Evaluation of a practice team-supported, self-managed in vivo exposure program for patients with panic disorder and agoraphobia in primary care

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Background
Panic disorder and agoraphobia are highly prevalent disorders which heavily affect patients’ quality of life and lead to considerable health economic costs (e.g., Wittchen et al. 2011). It has been shown that the treatment of chronic diseases can be optimized by methods derived from the Chronic Care Model (Bodenheimer et al. 2002). Clinical research demonstrated the effectiveness of anxiety treatment with guided self-help therapies (e.g., Cuijpers et al. 2010). International clinical guidelines recommend the ambulant treatment of anxiety disorders in primary care by means of well-proven behaviour therapy-oriented procedures (APA 2009, DGPPN 2000, NICE 2011). However, evidence-based treatment programs for application in small primary care practices are not available to date. The "Jena-Paradise"-study develops and evaluates a family practice team-supported, directed exposure training for the treatment of panic disorder and agoraphobia in primary care.

Hypothesis
A practice team-supported, self-directed exposure training for patients with panic disorder with or without agoraphobia (ICD-10: F41.0, F40.01) in primary care yields significantly greater reductions in clinical anxiety symptoms as well as lower health economic costs than “Usual Care” plus recommended standard after six months of treatment.

Methods
Design: prospective, controlled two-armed, multi-centered, cluster-randomised interventional trial

Study population: 444 adult patients of both sexes (observational units) from 74 German family practices (clusters)
- Inclusion criteria: Panic disorder with or without agoraphobia (ICD-10: F41.0 or F40.01); positive screening (PHQ, Brief OASIS); private telephone
- Exclusion criteria: acute suicidality; acute or chronic psychosis; dependence on psychoactive substance; severe physical illness; current psychotherapeutic treatment of anxiety

Outcome measures:
- primary: clinical severity of anxiety (Beck Anxiety Inventory, BAI)
- secondary: anxiety-related reduction of mobility (MI); anxiety-related cognitions (ACQ); anxiety sensitivity (AS-3); number and severity of panic attacks (PAS); depressiveness (PHQ-9); patient activation (PAM); health-related quality of life (EQ-5D); direct and indirect costs from a societal perspective and incremental cost-effectiveness ratio (ICER)

Measurement timepoints:
- T0 (baseline before treatment); T1 (6 months after baseline); T2 (12 months after baseline)

Interventions
1. All investigators (family practitioners) will be trained in symptomatology, diagnostics and evidence-based therapy of panic disorder and agoraphobia
2. Only in the intervention arm of the study practice teams (i.e. investigators and associated health care assistants) will additionally be trained in applying the practice team-supported, self-directed exposure training which has to be carried out in terms of a practice team-based Case Management and comprises the following treatment elements:
   - introducing and motivating patients to in vivo exposure through manualised behaviour therapy-oriented consultations with the family practitioner
   - monitoring of anxiety symptoms and treatment progress through protocol-based periodical telephone calls carried out by the health care assistant

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