



Cost-effectiveness and long-term follow-up of three forms of minimal-contact cognitive behaviour therapy for severe health anxiety: Results from a randomised controlled trial



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ABSTRACT

Strategies to increase the availability of cognitive behaviour therapy (CBT) for severe health anxiety (SHA) are needed, and this study investigated the cost-effectiveness and long-term efficacy of three forms of minimal-contact CBT for SHA. We hypothesised that therapist-guided internet CBT (G-ICBT), unguided internet CBT (U-ICBT), and cognitive behavioural bibliotherapy (BIB-CBT) would all be more cost-effective than a waiting-list condition (WLC), as assessed over the main phase of the trial. We also hypothesised that improvements would remain stable up to one-year follow-up. Adults ($N = 132$) with principal SHA were randomised to 12 weeks of G-ICBT, U-ICBT, BIB-CBT, or WLC. The primary measure of cost-effectiveness was the incremental cost-effectiveness ratio, or the between-group difference in per capita costs divided by the between-group difference in proportion of participants in remission. The Health anxiety inventory (HAI) was the primary efficacy outcome. G-ICBT, U-ICBT, and BIB-CBT were more cost-effective than the WLC. Over the follow-up period, the G-ICBT and BIB-CBT groups made further improvements in health anxiety, whereas the U-ICBT group did not change. As expected, all three treatments were cost-effective with persistent long-term effects. CBT without therapist support appears to be a valuable alternative to G-ICBT for scaling up treatment for SHA.

Severe health anxiety (SHA) is a prevalent psychiatric disorder (Sunderland, Newby, & Andrews, 2013; Tyrer et al., 2011) with a chronic course in about 50% of cases (olde Hartman et al., 2009). With SHA follows significant functional impairment, heightened health care consumption, and a marked increase in sick leave (Barsky, Ettner, Horsky, & Bates, 2001; Mykletun et al., 2009; Sunderland et al., 2013). This makes the dissemination of cost-effective treatments for SHA a pressing matter, both from the perspective of the individual and that of society at large.

The most researched and well-established psychological treatment for SHA cognitive behaviour therapy (CBT) (K. Cooper, Gregory, Walker, Lambe, & Salkovskis, 2017), but the availability of CBT is poor. In order to facilitate large-scale treatment dissemination there is growing interest in minimal-contact formats; protocols with little or no therapist involvement (e.g., Holmes et al., 2018; Tyrer, Eilenberg, Fink, Hedman, & Tyrer, 2016). One such format is therapist-guided internet

CBT (G-ICBT), which may be likened to an online self-help book with text-based therapist support (Hedman, Ljótsson, & Lindefors, 2012). Another such format is unguided internet CBT (U-ICBT) where the treatment is conveyed via the internet, but without therapist support. Third, there is also cognitive behavioural bibliotherapy (BIB-CBT), where the treatment is delivered in book form.

A strength of all three minimal-contact formats is that, compared with conventional CBT, they make it easier to reach patients who have inflexible schedules or live far from health care clinics. Because G-ICBT requires merely one fourth of the therapist time of conventional CBT (e.g., Hedman et al., 2011), and U-ICBT and BIB-CBT may be delivered without a therapist altogether, another strength of minimal-contact CBT is high probability of cost-effectiveness, i.e., large effects at low costs, which is an important indicator of the value and clinical utility of psychological treatments (Drummond, 2015b). A possible advantage of the BIB-CBT format over G-ICBT and U-ICBT is that BIB-CBT does not

Abbreviations: BIB-CBT, cognitive behavioural bibliotherapy; EQ-5D, EuroQol 5D; G-ICBT, therapist-guided internet cognitive behaviour therapy; HAI, 64-item Health anxiety inventory; ICER, incremental cost-effectiveness ratio; QALYs, quality-adjusted life years; SHA, severe health anxiety; TIC-P, Trimbos and Institute of medical technology assessment cost questionnaire on costs associated with psychiatric illness; U-ICBT, unguided internet cognitive behaviour therapy; WLC, waiting-list control condition

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require the setup and maintenance of an online platform. On the other hand, an advantage of G-ICBT and U-ICBT over BIB-CBT is that in many cases it may be easier to track patient adherence and administer symptom measures via the web-based platform once it has been properly set up.

The effects of G-ICBT have been studied in more than 100 randomised controlled trials (Hedman et al., 2012), of which at least 38 for anxiety disorders (Olthuis, Watt, Bailey, Hayden, & Stewart, 2016), and G-ICBT is probably as efficacious as face-to-face CBT for several mental health problems (Carlbring, Andersson, Cuijpers, Riper, & Hedman-Lagerlöf, 2018). In the treatment of anxiety disorders, the typical finding is that therapist-guided treatments, such as G-ICBT, have larger effects than pure self-help treatments such as U-ICBT and BIB-CBT which nevertheless appear efficacious in their own right (Baumeister, Reichler, Munzinger, & Lin, 2014; Haug, Nordgreen, Öst, & Havik, 2012). Prior to the present trial, two studies had shown promising waiting-list controlled effects of BIB-CBT for SHA, but both studies suffered from methodological shortcomings. One employed an unconventional operationalisation of SHA and reported large baseline group differences (F. A. Jones, 2002), and the other study did not employ randomisation (Buwalda & Bouman, 2009).

Our research group has demonstrated that G-ICBT is efficacious for SHA (Hedman, Axelsson, Andersson, Lekander, & Ljótsson, 2016; Hedman et al., 2011, 2014), which has also been corroborated by Newby et al. (2018). G-ICBT for SHA is a cost-effective treatment, both compared with an attention control and an active control condition (Hedman, Andersson, et al., 2013; Hedman, Andersson, Ljótsson, Axelsson, & Lekander, 2016). We recently corroborated the efficacy of G-ICBT for SHA, and also investigated if U-ICBT and BIB-CBT are feasible treatments for SHA (Hedman, Axelsson, et al., 2016). Both G-ICBT, U-ICBT, and BIB-CBT were superior to a waiting list condition, with similar effect sizes, and there were no significant differences between the three treatment formats. Importantly, this indicates that the contribution of therapist support to the overall effect of G-ICBT for SHA is likely to be small, and that the treatment may be readily administered in book form instead of via an online treatment platform. There is, however, also a need to evaluate the cost-effectiveness and long-term effects of U-ICBT or BIB-CBT for SHA.

In the present study, we aimed to evaluate the cost-effectiveness and long-term efficacy of G-ICBT, U-ICBT, and BIB-CBT for SHA. We first hypothesised that, from a societal perspective, all these forms of minimal-contact CBT would be more cost-effective than a waiting-list condition, as assessed over the twelve-week treatment period. Second, we hypothesised that G-ICBT, U-ICBT, and BIB-CBT would show sustained effects on health anxiety from treatment termination up until a one-year follow-up assessment. Last, as a secondary analysis, we also compared the cost-effectiveness and long-term symptom course of the three treatments.

1. Methods

1.1. Design and setting

This was a cost-effectiveness and longitudinal efficacy study based on a randomised waitlist-controlled superiority trial ($N = 132$) of three forms of minimal-contact CBT for severe health anxiety (Hedman, Axelsson, et al., 2016). After the baseline assessment, based on a true random number service (www.random.org), participants included in the trial were randomised by EAx in a 1:1:1:1 ratio without matching, to either therapist-guided internet CBT (G-ICBT), unguided internet CBT (U-ICBT), unguided cognitive behavioural bibliotherapy (BIB-CBT), or a waiting-list condition (WLC). The trial was powered at 85% for a simple mean difference significance test ($\alpha = 0.05$) to find large waiting-list controlled effects (equivalent to Cohen's $d = 0.8$) on complete-case data, assuming 10% data loss. The trial was based at Karolinska Institutet in Stockholm, approved by the regional ethics review

board (2013/375-31/5), and pre-registered at ClinicalTrials.gov (NCT01966705). Participants provided informed consent, and data was collected between 4 December 2013 and 1 February 2016.

1.2. Recruitment and participants

This trial employed online self-referral and was advertised in a nationwide newspaper under the heading “Do you worry a lot about your health?”. Both the advertisements and the study website clearly stated that the trial was intended for individuals with “a persistent fear of being ill or acquiring a disease”. Eligibility criteria were assessed by a psychologist through a structured telephone interview based on the Mini international neuropsychiatric interview (Sheehan et al., 1998) and Health preoccupation diagnostic interview (Axelsson, Andersson, Ljótsson, Wallhed Finn, & Hedman, 2016). The target population was Swedish adults with SHA as their primary psychiatric condition. Key eligibility criteria were: (1) a principal diagnosis of DSM-5 somatic symptom disorder or illness anxiety disorder, (2) not severe depression (DSM operationalisation) or suicidal ideation (unpublished brief structured interview), (3) no other on-going psychological treatment for SHA, and (4) either no or stable (\geq two months) antidepressant medication. Participant flow is presented in Fig. 1, and sample characteristics in Table 1. According to participant self-reports, 50/132 (38%) first heard about the trial via the internet, 15/132 (11%) were referred via primary care, 10/132 (8%) via the Swedish national service for medical counselling, 6 (5%) via psychiatric clinics, 50/132 (38%) were informed about the study through other sources, and 1/132 (1%) was missing. On the whole, the sample was very similar to those of our previous trials, where SHA was operationalised as DSM-IV hypochondriasis (Table A.6-A.12; Hedman et al., 2011; Hedman et al., 2014). For more details, see Hedman, Axelsson, et al. (2016).

1.3. Treatments

All three treatments (G-ICBT, U-ICBT, and BIB-CBT) were twelve weeks long and based on the same self-help text with bundled exercises from a validated G-ICBT protocol (Hedman et al., 2011, 2014). In the internet treatments (G-ICBT and U-ICBT), the treatment content was accessed through a password-protected and encrypted website (Appendix B). Participants randomised to G-ICBT communicated with their therapist via an integrated email-like system ($M = 5.3$ min/week; $SD = 3.0$), whereas the U-ICBT group did not have any therapist support. Participants randomised to BIB-CBT had access to the treatment in the form of a booklet with bundled paper worksheets, and also had no therapist support. A more comprehensive description of the treatments is provided in Appendix A.

1.4. Assessment of clinical outcomes

Primary efficacy outcome was health anxiety, as measured with the 64-item Health anxiety inventory (HAI), here scored 0–192; arguably the gold standard dimensional measure of health anxiety, with excellent psychometric properties (Hedman, Ljótsson, et al., 2015; Salkovskis, Rimes, Warwick, & Clark, 2002). Health-related quality of life was measured with the EuroQol 5D (EQ-5D; EuroQol Group, 1990). Additional secondary outcomes were the 18-item short Health anxiety inventory (SHAI-18; Alberts, Hadjistavropoulos, Jones, & Sharpe, 2013), the Illness attitude scales (Hiller, Rief, & Fichter, 2002), the 14-item Whiteley index with yes/no items (Pilowsky, 1967), the Beck anxiety inventory (Beck, Epstein, Brown, & Steer, 1988), the Anxiety sensitivity index (Reiss, Peterson, Gursky, & McNally, 1986), the Montgomery-Åsberg depression rating scale – self-rated (Svanborg & Åsberg, 1994), the Insomnia severity index (Morin, Belleville, Belanger, & Ivers, 2011), and the Sheehan disability scale (Leon, Olfson, Portera, Farber, & Sheehan, 1997). Treatment credibility was also assessed based on the C-scale (Borkovec & Nau, 1972).

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