### Trial Description

#### Title

Feasibility study of a smartphone-based online training to manage panic attacks and agoraphobia

#### Trial Acronym

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#### URL of the trial

http://www.geton-training.de/Panik.php

#### Brief Summary in Lay Language

The online panic training GET.ON Panik is for persons suffering from panic attacks and agoraphobia and who want to learn to deal with it more constructively. The main focus is on practical exercises to confront with anxiety. The purpose of these exercises is to expose oneself consciously to individual fear-evoking situations or to provoke physical symptoms similar to panic. In this way it is possible to gain new and helpful experiences with anxiety - namely that anxiety is extremely unpleasant but possible to endure or that fear is a temporary feeling that becomes more bearable with increasing practice and that feared consequences are often less severe than expected. As support for these exercises a mobile application (app) for the smart phone will be used which allows an everyday training. This app contains a diary in which single panic attacks are documented and the development of anxiety symptoms during the training is recorded. Furthermore every week participants receive a written feedback on completed exercises from their personal trainer via email. The aim of the study is both a review of the feasibility and acceptance of the smartphone app, which will be offered as a part of the online training GET.ON Panik, and a first evaluation of the effectiveness of the online training. GET.ON Panik should help affected people to reduce panic attacks and their fear of panic attacks in the long term and to increase the quality of life.

#### Brief Summary in Scientific Language

Panic disorder with and without agoraphobia is one of the most prevalent anxiety disorders worldwide (Jacobi et al., 2004). Current meta-analyses prove a good efficacy of internet-based interventions for panic disorders on average (Andrews et al., 2010; Cuijpers et al., 2009; Haug, Nordgreen, Ost, & Havik, 2012). In cognitive oriented trainings clients typically complete exercises at their computers at home. However, in trainings that aim more at the behavior and the experience during the exposure with fear, it is necessary to integrate exercises in everyday situations. In most cases this does not happen in front of the computer. Smartphones, as a time- and location-independent technology, represent a promising support during exposition exercises (Heron & Smyth, 2010). The main objective of this feasibility study is to evaluate the usability and acceptance of a newly developed mobile application for the smartphone as part of the online training GET.ON Panik. In addition, a first review of the efficiency of the online training takes place. After the changes that arise out of the results of the
feasibility study, a randomized controlled trial will be conducted. In the feasibility study 10 participants will be recruited from the general population. For a better description of the sample a SKID interview will be done. The measurement of the acceptance of the mobile application will be made with the help of a questionnaire that is developed according to the Technology-Acceptance-Model (Davis, Bagozzi, & Warshaw, 1989). This model is a in the literature generally accepted approach, explaining the users behavior utilizing the technology. Besides, a semi-structured interview regarding the acceptance and usability of the smartphone app will be conducted. The reduction of the panic and agoraphobia symptoms will be determined through the Panic and Agoraphobia Scale (P&A), the Body Sensations Questionnaires, Agoraphobic Cognitions Questionnaires and Mobility Inventory (AKV) and the Hamilton Anxiety Rating Scale (HAMA). Inclusion criteria for the participation is a minimum age of 18 years, mild to moderate panic symptoms with and without agoraphobia (P&A 9-28), internet access, availability of a smartphone (iPhone or Android-based device) and a signed informed consent via mail or email. Persons with an increased suicide risk will be excluded (Beck Depression Inventory item 7 suicidality > 1, SCID section A: affective disorder, question A9).

Organizational Data

- DRKS-ID: DRKS00004985
- Date of Registration in DRKS: 2013/05/22
- 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.: 2013-11k , Marburg- Ethikkommission des Fachbereichs Psychologie der Philipps Universität Marburg

Secondary IDs

- ICD10: F41.0 - Panic disorder [episodic paroxysmal anxiety]
- ICD10: F40.01 - [generalization F40.0: Agoraphobia]

Interventions/Observational Groups

- Arm 1: six-week online training with supporting emails (guided self-help). The total sample (N = 10) gets access to “GET.ON Panik” and the smartphone app “GET.ON PAPP”. Both are components of an online training to manage panic attacks and agoraphobia based on cognitive behavioral therapy. The training aims at reducing the severity of panic symptoms which are measured by the Panic and Agoraphobia Scale (P&A). A lesson consists of information,
The smartphone supports during homework regarding the diary and exposures tasks. The expected average processing time of a lesson is approximately 60 minutes. Within the feasibility study the acceptance and usability of the smartphone app will be reviewed.

**Characteristics**

- **Study Type**: Interventional
- **Study Type Non-Interventional**: [---]*
- **Allocation**: Single arm study
- **Blinding**: Open (masking not used)
- **Who is blinded**: [---]*
- **Control**: Uncontrolled/Single arm
- **Purpose**: Other
- **Assignment**: Single (group)
- **Phase**: N/A
- **Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels)**: N/A

**Primary Outcome**

Acceptance of the mobile application measured with a questionnaire developed according to the Technology-Acceptance-Model (Davis, Bagozzi, & Warshaw, 1989) after the training (8 weeks). At this stage a semi-structured interview regarding the acceptance of the mobile application will be conducted additionally.

**Secondary Outcome**

- **Panic and agoraphobia symptoms**:
  - measures with Panic and Agoraphobia Scale (P&A), pre and post (8 weeks)
  - measures with Questionnaire on Body-related Anxiety, Cognitions and Avoidance (AKV), pre and post (8 weeks)
  - measures with Hamilton Anxiety Scale (HAMA), pre and post (8 weeks);

- **Depressive symptoms**: measures with Center for Epidemiologic Studies Depression Scale (CES-D), pre and post (8 weeks);

- **Quality of life**:
  - measures with Short version of Health Survey (SF-12), pre and post (8 weeks)
  - measures with EuroQuol (EQ-5D), pre and post (8 weeks)

**Countries of recruitment**

- DE Germany

**Locations of Recruitment**
Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/05/07**
- Target Sample Size: **10**
- 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

- clinical relevant complaints about panic attacks and agoraphobia (Panic and Agoraphobia Scale 9-28), internet access, availability of a smartphone, valid email address

Exclusion criteria

- suicidality at baseline, measured with item 9 of the BDI II (value > 1) and question A9 of the SCID, section A: affective disorder
- current psychotherapeutic treatment or on the waiting list for such a treatment
- not willing to sign the consent form

Addresses

- **Primary Sponsor**
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Sources of Monetary or Material Support

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(German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)

European Union (finanzielle Förderung organisiert über NBank bzw. Niedersächsisches Ministerium für Wirtschaft, Arbeit und Verkehr Friedrichwall 1
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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.