Trial Description

Title

Effects of a supportive German online program for people with depression or adjustment: A randomized controlled trial

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Mental illness and behavioral disorders are a major cause of disability. Currently there are more than eight million people in Germany suffering from depression. Thus, the third highest percentage of all lost work days and the highest percentage of all sick days are caused by mental illness. Scientific studies revealed that the average waiting time from diagnosis to admission to treatment is about five months. During this waiting period there is usually no additional treatment beyond the practitioner's standard care and the disease manifests itself increasingly. Psychological counseling over the internet has the potential to fill these gaps. Due to the easy access and the possibility of anonymous usage, online applications can also reach people who are unable or unwilling (because of fear or shame) to seek conventional (medical) help. Above all, they can support affected individuals in underserved regions and facilitate during the period of time prior to the start of treatment. Internet-based psychotherapeutic treatment programs are being developed for about 20 years and are particularly common in countries like Britain, the Netherlands, Australia and the USA.
The aim of this research project is to evaluate the effectiveness of a supportive German online program for people with depression or adjustment disorder which corresponds to the individual needs of each user. For this purpose, the supportive self-help-program will be compared to online provided weekly information texts on depression and health. Study participants (insured by the commercial insurance KKH with mild to moderate depression or adjustment disorder) receive a personal pseudonymized code and are assigned to one of the two online support programs by a computerized random procedure. Over a period of 12 months, online surveys on the health status of the study participants are conducted at five different times. The online questionnaire is based on standardized diagnostic instruments and was developed in-house. Primary outcome measures include the improvement of depression or symptoms of adjustment disorder and a reduction of sick days. Furthermore, the use of medical care as well as aspects of self-efficacy and the quality of life are obtained. Analyses are carried out including anonymised secondary data/routine records of the KKH insurance company. The research project is intended to gain knowledge about the effectiveness and efficiency of internet-based supportive programs for people with depression and will evaluate on a representative sample if usage of this certain program can help reducing the number of sick days caused by depression. Considering the rising expenditures of the German health care system for mental disorders, this research project could dedicate important findings for an alternative support system for people suffering from depression or adjustment disorders.

Brief Summary in Scientific Language

The aim of this research project is to evaluate the effectiveness of a supportive German online program as an additional offer to primary care in patients with mild to moderate depression and adjustment disorders. Considering the increase of depressive disorders and a concurrent psychotherapeutic/psychiatric shortage in many regions, online-based interventions are becoming more and more important as an alternative care model.
As part of a prospective randomized controlled longitudinal study, the supportive self-help-program is compared to weekly online available information on depression and health. The target group consists of insurants of the commercial insurance KKH with a principal diagnosis of mood disorders (F32.0, F32.1, F33.0, F33.1 and F34.1) or adjustment disorder (F43.2) at an age between 18 to 65 years. Study participants receive a personal pseudonymized code. The allocation to one of the two online applications is acquired by using computerized randomization. It is expected that the individualized supportive online program in comparison with the non-specific online-based information on depression and health will be more effective in improving disease progression. Primary outcome is the improvement of the state of depression or adjustment disorder. Secondary outcomes are a reduction of sick days, an improvement in patient reported outcomes (PROs, including quality of life, self-efficacy, physical and mental stress symptoms), as well as a decrease in the use of services of the statutory health insurance (esp. hospitalization, prescriptions, doctor consultations). Primary and secondary outcome measures are collected online at five times as part of a pre-post design with catamneses over a period of 12 months. The online questionnaire is based on standardized diagnostic instruments and was developed in-house. Evaluations are carried out including pseudonymized secondary data (routine data) of the KKH.
The research project intends to gain knowledge about the effectiveness and efficiency of online-based supportive programs for people with depression and, for the first time, will evaluate on a representative sample if usage of this certain program can help reducing the number of sick days caused by depression. Considering the rising expenditures of the German health care system for mental disorders, this research project could dedicate important findings for an alternative support system for people suffering from depression or adjustment disorders.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00004616**
- Date of Registration in DRKS: **2013/01/07**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***

DRKS-ID: **DRKS00004616**
Date of Registration in DRKS: **2013/01/07**
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.: **Rössler_201210 , Beirat für Ethikfragen in der Forschung**
  Leuphana Universität Lüneburg
  Scharnhorststr. 1
  21335 Lüneburg
  Deutschland
  ethikbeirat@leuphana.de
  www.leuphana.de

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: **F34.1 - Dysthymia**
- ICD10: **F43.2 - Adjustment disorders**

Interventions/Observational Groups

- Arm 1: **Intervention: online intervention with 12 weekly training sessions based on the individual needs of the user including video, audio and written information as well as specific assistance to deal with depressive symptoms.**
- Arm 2: **Control: 12-week online-based written information on depression and health. The written information contains texts, instructions and suggestions for a healthy lifestyle.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control**
- Purpose: **Health care system**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Improvement of depressive symptoms or symptoms of adjustment disorder (weekly screening by the PHQ-9; pre-post measurement with two follow-ups by the BDI-II)

Secondary Outcome

Reduction of sick days (routine data analysis) and positive effects on patient reported outcomes (PROs; including quality of life, self-efficacy, physical and mental stress symptoms measured by EQ-5D, MANSA, ASF, SCL-14) and the use of disease-related services covered by the German statutory health insurance (SHI) (e.g. prescriptions, doctor consultations and hospitalization from routine data analysis).

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- other **Leuphana Universität Lüneburg, 21335 Lüneburg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/01/28**
- Target Sample Size: **608**
-

Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2013/01/28**

Target Sample Size: **608**

Monocenter/Multicenter trial: **Monocenter trial**

- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

F32.0; F32.1; F33.0; F33.1; F34.1; F43.2;
Current incapacity to work certificate;
Internet access/e-mail account

Exclusion criteria

Presence of severe depression;
Risk of suicide (dedicated collection of active and passive suicidal tendencies);
Missing declaration of consent ("informed consent")

Addresses

- **Primary Sponsor**

Leuphana Universität Lüneburg
Innovations-Inkubator
Kompetenztandem "Vernetzte Versorgung"
Mr. Prof. Dr. med. Dipl.-Psych. Wulf Rössler
Rotenbleicher Weg 67
21335 Lüneburg
Germany

Telephone: **0049 (0)4131 677 7666**
Fax: **0049 (0)4131 677 7601**
E-mail: **roessler at dgsp.uzh.ch**
URL: **http://www.leuphana.de/inkubator/gesundheit/vernetzte-versorgung.html**

- **Contact for Scientific Queries**

Leuphana Universität Lüneburg

Contact for Scientific Queries

Innovations-Inkubator
Kompetenztandem "Vernetzte Versorgung"
Mr. Dr. Dipl.-Soz. Jörn Moock
Rotenbleicher Weg 67
21335 Lüneburg
Germany

Telephone: **0049 (0) 4131 677 7824**
Fax: **0049 (0)4131 677 7601**
E-mail: **joern.moock at inkubator.leuphana.de**
URL: **http://www.leuphana.de/inkubator/gesundheit/vernetzte-versorgung.html**

- **Contact for Public Queries**

Leuphana Universität Lüneburg
Innovations-Inkubator
Kompetenztandem "Vernetzte Versorgung"
Zusatzmodul "Onlinetherapie"
Mr. Dipl.-Psych. Kai Kossow
Rotenbleicher Weg 67
21335 Lüneburg
Germany

Telephone: **0049 (0) 4131 677 7887**
Fax: **[---]***
E-mail: **studie.depressionshelfer at leuphana.de**
URL: **http://www.leuphana.de/inkubator/gesundheit/vernetzte-versorgung.html**

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.)**

NBank
Europäischer Fonds für Regionale Entwicklung Land Niedersachsen
Günther-Wagner-Allee 12-16
30177 Hannover
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **http://www.efre.niedersachsen.de/;**

Status

- Recruitment Status: **Recruiting ongoing**

- 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.*