Trial Description

Title

Internet-based prevention of Major Depression

Trial Acronym

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URL of the trial

https://www.geton-training.de/DepressionPrevention.php

Brief Summary in Lay Language

The online-training GET.ON Mood is aimed to reach people with mild to moderate depressive complaints who are searching for help but whose complaints do not require psychotherapy, yet. Major Depression is a severe disorder and the number of people suffering from Major Depression will further increase in the near future. In addition to the pain and suffering of the individual, economic costs are tremendous. Prevention as a supplement to ordinary treatment has been assumed to play a crucial role in decreasing the enormous burden of this disease. Preventive face-to-face courses have already been found to be effective. The risk that people with mild to moderate depressive complaints develop a full-blown depression is reduced when they take part in such preventive courses. But people do not make use of these services. A lack of time and motivation, as well as reluctance of searching help due to a fear of stigmatization, are just some reasons why people do not participate in face-to-face courses. Internet-based trainings might help to overcome these barriers because people can stay anonymous and can access the trainings whenever they want to. Furthermore, these interventions require less therapeutic resources. Thus, health care costs might be reduced. The aim of this study is to examine whether the online-training GET.ON Mood is effective in reducing the number of people developing a full-blown depression among people who have mild to moderate depressive complaints. In addition, the online-based treatment might generally lighten depressive symptoms and anxious feelings and change quality of life for the better.

Brief Summary in Scientific Language

Major depressive disorder (MDD) is projected to be the leading cause of premature mortality and disability by 2030. MDD is associated with a considerable loss of quality of life, increased mortality rates, and enormous economic costs. Prevention is suggested as an adjunct to treatment that may contribute to reducing the enormous burden of MDD. Preventive f2f interventions are proven to be effective in reducing the incidence of MDD. Low participation rates and high costs of comprehensive implementation, however, require new approaches to depression prevention going beyond the limits of traditional f2f interventions. Online interventions may attract people not making use of traditional services as well as they may cut costs. However, while Internet-based interventions are effective in reducing depressive symptoms, less is known about their potential to prevent the onset of MDD. Therefore, the aim of this study is to evaluate the

**(cost-) effectiveness of a guided Internet-based intervention on the onset of MDD in participants with subthreshold depression.
We will conduct a randomised controlled trial (RCT) to compare the (cost-) effectiveness of the GET.ON Mood training with a psychoeducation-only control. Adults with subthreshold depression (N=406) will be recruited and randomised to one of the two conditions with follow-ups at post-treatment, 6, and 12 months. The primary outcome is time to onset of MDD assessed within a 12- months follow-up with the SCID/DSM-IV section for mood disorders. Clinicians conducting the SCIDs at 6- and 12-months follow-up are blinded to treatment condition. That means that they do not know whether a participant is in the intervention or control group. Secondary outcomes include depressive symptomatology, anxiety and quality of life. An economic evaluation using a societal perspective will be conducted to examine the intervention's cost-effectiveness.**

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

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Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00004709**
- Date of Registration in DRKS: **2013/02/19**
- 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.: **AZ-2012-35K , Ethik-Kommission des Fachbereichs Psychologie an der Philipps-Universität Marburg**

Secondary IDs

Health condition or Problem studied

- Free text: **Depression**
- ICD10: **F32 - Depressive episode**

Interventions/Observational Groups

- Arm 1: **interactive 6-weeks self-help training (GET.ON Mood) with 6 lessons that focus on psychoeducation, behavioural activation, and problem-solving.**

Additionally, 3 modules (better sleep, less worrying, relaxation) free to choose are offered. After completing each lesson participants receive an individualised feedback written by an online-trainer. Participants are also asked to keep a mood- and activity diary. Participants are not blinded to treatment condition meaning that they know whether they are in the intervention (GET.ON Mood) or control group (psychoeducation-only).

- Arm 2: **Psychoeducation-only control without guidance provided by an online-trainer.**

Characteristics

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

Primary Outcome

The primary outcome is time to onset of MDD within a 12 months follow-up with the SCID/DSM-IV section for mood disorders assessed at 6- and 12-months follow-up.

Secondary Outcome

-depressive symptomatology (CES-D): baseline, post (7 weeks), 6, and 12 months
-quality of life (EuroQol, SF-12): baseline, post, 6, and 12 months
-direct and indirect health care costs (German adaptation of the Trimbos/iMTA questionnaire for costs associated with psychiatric illness (TiC-P)): baseline, 6 and 12 month
- Symptoms of anxiety (HADS, anxiety subscale): baseline, post, 6, and 12 months
-problem-solving (social problem-solving inventory, short version): baseline, post, 6, and 12 months
- behavioural activation (behavioural activation depression scale, BADS): baseline, post, 6, and 12 months
- Worrying (Penn State-Worrying-Questionnaire, PSQW, short version): baseline, post, 6, and 12 months
- Insomnia Severity, Insomnia Severity Index (ISI): baseline, post, 6 and 12 month-follow-up
- Mastery (Pearlin & Schooler Mastery Scale): baseline, post, 6 and 12 months
- Treatment credibility/participants' expectancy (Treatment credibility/patient expectancy questionnaire, CEQ): baseline and post
- participants' satisfaction (participants' satisfaction questionnaire): post

- Attitudes towards psychological help: baseline, post, 6 – and 12 months
-side-effects of psychotherapy (INEP): post and 6 months

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- other **Leuphana Universität Lüneburg (Teilnehmer werden über die Forschungswebsite www.geton-training.de rekrutiert / participants are recruited via the research website www.geton-training.de), Lüneburg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/03/01**
- Target Sample Size: **406**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

-18 years of age
-depressive symptoms (CES-D equal or greater to 16)
- internet access
- valid email address

Exclusion criteria

-Acute major depressive episode, psychotic symptomatology, bipolar disorder
-Major depressive episode in the past six months
-Receiving treatment for any kind of mental health disease
-Being on a waiting list for any kind of mental health treatment
- Suicidal risk (BDI item 9 > 1)

Addresses

■ **Primary Sponsor**

Leuphana Universität Lüneburg
GET.ON Gesundheitstraining.Online / Innovations-Inkubator
Mr. David Ebert
Rotenbleicher Weg 67
21335 Lüneburg
Germany

Telephone: **041316777654**
Fax: **[---]***
E-mail: **ebert at inkubator.leuphana.de**
URL: **http://www.leuphana.de/inkubator/gesundheit/geton.html**

■ **Contact for Scientific Queries**

Leuphana Universität Lüneburg
GET.ON Gesundheitstraining.Online / Innovations-Inkubator
Ms. M.Phil Claudia Buntrock
Rotenbleicher Weg 67
21335 Lüneburg
Germany

Telephone: **041316777639**
Fax: **[---]***
E-mail: **buntrock at inkubator.leuphana.de**
URL: **[---]***

■ **Contact for Public Queries**

Leuphana Universität Lüneburg
GET.ON Gesundheitstraining.Online / Innovations-Inkubator
Ms. M.Phil Claudia Buntrock
Rotenbleicher Weg 67
21335 Lüneburg
Germany

Telephone: **041316777639**
Fax: **[---]***
E-mail: **buntrock at inkubator.leuphana.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.)**

Investitions-und Förderungsbank Niedersachsen (NBank)
Günther-Wagner-Allee 12-16
30177 Hannover

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Investitions-und Förderungsbank Niedersachsen (NBank)
Günther-Wagner-Allee 12-16
30177 Hannover
Germany

Telephone: **0511 300310**
Fax: **[---]***
E-mail: **info at nbank.de**
URL: **www.nbank.de**

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

European Union
1000 Brüssel
Belgium

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **http://www.europa.eu**

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2015/03/31**

Trial Publications, Results and other documents

- Paper **Study Protocol "Evaluating the efficacy and cost-effectiveness of web-based indicated prevention of major depression: design of a randomised controlled trial."**
- Paper **Buntrock et al (2016)_Effect of a Web-Based Guided Self-help Intervention for Prevention of Major Depression in Adults With Subthreshold Depression A Randomized Clinical Trial**
- Paper **Buntrock et al (2015)_Effectiveness of a Web-Based Cognitive Behavioural Intervention for Subthreshold Depression: Pragmatic Randomised Controlled Trial**
- Paper **Buntrock et al (2017)_Preventing Depression in Adults With Subthreshold Depression: Health-Economic Evaluation Alongside a Pragmatic Randomized Controlled Trial of a Web-Based Intervention**

** 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.*