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Effects of a supportive German online program for people with depression or adjustment

Submission date
03/01/2013

Recruitment status
No longer recruiting

Registration date
05/02/2013

Overall study status
Completed

Last Edited
19/06/2017

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Background and study aims
Mental illness and behavioral disorders are a major cause of disability and incapacity of work. Scientific studies revealed that the average waiting time from diagnosis to admission to treatment is about five months. Psychological counseling over the internet has the potential to bridge this waiting time. Online applications are characterized by an easy access and the possibility of anonymous usage and could fill supply gaps in underserved regions. The aim of this study is to find out how well a supportive German online program for people with depression or adjustment disorder works in order to alleviate (improve) symptoms and reduce the number of sick days. 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.

Who can participate?
Women and men aged between 18 and 65 with mild to moderate depression or adjustment disorder who are insured by the commercial insurance KKH in Germany.

What does the study involve?
The individualized self-help-program is compared to online available weekly information texts on depression and health. Participants are randomly allocated to one of the two groups. Over a period of 12 months beginning in January 2013, 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. Outcome measures include the alleviation of symptoms and a reduction of sick days. Furthermore, the use of medical care as well as aspects of self-efficacy and the quality of life will be obtained. Analyses are carried out including anonymized secondary data/routine records of the KKH insurance company.

What are the possible benefits and risks of participating?
The individualized self-help-program is an additive offer of support beyond basic and customary care and may help participants to better manage their symptoms. Participants are able to use the usually fee-based online program for free. Those who are allocated to the control group with the online offered information texts have the opportunity to use the individualized self-help program free of cost once the study is completed. A negative impact on the health of

participants is not expected but cannot be ruled out on a case-by-case basis. Participating in the study cannot replace medical consultations or therapy. Participants are reminded to use medical and therapeutic services when needed.

Where is the study run from?
Leuphana University Lueneburg (Germany)

When is the study starting and how long is it expected to run for?
January 2013 to January 2014

Who is funding the study?
The federal state of Lower Saxony and the European Regional Development Fund

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
DRKS00004616

Study information

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

Study objectives
It is expected that an individualized supportive online program in comparison with a non-specific online-based information on depression and health will be more effective in improving disease progression.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Committee on ethical issues in research at Leuphana University Lueneburg, 05/12/2012

Study design
Prospective randomized controlled longitudinal study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Internet/virtual

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Mild depressive episode, Moderate depressive episode, Recurrent depressive disorder, current episode mild, Recurrent depressive disorder, current episode moderate, Dysthymia, Adjustment disorders

Interventions
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.

Control: 12-week online-based written information on depression and health. The written information contains texts, instructions and suggestions for a healthy lifestyle.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure

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 measures
1. Reduction of sick days (routine data analysis)
2. 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)
3. 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)

Overall study start date
14/01/2013

Completion date
15/01/2014

Eligibility

Key inclusion criteria
1. 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, either sex.
2. Current incapacity to work certificate and an Internet access/e-mail account

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
608

Key exclusion criteria
1. Presence of severe depression
2. Risk of suicide (dedicated collection of active and passive suicidal tendencies)
3. Missing declaration of consent ("informed consent")

Date of first enrolment
14/01/2013

Date of final enrolment
15/01/2014

Locations

Countries of recruitment
Germany

Study participating centre
Rotenbleicher Weg 67
Lueneburg
Germany
21335

Sponsor information

Organisation
NBank (Germany)

Sponsor details
European Regional Development Fund (Europäischer Fonds für Regionale Entwicklung Land Niedersachsen)
Günther-Wagner-Allee 12-16
Hannover
Germany
30177

Sponsor type
Other

Website
http://www.efre.niedersachsen.de

ROR
https://ror.org/03h3mye18

Funder(s)

Funder type
Government

Funder Name
Federal state of Lower Saxony (Germany) - The European Regional Development Fund, within the framework of the Innovation-Incubator at Leuphana University Lueneburg

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	15/06/2017		Yes	No