Trial Description

Title

Effectiveness and cost-efficacy of an internet-based intervention for the prevention of major depression in patients with back pain and subthreshold depression - a randomized controlled trial.

EK-confirmed substudy of "Effectiveness of a guided web-based intervention for depression in back pain rehabilitation aftercare."

Trial Acronym

PROD-BP

URL of the trial

[---]*

Brief Summary in Lay Language

Background: Current care for patients with depression is mainly curative and linked with several disadvantages. For instance long wait for therapy. Furthermore, not all patients are treated in conformity with professional medical guidelines and even if there is no guarantee for a non-chronic course of disease. As a result of this prevention gets more and more important. Thereby Internet- and mobile-based interventions (IMIs) are an economic way of implementation in patients with depression. Research shows that IMIs are effective and because of their temporal and local flexibility they can be easily integrated in the everyday life. Especially prevention seems to be effective in risk group with multiple risk indicators. For depression both physical diseases and subthreshold depression are risk indicators. This study investigates if an Internet -based intervention is effective in patients with chronic back pain and subthreshold depression.
Method: 406 patients with back pain and subthreshold depression will be asked after their rehabilitation, if they volunteer for an Internet-based aftercare program. If they do not have a depression disorder, they get either a preventive depression intervention (PROD-BP) or treatment as usual (TAU). PROD-BP is based on techniques of Cognitive Behavioral Therapy (CBT) and consists of six weekly units, which lasts about 1.5 hours each. Aim of PROD-BP is to prevent or at least delay a depression disorder.
Discussion: Prevention is primary indicated in risk groups with multiple risk indicators like the current sample. If this study is effective in the prevention of depression, the study design will maybe be transferred to other physical diseases and maybe be implemented as a routine aftercare program for inpatients

Brief Summary in Scientific Language

Background: Reducing the disease burden of major depressive disorder (MDD) is of major public health relevance. The prevention of depression is regarded as one possible approach, with a focus on people with multiple risk factors such as back pain and subthreshold depressive symptoms. Thereby, web-based interventions might be a promising solution to scale up preventive interventions. The aim of this

study is the evaluation of an Internet- and mobile-based intervention for preventing the onset of depression in back pain patients (PROD-BP) with depressive symptoms.
Methods: PROD-BP is a multicenter randomized controlled trial (RCT) of parallel design aiming to investigate the (cost-) effectiveness of an internet-based depression prevention intervention for back pain patients with depressive symptoms. The intervention is based on Cognitive Behavioral Therapy (CBT) including 6 weekly plus three optional modules and two booster sessions after end of intervention. Trained eCoaches (psychologists) provide guidance by sending feedback emails after each module. A total of 406 participants will be recruited from at discharge from inpatient health care and allocated to either intervention or treatment as usual (TAU). Log-rank survival analyses will be conducted to estimate incidence rate differences between intervention and control group. Primary patient-relevant endpoint of the trial is the onset of depression measured by the telephone-administered Structured Clinical Interview (SCID). Key secondary endpoints are health-related quality of life, depression severity, pain intensity, pain-related disability, work-capacity, satisfaction with the intervention and intervention adherence, side effects of psychotherapy as well as costs of the intervention.
Discussion: Multiple risk-factors indicate the use of prevention strategy to lower the personal and societal burden of depression. If this first study examining an Internet-based preventive depression intervention in a sample of chronically ill patients with depressive symptoms proves its effectiveness, it could be implemented into routine care and extended to other chronic conditions.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00007960**
- Date of Registration in DRKS: **2015/08/12**
- 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.: **297/14_150513 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **F32.0 - Mild depressive episode**
- ICD10: **F32.1 - Moderate depressive episode**
- ICD10: **F33.0 - Recurrent depressive disorder, current episode mild**
- ICD10: **F33.1 - Recurrent depressive disorder, current episode moderate**
- ICD10: **M40-M54 - Dorsopathies**
- ICD10: **R52.1 - Chronic intractable pain**
- ICD10: **R52.2 - Other chronic pain**
- ICD10: **G50-G59 - Nerve, nerve root and plexus disorders**

Interventions/Observational Groups

- Arm 1: **Online-Training RückCare-P**
  The intervention is based on Cognitive Behavioral Therapy (CBT) including 6 weekly plus three optional modules and two booster sessions after end of intervention. Trained eCoaches (psychologists) provide guidance by sending feedback emails after each module.
- Arm 2: **Usual care/ Treatment as usual**
  In-patient rehabilitation aftercare may vary between different clinics and patients. There is no minimum treatment defined.

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **assessor, data analyst**
- Control: **Other**
- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Onset of depression measured by the telephone-administered Structured Clinical Interview for DSM-IV (SCID) within one year after randomisation.

Secondary Outcome

Online-Questionaires at baseline, 9-weeks post randomisation, 6 and 12 months after randomisation.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Rehaklinik Sonnhalde, Donaueschingen**
- Medical Center **Theresienklinik , Bad Krozingen**
- Medical Center **RehaKlinikum Bad Säckingen, Bad Säckingen**
- Medical Center **Rehakliniken , Bad Waldsee**
- Medical Center **Baden Klinik, Bad Krozingen**
- Medical Center **Schön Klinik , Bad Staffelstein**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/10/21**
- Target Sample Size: **406**
- 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

Those who signed the informed consent form will be included in the study if they meet the following criteria: a) age 18 and above, b) presence of back pain, c) sufficient knowledge of German language, d) medically suitable, e) adequate

computer and internet skills for an internet-based depression intervention, f) internet access, g) depressive symptomatology (Patient Health Questionnaire ≥ 5).

Exclusion criteria

Patients will be excluded who meet DSM-IV criteria for a) current depressive episode or b) a bipolar disorder. Additionally patient will be excluded in case of c) an ongoing psychotherapy, respectively being on a waiting list for psychotherapy, d) being suicidal or reporting suicidal acts in history.

Addresses

■ **Primary Sponsor**

Universität Ulm
Mr. Prof. Harald Baumeister
Albert-Einstein-Allee 47
89069 Ulm
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **harald.baumeister at uni-ulm.de**
URL: **[---]***

■ **Contact for Scientific Queries**

Universität Freiburg, Abteilung Rehabilitationspsychologie und Psychotherapie
Mr. Dr. Lasse Sander
Engelberger Str. 41
79085 Freiburg
Germany

Telephone: **00497612033049**
Fax: **[---]***
E-mail: **lasse.sander at psychologie.uni-freiburg.de**
URL: **[---]***

■ **Contact for Public Queries**

Universität Freiburg, Abteilung Rehabilitationspsychologie und Psychotherapie
Mr. Dipl.-Psych. Lasse Sander
Engelberger Str. 41
79085 Freiburg
Germany

Telephone: **00497612033049**
Fax: **[---]***
E-mail: **lasse.sander at psychologie.uni-freiburg.de**
URL: **[---]***

- **Collaborator, Other Address**

  Universität Ulm, Klinische Psychologie und Psychotherapie
  Mr. Prof. Harald Baumeister
  Albert-Einstein-Allee 47
  D-89081 Ulm
  Germany

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **harald.baumeister at uni-ulm.de**
  URL: **[---]***

Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

  Universität FreiburgAbteilung Rehabilitationspsychologie und Psychotherapie
  Engelberger Str. 41
  79085 Freiburg
  Germany

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

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

  Deutsche Forschungsgemeinschaft DFG
  53170 Bonn
  Germany

  Telephone: **0228 8851**
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2018/09/28**

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.*