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Effectiveness and cost-effectiveness of individually tailored Internet-delivered cognitive behavior therapy for anxiety disorders in a primary care population: A randomized controlled trial

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ABSTRACT

A significant proportion of the general population suffers from anxiety disorders, often with comorbid psychiatric conditions. Internet-delivered cognitive behavior therapy (ICBT) has been found to be a potent treatment for patients with specific psychiatric conditions. The aim of this trial was to investigate the effectiveness and cost-effectiveness of ICBT when tailoring the treatment to address comorbidities and preferences for primary-care patients with a principal anxiety disorder. One hundred participants were recruited through their primary-care contact and randomized to either treatment or an active control group. The treatment consisted of 7–10 weekly individually assigned modules guided by online therapists. At post-treatment, 46% of the treatment group had achieved clinically significant improvement on the primary outcome measure (CORE-OM) and between-group effect sizes ranged from $d = 0.20$ to 0.86, with a mean effect of $d = 0.59$. At one-year follow-up, within-group effect sizes varied between $d = 0.53$ to 1.00. Cost analysis showed significant reduction of total costs for the ICBT group, the results were maintained at one-year follow-up and the incremental cost-effectiveness ratio favored ICBT compared to control group. Individually tailored ICBT is an effective and cost-effective treatment for primary-care patients with anxiety disorders with or without comorbidities.

Trial Registration: Clinicaltrials.gov: NCT01390168.

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Background

In Europe, anxiety disorders have an estimated 12-month prevalence of nearly 14 percent (Alonso et al., 2004b; Wittchen et al., 2011). Comorbidity across different anxiety and mood disorders is high in the general population (Alonso et al., 2004a) and the occurrence of an additional Axis-I diagnosis is even higher in individuals seeking treatment for their anxiety in primary care centers for treatment of stress, anxiety and related disorders (Brown, Campbell, Lehman, Grisham, & Mancill, 2001). The most common comorbid disorder for individuals with one anxiety disorder is a mood disorder or another anxiety disorder. All of these conditions are associated with reduced quality of life (Mendlowicz & Stein, 2000; Olatunji, Cisler, & Tolin, 2007), an increased risk of developing somatic disorders (Denollet, Maas, Knottnerus, Keyzer, & Pop, 2009), and high societal costs (Smit, Cuijpers, et al., 2006).

Despite these high numbers of individuals suffering from anxiety disorders, only a small proportion receive adequate treatment (Weisberg, Dyck, Culpepper, & Keller, 2007; Wittchen & Jacobi, 2005). Primary care facilities often lack resources to meet the need for psychological treatments in general and evidence-based treatments in particular. One way of increasing access to evidence-based psychological treatments in primary care could be to use guided Internet-delivered cognitive behavior therapy (ICBT)

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(Andersson, 2009; Carlbring & Andersson, 2006). Guided ICBT has been shown to be effective for a variety of anxiety and mood disorders (Andrews, Cuijpers, Craske, McEvoy, & Titov, 2010; Spek et al., 2007), and has also been found to be cost-effective when compared to no treatment or to conventional cognitive behavior therapy (Hedman, Andersson, Ljótsson, Andersson, Rück, Mörtberg, et al., 2011; Hedman, Andersson, Ljótsson, Andersson, Rück, & Lindefors, 2011; Hedman, Ljótsson, & Lindefors, 2012). There is some evidence for the long-term effects of ICBT for anxiety disorders (Carlbring et al., 2011; Carlbring, Nordgren, Furmark, & Andersson, 2009; Hedman, Furmark, et al., 2011; Paxling et al., 2011), and the evidence base for the clinical effectiveness of ICBT is growing, showing promising results (Bell, Colhoun, Carter, & Frampton, 2012; Hedman, Ljótsson, et al., 2013; Hoifodt, Strom, Kolstrup, Eisemann, & Waterloo, 2011; Mewton, Wong, & Andrews, 2012; Roy-Byrne et al., 2010; Ruwaard, Lange, Schrieken, Dolan, & Emmelkamp, 2012). One potential problem when disseminating guided ICBT in primary care is that many randomized controlled trials (RCTs) on guided ICBT make use of strict single diagnosis protocols and suffer from high exclusion rates. One example is a study by Carlbring et al. (2005), where over 80% of the individuals applying for the study were excluded, the lion's share because panic disorder was not their primary problem. The impact of existing co-morbidity on these protocols is largely unknown. In the field of guided ICBT, there is some evidence that comorbidity is reduced following ICBT for social anxiety disorder (Titov, Gibson, Andrews, & McEvoy, 2009). Overall, however, it is reasonable to assume that patients with comorbidities present with more deficits in their functioning and that treatments that focus on only one aspect of the problem may run the risk of going against patient preferences, which potentially can affect outcome. In CBT, different approaches have been developed to deal with comorbidity and high exclusion rates. One such approach is the unified transdiagnostic treatment protocol (Barlow, Allen, & Choate, 2004), in which common shared characteristics across treatments for specific conditions are assumed to serve as active ingredients across disorders. But still there is not much evidence that a unified treatment approach is more effective than conventional CBT (Craske, 2012).

There have been some promising results from the ICBT format for the delivery of transdiagnostic treatment (Dear et al., 2011; Titov, Andrews, Johnston, Robinson, & Spence, 2010; Titov et al., 2011). Another way of dealing with comorbidities is by addressing them directly, using individually tailored treatments. When tailoring the treatment both the patient and the therapist are allowed to influence the protocol.

A similar tailored program used in this study has been shown to be effective previously in a heterogeneous self-recruited sample, both directly at post-treatment and at a long-term follow-up (Carlbring et al., 2011). In another study, the same protocol approach was tested for young adults and adults with panic symptoms (Silfvernagel et al., 2012). Moreover, tailored ICBT was found to be more effective for more severely depressed patients compared to moderately depressed patients in a controlled trial comparing standard ICBT versus tailored ICBT for depression (Johansson et al., 2012). All of these previous studies were efficacy trials and tailored ICBT has not been tested in any published effectiveness study. The current study, designed to be clinically representative (Shadish, Matt, Navarro, & Phillips, 2000), aims to investigate whether this approach could be beneficial for a sample recruited through their primary-care contact and to explore if it is a cost-effective alternative. We expected, on the basis of previous efficacy trials, that the treatment would be moderately effective, both at post-treatment and at a one-year follow-up. We also expected that the treatment would be cost-effective.

Method

Ethics statement

The study was approved by the regional Ethical Board and has been registered in clinicaltrials.gov (NCT01390168). Written informed consent was collected from all participants by surface post.

Study design

The present study was an effectiveness study examining the effects of ten weeks of ICBT with scheduled e-mail guidance compared against an active waiting list control group who had access to health care and can be viewed as equivalent to care-as-usual when comparing pre- to post-treatment and pre-to-one-year follow-up results. For the full study design, we refer to the published study protocol (Nordgren, Andersson, Kadowaki, & Carlbring, 2012). We made two changes to the protocol in the present study by not using ANCOVA for data analysis, but instead using a linear mixed model because of the large amount of missing data in the follow-up measurements (Gueorguieva & Krystal, 2004). Moreover, we managed to include only 100 participants, instead of the 128 outlined in the protocol. This change was made because of time limits of the project and funding. Inclusion took place in 18 different primary care settings, in ten different cities, between January 2010 and April 2011. A new power calculation based on 100 participants revealed a power of 84%, given an alpha-level of .05 and an effect size of $d = 0.6$.

A total of 100 patients were recruited through their primary care contact (e.g., physician) and were randomly assigned by an online true random-number service independent of the investigators and therapists to either immediate treatment or control. The control group received treatment after ten weeks, leaving no control group for the follow-up measurements.

Inclusion and exclusion criteria

To be included in the study, participants had to fulfill the DSM-IV (American Psychiatric Association, 2000) criteria for any anxiety disorder as a primary diagnosis. Hence, all participants had a clinically significant impairment because of at least one anxiety disorder with or without comorbid problems. Participants had to be at least 18 years old, have Internet access, not be participating in any ongoing psychological treatment, and if taking any medication for anxiety or depression, this had to be at an unchanged dosage for at least 12 weeks pre-treatment. Participants with a suicidal risk, defined as scoring >3 on item 9 of the Montgomery Åsberg Depression Rating Scale (MADRS-S; Svanborg & Åsberg, 1994), were further interviewed using the SAD PERSONS scale (Patterson, Dohn, Bird, & Patterson, 1983) during a telephone-administered diagnostic interview and were excluded if their risk of suicide was confirmed (they then were referred back to their original primary care setting). Scoring above 30 on the MADRS-S or below 9 on the Beck Anxiety Inventory (BAI; Beck, Epstein, Brown, & Steer, 1988) also served as reasons for exclusion.

Recruitment and participants

Participants were recruited from a clinical population, typically by their general practitioner or nurse, when seeking help at their primary care setting. Prescribing clinicians were informed about the intervention and the inclusion criteria in order to decide for whom this might be adequate, regardless if the patient presented themselves with anxiety as their primary complaint. Based on the

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