tendency, addictive disorder, orientation disorder or ongoing early retirement proceedings

Addresses

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Status

- Recruitment Status: Recruiting complete, follow-up complete
- Study Closing (LPLV): 2014/06/30

Trial Publications, Results and other documents