Trial Description

Title

Evaluation and implementation of a computer-aided cognitive-behavioural oriented self-help program (MoodGym) for general practitioner patients with mild to moderate depressive symptoms – a cluster-randomized study

Trial Acronym

Aktiv-Studie - Aktiv aus der Depression

URL of the trial

[---]*

Brief Summary in Lay Language

Depressive disorders belong to the most common psychiatric disorders in adult age. They occur in various forms with mild, moderate to severe symptoms. They can occur as a single episode or as recurrent epsiodes. General practitioners (GPs) play an important role in the care of people with depression. There has been evidence in many studies that the GP is the first contact person in case of a depression among the general population. Thus, approximately two-thirds of patients with depression seek help in a GP practice due to their psychological problems. In this project, an internetbased cognitive-behavioural oriented self-help program (MoodGym) will be examined in a sample of primary care patients with mild to moderate depression symptoms. It will be investigated whether the program contributes to the reduction of depressive symptoms, whether patients confirm the value of such a program and whether its use is cost-effective. The internetbased cognitive-behavioural oriented self-help program (MoodGym) was designed and developed by staff at the Centre for Mental Health Research at the Australian National University, in collaboration with mental health experts, web and graphic designers, and software engineers. The English MoodGym program already counts more than 600.000 registrated users worldwide, it is available since 2004 and its access is free of charge. In Australia the programm has already been proven to be effective in reducing depression and anxiety symptoms, to be accepted by its users and to show cost-effectiveness. For the present study the English version of the MoodGYM program has been translated into German. Patients with mild to moderate depression will be recruited in cooperation with GP practices in Saxony and Thuringia. Thus, the participating GP practices will be randomly allocated to an intervention group and a control group. Patients in the control group will receive standard primary care treatment and will fill out questionnaires regarding the course of depression symptoms, quality of life and the enhancement of activities at three different assessment points (in GP practice, after 6 weeks, after 6 months). Patients in the intervention group will also receive standard primary care treatment and additionally gain access to the German internetbased cognitive-behavioural oriented self-help program (MoodGym). Patients in the intervention group will be asked to fill out the same questionnaires as the controll group (in GP practice, after 6 weeks, after 6 months). For cost-effectiveness analysis economical health insurance data from Allgemeine Ortskrankenkasse AOK will be investigated after informed consent of the insured patients.

Brief Summary in Scientific Language

This project aims to implement and evaluate the internetbased cognitive-behavioural oriented self-help program MoodGYM regarding individuals with mild to moderate depressive disorders within primary care setting. MoodGym was designed and developed by staff at the Centre for Mental Health Research at the Australian National University, in collaboration with mental health experts, web and graphic designers, and software engineers. MoodGYM is a computer-aided, interactive and comprehensible training programm which aims to prevent and reduce depressive symptoms. It is based on techniques used in Cognitive Behavioural Therapy (CBT), a well accepted and evaluated treatment method for depression. Thus, this program adresses topics like the coherence between thoughts and feelings, how to cope with relationships problems or stress and gives the opportunity to learn specific relaxation techniques. Even though MoodGYM uses CBT techniques it is not equal to psychotherapy treatment. Hence, it has to be classified as a self-management and self-help program.
The English MoodGYM program has already shown good results regarding its effectiveness and user acceptance in Australia. The internetbased cognitive-behavioural oriented self-help program MoodGYM has been translated into German language. The present study aims to examine the program regarding its effectiveness and user acceptance in individuals with mild to moderate depression symptoms but also regarding its cost-effectiveness from a health care provider's perspective (Gesetzliche Krankenversicherung GKV) in Germany.
The study design is a cluster-randomized controlled trial, in which approximately 100 recruited general practitioners (GP) in Saxony and Thuringia will be randomized to an intervention group (IG) and a control group (CG). The study furthermore aims to include approximately 632 study patients in cooperation with these GP practices. Patients in the control group will receive standard primary care treatment (TAU). Patients in the intervention group will also receive standard primary care treatment (TAU) and additionally gain access to the German internetbased cognitive-behavioural oriented self-help program (MoodGym). Patients will be asked to fill out questionnaires regarding the course of depression symptoms (Beck's depression inventory BDI-II, PHQ-9), psychiatric comorobidity (PHQ anxiety module), quality of life (EQ-5D) and the enhancement of activities at three different assessment points (in GP practice, after 6 weeks, after 6 months). For health economics evaluation sector-specific individual routine data of the Allgemeine Ortskrankenkasse (AOK) will be provided via the Scientific Institute of the AOK (Wissenschaftlichen Institut der AOK (WIdO)). These analyses will refer to a longterm-follow-up 36 months after baseline assessment. Changes over time of outcome measures and healthcare costs will be compared between IG and KG (intention-to-treat- and per-protocol-analysis). The primary outcome will be the change of depressive symptoms (BDI-II score, PHQ-9 score). Secondary outcomes will be program acceptance, quality of life (EQ-5D), the enhancement of activities and the direct healthcare costs from a provider's perspective as well as the incremental cost-effectiveness-ratio (measure: quality-adjusted life years (QALYs) based on the EQ-5D Index).

Organizational Data

- DRKS-ID: **DRKS00005075**
- Date of Registration in DRKS: **2013/07/17**
- 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**

DRKS-ID: **DRKS00005075**
Date of Registration in DRKS: **2013/07/17**
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.: **375-12-05112012 , Ethikkommission an der Medizinischen Fakultät der Universität Leipzig**

Secondary IDs

Health condition or Problem studied

- Free text: **Depression**
- 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**

Interventions/Observational Groups

- Arm 1: **Treatment as usual in primary care (TAU) plus MoodGym, an internetbased cognitive-behavioural oriented self-help program. MoodGYM comprises five interactive modules ("Feelings", "Thoughts", "Unwarping", "De-stressing", "Relationships"), which are designed to be completed in order by the study participants within a period of 6 weeks. Thereby study participants may work through these modules as fast or slow as they want and at individual times (e.g. once a week). Every module contains interactive exercises, examples and tests.**
The "Feelings" module (processing time about 20 minutes) deals with the coherence of thoughts, feelings and behaviour using psycheducative elements and concrete exercises (e.g. emotion protocol). This module also explains the role of negative thinking patterns and biased perceptions of situations. Within the "Thoughts" module (processing time about 25 minutes) study participants learn how to perceive their personal needs and und how to identify cognitive schema.
The "Unwarping" module (processing time about 30 minutes) shows strategies on how to question and change warped thinking and needs.
The "De-stressing" module (individual processing time, about 30-60 minutes) gives information on the development and effects of stress, the role of chronic stress factors and critical life events. Study participants will have the opportunity to learn relaxation techniques (e.g. Progressive relaxation) using

audio material).
The "Relationship" module (individual processing time, about 25 minutes) will provide simple problem solving strategies for relationship problems as well as strategies on how to cope with relationship breakups.

- Arm 2: **Treatment as usual in primary care (TAU)**

Characteristics

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

Primary Outcome

change in depression symptoms: assessment via questionnaires (BDI-II and PHQ-9) at three
assessment points (at GP practice; after 6 weeks, after 6 months)

Secondary Outcome

Assessment via questionnaire: program acceptance, increase in activities, quality of life (EQ-5D) at three assessment points (at GP practice; after 6 weeks, after 6 months);

Direct healthcare costs from a provider’s perspective, incremental cost-effectiveness-ratio (measure: quality-adjusted life years (QALYs) based on the EQ-5D Index). For health economics evaluation sector-specific individual routine data of the Allgemeine Ortskrankenkasse (AOK) will be provided 36 months after baseline assessment (after written consent of study participants via Wissenschaftliches Institut der Allgemeinen Ortskrankenkasse (WIdO)).

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Doctor's Practice **Sachsen und Thüringen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/02/06**
- Target Sample Size: **632**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **65 Years**

Additional Inclusion Criteria

AOKPlus insured for at least one year; internet access and use; German native speaker; clinical diagnosis of “mild to moderate first or recurrent depressive disorder" according to ICD-10: F32.0, F32.1, F33.0 F33.01; PHQ-9 score between 5 and 14

Exclusion criteria

Severe depressive episode ICD-10: F32.2, F32.3, F33.2, F33.3, persistent affective disorder F34, bipolar affective disorder F31, schizophrenia and schizoaffective disorders F20-F29, dependence syndrome (except nicotine) F10- F16, F18, F19, dementia und organic mental disorders F00-F09, being in psychotherapeutic treatment, existing suicidality, episode of grief, severe somatic disease (e.g. final stadium of cancer)

Addresses

- **Primary Sponsor**

  Institut für Sozialmedizin, Arbeitsmedizin und Public Health (ISAP), Universität Leipzig
  Philipp-Rosenthal-Straße 55
  04103 Leipzig
  Germany

  Telephone: **[---]***

Primary Sponsor

Institut für Sozialmedizin, Arbeitsmedizin und Public Health (ISAP), Universität Leipzig
Philipp-Rosenthal-Straße 55
04103 Leipzig
Germany

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

■ **Contact for Scientific Queries**

Institut für Sozialmedizin, Arbeitsmedizin und Public Health (ISAP), Universität Leipzig
Ms. Prof. Dr. med. Steffi G. Riedel-Heller
Philipp-Rosenthal-Str. 55
04103 Leipzig
Germany

Telephone: **0341 - 97 15406**
Fax: **[---]***
E-mail: **diana.stoetzer at medizin.uni-leipzig.de**
URL: **[---]***

■ **Contact for Public Queries**

Institut für Sozialmedizin, Arbeitsmedizin und Public Health, Universität Leipzig
Ms. Dr. Margrit Löbner
Philipp-Rosenthal-Str. 55
04103 Leipzig
Germany

Telephone: **0341 - 97 24591**
Fax: **[---]***
E-mail: **margrit.loebner at medizin.uni-leipzig.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.)**

AOK Bundesverband
Rosenthaler Straße 31
10178 Berlin
Germany

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

AOK Bundesverband
Rosenthaler Straße 31
10178 Berlin
Germany

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

Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- Study Closing (LPLV): **[---]***

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.*