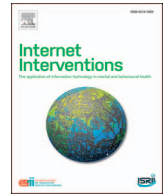




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# Implementation of internet-delivered CBT for children with anxiety disorders in a rural area: A feasibility trial

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## ABSTRACT

Child anxiety disorders are highly prevalent and cause significant impairment. Cognitive behavioral therapy (CBT) is recommended for child anxiety disorders, but access to CBT is limited, particularly in rural areas. Internet-delivered CBT (ICBT) can help increase the availability of evidence-based interventions and evidence is beginning to accumulate to indicate that ICBT is efficacious for children with anxiety disorders. However, whether the results of controlled trials are transferrable to real-world clinical settings is unclear. The objective of this study was to evaluate whether therapist-guided ICBT is feasible and potentially effective when implemented in an outpatient clinic in rural Sweden. Children ( $N = 19$ ) aged 8–12 with anxiety disorders underwent a 12-week ICBT program called BiP Anxiety. Feasibility measures included treatment satisfaction, compliance and feedback from clinicians. Clinical outcome measures were clinician-, parent- and child ratings of anxiety symptoms and functional impairment. Overall, participants and clinicians were satisfied with the treatment content and format. There were statistically significant changes from pre- to post-treatment on the primary outcome measure ( $t = -4.371$ ,  $p < 0.001$ ), as well as on all secondary outcome measures. Therapeutic gains were maintained for up to three months from the post-treatment assessment. At follow-up, 68% were no longer in need of treatment and could be discharged from the clinic. The study suggests the feasibility of implementing ICBT in regular health care. Implementation of ICBT could dramatically increase access to evidence based treatment for children with anxiety disorders who live far away from specialist clinics.

## 1. Background

Anxiety disorders are the most common mental health problems among children (Thapar et al., 2015) and, if not treated, can lead to increased risk of depression, substance abuse and impairment in social and emotional functioning later in life (Kendall et al., 2004). Intervention at an early stage is therefore important.

Cognitive behavior therapy (CBT) is known to be effective for children with anxiety disorders and is recommended as the first-line treatment (NICE, 2014). Unfortunately, children seldom get access to evidence based treatments (Shafran et al., 2009) and one possible reason for this is the shortage of CBT trained professionals (Comer and Barlow, 2014). This is particularly problematic for large countries with low population density and vast rural areas, such as Sweden, where travel distance to the nearest treatment facility is one of several barriers to seeking help (Swedish National Board of Health and Welfare, 2016).

Internet-delivered CBT (ICBT) is one possible way of increasing the availability of evidence-based treatments both by reducing waiting time and decreasing the dependency on geographical proximity. ICBT is an effective treatment for adults with anxiety disorders and has been shown to be a potentially cost-effective alternative to traditional face-to-face CBT (Hedman et al., 2012). Research specifically on ICBT for children has increased in recent years and there are now several meta-analyses showing that ICBT is also an effective treatment for young people (Podina et al., 2016, Vigerland et al., 2016a, Pennant et al., 2015). ICBT for children with anxiety has been shown to reduce symptoms as well as increase functioning (Donovan and March 2014, March et al., 2009, Vigerland et al., 2016b, Vigerland et al., 2013) and with this mounting evidence of efficacy, steps should be taken toward implementation in routine health care.

However, before ICBT can be implemented within regular health care, it is important to establish the feasibility and efficacy of ICBT

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outside the confines of tightly controlled clinical trials. It has been suggested that the effects of clinical trials conducted in research settings may not be generalizable to real-life clinical settings. Weisz et al. (2015) have argued that clinical research usually is conducted in controlled settings where scientific precision (e.g. reliability and validity) is prioritized. For example, children in regular health care might be less motivated to participate in treatment and families might be more likely to drop out or not attend appointments. Further, clinicians in regular care may have a heavy workload and thus have less time to follow therapist manuals (i.e., therapist drift). Weisz et al. (2015) also propose that clinicians in regular health care could be less devoted to their organization and workplace compared to researchers and that clinical work at a clinic is constricted more often than in research by regulations and rules.

Research on implementation of ICBT for children with anxiety has been extremely scarce. Two recently conducted trials (Storch et al., 2015, Stasiak et al., 2016) have investigated the effects of computerized CBT for children with anxiety in clinical settings. Storch et al. (2015) evaluated a therapist-supported computerized intervention, where 61% of the children were in remission at post-treatment. However, the patients in this trial had to attend the clinic for each session where the first half of treatment was computerized with limited therapist-support and the second half of treatment was more similar to traditional face-to-face therapy. Stasiak et al. (2016) evaluated a computerized program for children with anxiety that had recently experienced an earthquake, where 55% were in remission 6-months after ended treatment. In this trial, patients were primarily recruited via primary care and the majority had no clinical anxiety prior to the earthquake. However, there remains a need to investigate the feasibility of a geographically independent intervention with limited therapist-support when implemented in an outpatient clinic with clinically referred patients treated by the clinicians working at the clinic.

An opportunity to cooperate with a regular child- and adolescent mental health care service (CAMHS) in rural Sweden arose for our research group, and a small and pragmatic feasibility study, with limited resources, was therefore planned to evaluate the preliminary feasibility of implementing an ICBT program called BiP Anxiety, previously evaluated in a pilot and a randomized control trial in research setting (Vigerland et al., 2016b, Vigerland et al., 2013).

Hence, the aim of this study was to evaluate the feasibility of BiP Anxiety for children with anxiety disorders in a CAMHS in rural Sweden. Specifically, to measure feasibility the following research questions were formulated: 1) Is ICBT effective in reducing anxiety and functional impairment? 2) Do families accept and complete treatment? 3) Are the children and their parents satisfied with the treatment? 4) Do the clinicians find ICBT acceptable?

## 2. Method

### 2.1. Participants

Children ( $N = 19$ ) were consecutively recruited through an outpatient CAMHS clinic in a rural county in Sweden, Region Jämtland Härjedalen. This CAMHS clinic serves an area of approximately 50,000 km<sup>2</sup> (approximately the size of Denmark) and consists of an outpatient clinic and an inpatient clinic. It is commissioned to offer both primary and secondary mental health services to youth.

Study participants were recruited from October 2014–March 2015. Although all clinicians at the CAMHS were informed about the study, patients were not systematically informed about the study. Participants were recruited mainly through the clinicians working in the trial, although colleagues could refer on-going cases to the ICBT team.

The inclusion- and exclusion criteria were selected out of ethical consideration for the patients, that is minimizing the risk of including severely ill patients to a treatment that has not yet been tested in this particular setting. Inclusion criteria were a) a principal diagnosis of

separation anxiety disorder, generalized anxiety disorder or specific phobia, b) 8–12 years of age, c) stable psychotropic medication three months prior to inclusion, d) basic proficiency in Swedish e) access to a computer and internet connection, and f) at least one parent that could participate in the treatment. Exclusion criteria were a) a neuropsychiatric disorder (autism spectrum disorder or attention-deficit/hyperactivity disorder) b) a principal diagnosis other than the anxiety disorders treated in this study, c) severe depressive symptoms/suicidality, d) an on-going treatment for anxiety e) on-going substance abuse, child maltreatment or any other abuse within the family, or f) the parent participating in treatment having a severe mental illness of their own.

The study was approved by the Ethical review board in Stockholm (reference number 2014/1225–31/4) and caregivers had to provide written consent allowing their child to participate in the study. ClinicalTrials.gov identifier: NCT02306356.

### 2.2. Measures

#### 2.2.1. Adherence, treatment satisfaction and clinician acceptability

Treatment completion rates (i.e., drop-out) and number of completed modules during treatment time were measured as a means to assess adherence. To measure child- and parent treatment satisfaction the *Client Satisfaction Scale* (CSS) was used (Ollendick et al., 2009). It consists of ten items measured on a 5-point scale. Questions include how the child's fear and avoidance have changed during the treatment, and whether or not the participant would recommend the treatment to others. Also, feedback was obtained from the clinicians working as ICBT-therapists to assess the acceptability of ICBT. The study-coordinator conducted a semi-structured group interview (i.e. focus-group) where clinicians were asked about their experiences and thought about working with ICBT. The group-interview was unstructured and notes were taken in forms of bullet-points (i.e., advantages and concerns about ICBT) that the clinicians helped to formulate. The information gained from the interview was then summarized by the study-coordinator and presented in this paper.

#### 2.2.2. Diagnostic assessment

Psychiatric diagnoses were assessed with support from *Mini International Neuropsychiatric Interview* for Children and Adolescents (Sheehan et al., 1998). Inter-rater and test-retest reliability coefficients have been shown to be acceptable to excellent. MINI-KID has been validated against the widely used K-SADS-PL where excellent concordance was found for anxiety and mood disorders, as well as for externalizing disorders, ADHD and eating disorders (Sheehan et al., 2010).

#### 2.2.3. Clinical outcome measures

The *Clinical Global Impression – Severity* (CGI-S; Guy, 1976) was used as primary outcome measure for clinically assessing symptom severity of the principal anxiety diagnosis. The CGI-S is a clinician rating made on a seven-point scale range from 1 = “Normal, not at all ill” to 7 = “Among the most extremely ill patients”. The scale has been validated for psychiatric disorders in general (Berk et al., 2008) and anxiety in particular (Zaider et al., 2003, Leon et al., 1993) suggesting it is sensitive for detecting change and is stable when measured at different time-points. Inter-rater reliability on the CGI-S was excellent (ICC = 0.86) and on the CGI-I it was good (ICC = 0.65) when comparing assessments made by the clinicians at the clinic with clinicians working in the research group.

*Clinical Global Impression - Improvement* (CGI-I; Guy, 1976) is part of the CGI-S scale evaluated by Guy et al., 1976 and is a clinician rating of symptom severity improvement when compared to pre-treatment severity. This measure is a seven-point scale that ranges from 1 = “Very much improved” to 7 = “Very much worse”.

*Children's Global Assessment Scale* (CGAS; Shaffer et al., 1983) is a

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