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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 12week 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 km² (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. focusgroup) 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

clinician assessment of global functioning, rated on a scale from 0 to 100, were higher scores indicate higher functioning. It has shown moderate to excellent inter-rater reliability, good stability over time and good concurrent as well as discriminant validity (Bird et al., 1987, Lundh et al., 2010).

Spence Children's Anxiety Scale – child and parent version (SCAS-C/P; Spence, 1998) is a child- and parent reported questionnaire of anxiety symptoms. The child version consists of 44 items (of which six are "filler items") and the parent version consists of 38 items. Both versions are on a four-point scale where a higher score indicates more anxiety symptoms. The internal reliability and consistency is high (Spence et al., 2003, Nauta et al., 2004).

Child Sheehan Disability Scale (CSDS; Whiteside, 2009) is a parentand child reported questionnaire for children with anxiety disorders. The questionnaire measures impairment in everyday functioning (in school, socially and at home/with family). The scale consists of three items on an eleven point scale that ranges from 0 = "not at all" to 10 = "very much".

Child Depression Inventory (CDI; Kovacs, 1985) is a self-measure of child depression symptoms. The short version of the CDI used in this study (Overholser et al., 1995) consists of 10 items graded from 0 (no symptoms) to 2 (severe symptoms). The questionnaire covers depressive symptoms such as self-blame, loss of appetite and insomnia. The CDI-S has shown high correlation to other measures of depression and should be considered a valid measure of depression symptoms (Ahlen and Ghaderi, 2016).

2.3. Procedure

Potentially eligible participants at the clinic were consecutively asked if they wanted to participate in the research project. Parents of children interested in participating in the study were briefly interviewed over the phone to assess eligibility based on relevant inclusionand exclusion criteria. Potential participants were interviewed using the MINI-KID at the clinic to confirm the principal diagnosis and establish psychiatric comorbidities. Clinician-reported socio-demographic and clinical data were collected through a case report form in connection to the initial face-to-face assessment. Included families were asked to login on the BiP platform and fill out a series of questionnaires including all measures at baseline as well as some additional socio-demographic and clinical data. At post treatment and at follow-up the child and parent were assessed using MINI-KID and were asked to fill out the questionnaires on the BiP platform.

Clinicians in this study were three CBT-trained psychologists working at the local CAMHS who were interested in participating in this project. The clinicians used ICBT during the trial as part of their regular work, which also included face-to-face CBT, neuropsychological assessments, non-manual-based individual and family treatments, meetings with schools and social services, as well administrative work. The clinicians conducted all clinical assessments, were responsible for delivering the ICBT and were also in charge of collecting data pre- and post-treatment as well as at follow-up. The clinicians received brief training (one day) in the ICBT treatment prior to the study and received weekly supervision by the study coordinator. To assure the reliability of the CGI-S and CGI-I assessments at pre, post and follow-up, an independent researcher blind to the original assessment conducted additional telephone interviews. The independent researcher telephoned the parent and conducted a semi-structured interview assessing the functional impairment (in school, at home, with friends and in extracurricular activities) and severity of the principal anxiety disorder, as well as secondary anxiety- or depression diagnoses, given at pre-treat-

2.4. Intervention

BiP Anxiety is an iterative development of a treatment program

previously evaluated in a pilot study and a randomized controlled trial (Vigerland et al., 2016b, Vigerland et al., 2013). Improvements were made based on clinical experience gained from previous trials, such as the creation of diagnosis-specific components and an increase of the amount of therapist-guided modules.

BiP Anxiety is entirely web-based and consists of 12 modules each for the child and parent. Participants are instructed to complete one module each week during the 12-week treatment period and both child and parent modules have to be completed before getting access to the next module. Families are encouraged to login at least twice a week to work with the treatment content and to read their clinicians' comments. Families are informed prior to treatment that participating in trial and working with the treatment can take 2–5 h a week including time for exposure training. Children and parents have separate logins and the parent is encouraged to complete his/her module first and then log in together with the child to complete the child module. This way, parents have the possibility to ask the clinician questions directly, without the child being present, before moving on to the child's module.

BiP Anxiety consists of texts, films and illustrations as well as different exercises for the parents to do on their own and together with the child. See Fig. 1 for a screenshots from the BiP platform. During the treatment, participants have regular (asynchronous) contact with a therapist through messages, comments on worksheets in the program and through phone calls when needed. The therapist logs on at least 3 times a week to check whether the family has been active, give comments on work sheets and reply to messages.

The treatment content is divided into three phases (Table 1) and is mainly exposure-based. Some treatment components are diagnosis-specific, depending on the participant's principal anxiety disorder, such as interoceptive exposure, social awareness training and worry exposure. In addition to the above-mentioned steps, the parent modules focus on family accommodation, parental coping strategies and how to coach the child through the treatment.

2.5. Data-analysis

Power calculations estimated that 20 participants were needed in order to detect a within-group effect size of Cohen's d=0.5 with 80% power. All statistics were calculated using SPSS version 23.

A piecewise linear mixed model (LMM; Gueorguieva and Krystal, 2004, Hesser, 2015) was used to detect statistical change from preto post-treatment and from post-treatment to follow-up. All available data (N=19) was used and no cases were excluded in the analysis. Chisquare test of model fit was conducted to evaluate and compare different linear mixed models. The model with the best log likelihood ratio for all outcome measures was a model with fixed- and random intercept and time with an unstructured covariance structure of the random effects. Normal probability plots, residual plots and Cook's distance was used to check assumptions.

Effect sizes (Cohen's d) were based on estimated difference between pre- to post-treatment and post-treatment to follow-up, together with the observed pooled standard deviation (Feingold, 2009). Effect sizes were categorized as small if d>0.2, medium if d>0.5 and large if d>0.8. Confidence intervals for the effect size were calculated with the formula $SE_d=\sqrt{[(1/N)+2(d^2/2\ N)(1-r)]}$ where d is the effect size derived from the LMM estimates.

Inter-rater reliability for the outcome measure CGI-S and CGI-I was calculated using the intra-class correlation coefficient (ICC) for comparing ratings made by clinicians at the local CAMHS and the independent blind researcher at pre- and post-treatment as well as follow-up. ICC was considered poor if < 0.40, fair if 0.40-0.59, good if 0.60-0.74, excellent if > 0.75 (Cicchetti, 1994). Independent t-tests were used to analyze missing data at post-treatment and follow-up.



Fig. 1. A screenshot from the BiP Anxiety programme, week 3/module 3, where short videos inform the child about important aspects of exposure training.

3. Results

3.1. Participants

Participants were N=19 children, aged 8–12 years, and their parents. Almost all participants were diagnosed with either separation anxiety (N=9) or generalized anxiety disorder (N=9). Socio-demographic and clinical data are presented in Table 2.

3.2. Participant retention and missing data

Two participants (11%) out of the total 19 dropped out of the ICBT-treatment. The reason for dropping out was that these families during treatment were judged to be in need of interventions other than CBT for anxiety, e.g., due to school problems.

The amount of missing data differed at different time-points (i.e., pre-post, follow-up) and was dependent on whether the measure was child-, parent- or clinician reported. Clinician reported measures, including the primary outcome measure CGI-S, had 11% missing at pre-and post-treatment, and 16% at follow-up. Parent reported measures

Table 2 Socio-demographic and clinical data.

	Total sample $(N = 19)$
Females, N (%)	12 (63)
Age children, M (SD)	10.5 (1.6)
Range	8–12
Age parents M (SD)	39.8 (5.5)
Range	30–49
Parent educational level, N (%)	
Only primary education	3 (15.8)
University studies	6 (31.6)
University degree	10 (52.6)
Child's principal diagnosis, N (%)	
Separation anxiety disorder	9 (47.4)
GAD	9 (47.4)
Specific phobia	1 (5.3)

Abbreviation. GAD = Generalized anxiety disorder.

had 53% missing at post-treatment and 37% at follow-up. Child-reported measures had 47% missing at both post-treatment and follow-up. Clinician reported data was missing due to information not being

Table 1
General content of BiP Anxiety. The treatment program consists of 12 weekly modules each for the child and parent.

Week/ module	Child	Parent							
	Phase 1: Psychoeducation, goa	ls and hierarchies							
1	Introduction to the program. Psychoeducation on emotions, fear and anxiety.	Introduction to the program. Psychoeducation on anxiety and CBT. Parental fears and accommodating behaviors.							
2	Psychoeducation on coping techniques (e.g., breathing and relaxation).	Psychoeducation on goals and exposure hierarchies.							
3	Psychoeducation on goals and exposure hierarchies.	Introducing reward systems and how to manage obstacles (e.g., motivation and practical issues). $\ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \ \$							
	Phase 2: Exposure to	raining							
4	Introduction and rationale to exposure training and the concept of habituation.	Introduction and rationale to exposure training and the concept of habituation.							
5–11	Follow-up on exposure training, modifying exposure hierarchies, repeating coping techniques and introducing problem-solving skills and cognitive techniques.	Follow-up on exposure training, modifying exposure hierarchies, repetition of parental behaviors and managing obstacles. Introducing problem-solving skills.							
	Phase 3: Maintenance and relapse prevention								
12	Summary and repetition of the treatment content, maintenance of improvements and relapse prevention.	Summary and repetition of treatment content, maintenance of improvement and relapse prevention.							

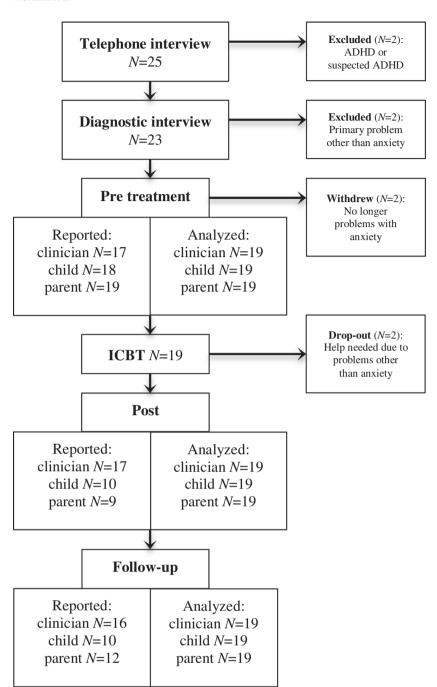


Fig. 2. Participant flow through the study, missingness at pre-treatment, post-treatment and follow-up as well as number of dropouts. *Abbreviation*. ADHD = Attention deficit hyperactivity disorder.

logged correctly. Child- and parent reported measures were missing mostly due to the child and/or parent forgetting or not wanting to login to the platform to answer the questionnaires (e.g., N=9 at post) and some data were missing due to study drop out (N=2). Missing data on child- and parent-reported measures at post-treatment and follow-up were significantly associated (p<0.05) with less improvement and lower treatment satisfaction post-treatment. Missing data on clinician-reported measures were statistically associated (p<0.05) with self-assessed higher anxiety symptoms and more functional impairment at pre-treatment. See Fig. 2 for participant flow during the trial and amount of missing data on reported measures.

3.3. Adherence and clinician support

Seventeen participants (89%) stayed in treatment, being more or less active during the treatment period (12 weeks). Information about

how many modules that were completed during the treatment was available for 15 participants.

On average, participants (both parent and child) completed six (SD=3) modules out of the total 12 modules. Ten participants (53%) reached at least module four and had thus planned their first exposure exercise. Although patients had been introduced to exposure, formulated goals and created hierarchies in module three, it is not until module four where they plan their first exposure exercise and are formally instructed to start conducting exposures. Data was only available for N=15 participants. No participant completed all 12 modules and the participant that progressed the furthest in the treatment program reached module ten. For a detailed visual overview of how many participants completed how many modules during treatment, see Fig. 3.

Therapist time in this study was on average 20 min a week per participant. This included time spent on both child and parent, answering messages and providing feedback on homework assignments.

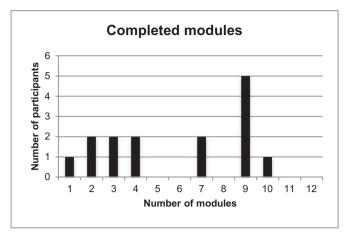


Fig. 3. A visual summary of how many participants completed how many modules during the 12-week treatment period. Available data were N=15.

3.4. Treatment satisfaction

Ten children and nine parents, out of 19 families participating, completed the treatment satisfaction scale, CSS-C/P, at post-treatment. Children and parents scored similarly on the CSS-C/P (children; $M=40.50,\ SD=4.81$, parents; $M=38.89,\ SD=5.88$; maximum score 50) and were considered to be generally satisfied with the treatment.

Families agreed, according to the CSS-C/P, that they would recommend the treatment to others (children; M=4.10, SD=1.20, parents; M=4.33, SD=0.71). They also agreed that the child's fear(s) had declined as a result of the treatment (children; M=4.80, SD=0.42, parents; M=4.56, SD=0.53) and that the child had less avoidant behaviors after completing treatment (children; M=4.10, SD=0.52, parents; M=4.44, SD=0.73). Two families did not think that the treatment was successful and would not recommend it to others.

When asked about what they learnt from the treatment (open ended question) some families reported "staying in the fearful situation even though it is scary" and "doing what is fearful, but in small steps". Families also described that learning more about anxiety and watching videos where other children described similar problems were helpful. When asked, some children described reward systems, psycho-educative videos and "forcing oneself to stay in scary situations" as components that helped them overcome their fears.

3.5. Feedback from the clinicians

All clinicians provided feedback on their experiences from working with ICBT. The clinicians were generally very satisfied with the ICBT and described both advantages and some concerns based on their experience. One reported advantage with ICBT was the reduced risk of therapist-drift (i.e., not following the treatment manual correctly), which made it easier for the clinicians to focus on exposure training. Clinicians also described that participants became self-sufficient and took responsibility for the treatment, as ICBT primarily was a self-help program. Furthermore, clinicians experienced the treatment as time saving compared to regular face-to-face CBT.

Data-collection and assessment prior to treatment, and to some extent also the treatment content, were some of the concerns described by the clinicians. The clinicians described data-collection as a challenge and they expressed the need for more support with this so that they could focus on assessment and treatment instead.

The clinicians would also have liked the pre-treatment assessments to be more comprehensive (for instance asking about motivation, and previous experience of CBT). Clinicians were concerned that the treatment was time consuming for the participants, in particular for the parents, and that not all families had understood this prior to starting the treatment.

Clinicians also reported being unsure how to handle inactive families and children not responding to treatment, e.g., where and when to terminate ICBT and offer something else instead. It was for example difficult for the clinicians to determine whether inactivity (i.e., not logging in working in the platform) meant that the child was not practising exposure tasks. Even though clinicians reported that ICBT did not work for all families, clinicians experienced that the treatment made it easier for them to subsequently assess what additional interventions were needed (e.g., whether or not more CBT was needed).

3.6. Clinical outcomes measures

CGI-S changed statistical significance significantly (t=-4.371, p<0.001) from pre- to post-treatment with a large effect size (Cohen's d=1.51). The change in CGI-S from post-treatment to follow-up was not significant (p>0.05) indicating that the improvement from pre-treatment was maintained to follow-up.

There were significant improvements (p < 0.05) on all child- and parent-reported measures from pre- to post-treatment with large effect sizes (Cohen's d > 0.8). Clinician-reported functional impairment also changed significantly (p < 0.05) from pre- to post-treatment with a large effect size (Cohen's d = -1.54).

Changes from post-treatment to follow-up were not significant on any secondary outcome measures (p>0.05), indicating that the changes from pre- to post-treatment were maintained up to three months after the end of treatment. See Table 3 for a detailed description of the results for all outcome measures.

3.7. Clinical improvement

At post-treatment, 63% (N=12) of all 19 participants had a symptom severity below "Moderately ill" (CGI-S < 4), and at follow-up the frequency had increased to 68% (N=13). Ten (53%) and eleven (58%) participants were assessed to be at least "Much improved" (CGI-I < 3) at post-treatment and follow-up, respectively.

Combining the CGI-I (improvement after completed treatment) and the CGI-S (symptom severity), nine participants (47%) were at least "Much improved" (CGI-I < 3) and had a symptom severity less than "Moderately ill" (CGI-S < 4) at post-treatment. At follow-up, ten participants (53%) fulfilled these criteria, indicating that at least approximately half of the participants benefited from the treatment.

At follow-up, 13 participants (68%) no longer needed further treatment for their principal anxiety disorder or any other disorder and were therefore discharged from the clinic. The remaining six participants (32%) were in need of further contact with the CAMHS unit.

4. Discussion

The main aim of this study was to examine the feasibility and potential efficacy of BiP Anxiety, a therapist-guided ICBT program for children with anxiety disorders, in an outpatient CAMHS clinic in a rural area. Although our research group has conducted several clinical trials on ICBT for children and adolescents with a range of psychiatric and functional gastrointestinal disorders (Vigerland et al., 2013, Lenhard et al., 2014, Bonnert et al., 2014, Vigerland et al., 2016b, Bonnert et al., 2016, Lenhard et al., 2017), this is the first trial conducted in a rural outpatient clinic where our research team was not directly involved in assessments, treatment or data-collection.

Similar to other studies evaluating internet-delivered CBT for children (e.g., Rooksby et al., 2015) both families and clinicians seemed to be generally satisfied with the treatment and the format. The feedback from the clinicians working with ICBT in this trial was generally positive and they mentioned decreased therapist drift and increased patient

Table 3

Primary- and secondary outcome measures: observed mean and standard deviation, estimated change and within-group effect sizes (Cohen's *d*) based the estimates derived from the linear mixed model.

Outcome (min-max)	Observed mean (standard deviation)		Pre-post		Post-FU		
	Pre	Post	FU	Estimated change	Cohen's d (95% CI)	Estimated change	Cohen's d (95% CI)
CGI-S	4.24	2.71	2.25	- 1.53***	1.52	- 0.33	0.25
(0-7)	(0.66)	(1.26)	(1.34)		(0.75, 2.28)		(-0.51, 1.02)
CGI-I		2.29	2.06				
(0-7)		(0.85)	(0.93)				
CGAS	61.25	72.94	75.67	11.60***	1.57	2.94	0.28
(0 - 100)	(5.00)	(9.20)	(11.75)		(0.79, 2.35)		(-0.50, 1.06)
SCAS-C	32.44	19.40	25.70	- 13.12***	1.22	3.52	0.34
(0-114)	(12.32)	(8.82)	(9.50)		(0.39, 2.06)		(-0.45, 1.22)
SCAS-P	33.84	23.11	21.50	- 12.20**	1. 05	0.56	0.05
(0-114)	(12.14)	(10.98)	(10.86)		(0.21, 1.89)		(-0.79, 0.89)
CSDS-C	12.28	6.00	7.79	- 5.74**	1.08	0.45	0.09
(0 - 30)	(5.79)	(4.81)	(5.53)		(0.26, 1.90)		(-0.74, 0.91)
CSDS-P	28.42	16.50	13.67	- 14.68***	1.33	-0.30	0.02
(0-30)	(9.62)	(12.50)	(11.81)		(0.46, 2.20)		(-0.84, 0.89)
CDI	7.33	3.30	4.60	- 3.04*	0.80	0.11	0.03
(0 - 20)	(4.04)	(3.53)	(4.58)		(0.00, 1.60)		(-0.77, 0.83)

Abbreviation. CGI-S = Clinical Global Impression – Severity; CGI-I = Clinical Global Impression – Improvement; CGAS = Children's Global Assessment Scale; SCAS-C/P = Spence Children's Anxiety Scale – child and parent version; CDI = Child Depression Inventory. Note. Higher score on CGAS (Children's Global Assessment Scale) indicate higher functioning. $^*p < 0.05$, $^*p < 0.01$, $^*p < 0.001$.

self-efficacy as advantages. Only two participants (11%) dropped out and a majority of those families reporting satisfaction questionnaires agreed that the treatment helped reduce anxiety symptoms and that they would recommend it to others. Half of participants (53%) completed the first four modules meaning they had been introduced to exposure and would have been able to work with exposure training with the support of a therapist the remaining weeks. While not all families were satisfied or sufficiently helped by the treatment, clinicians in the study described that the ICBT treatment made it easier to assess what additional intervention was needed to help the child after treatment, indicating that ICBT might be a good first step for children with anxiety disorders. However, it will be important to further investigate how to determine if ICBT is insufficient and when it should be terminated, as well as what additional support could be given during ICBT to make it more helpful.

The sample in this trial had somewhat higher CGI-S ratings than the trial conducted by Storch et al. (2015) and similar ratings of self- and parent rated symptoms of anxiety as seen in both the trial by Vigerland et al. (2016b) and Stasiak et al. (2016). However, functional impairment measured with CGAS was higher in this trial, indicating that the sample in this trial was less functionally impaired. This could be due to that the clinicians, working with ICBT for the first time, included less severe patients. Furthermore, this particular CAMHS is responsible for primary, as well as secondary, mental health car in the region, which might have resulted in less severe patients being offered ICBT.

Approximately half of the children in this trial benefited from the treatment. 47% post-treatment, and 53% at three months follow-up were clinically assessed as responders (at least "Much improved" and no more than "Mildly ill" on the CGI-I/S). There were significant changes from pre- to post-treatment on all clinician- and self-reported measures of anxiety symptoms and functional impairment with large effect sizes indicating that ICBT is potentially effective for at least a subgroup of children. In addition, three months after treatment, a majority of children (68%) were no longer in need of psychiatric treatment for their principal disorder or any other diagnosis and could be discharged from the clinic. These results are particularly interesting since therapist time in this trial (on average 20 min per patient/week) was approximately one third of what can be expected in regular face-to-face CBT.

The clinical outcomes of this trial are similar to the results seen in our previous studies conducted in a university setting where half of the participants were in remission at follow-up (Vigerland et al., 2016b,

Vigerland et al., 2013). These results are also comparable with two other randomized controlled trials, investigating ICBT in research setting (March et al., 2009, Spence et al., 2011). Responders in this trial are in comparison with those in the open trial by Stasiak et al. (2016) but somewhat lower than those seen in the randomized controlled trial of Storch et al. (2015). A Cochrane review (James, 2013) evaluating face-to-face CBT showed response-rates for remission were 60% for CBT compared to 18% for controls implying that the change seen in this trial from pre- to post-treatment could be more than just spontaneous recovery. These results, although not as favourable as seen in some other studies in clinical setting and those seen in face-to-face CBT, are still of clinical interest since a 50% clinically improvement has the potential to relieve a heavily loaded CAMHS. Also, ICBT has the advantage of being geographically independent, which is a necessity in rural areas.

4.1. Limitations

Missing data on child- and parent reported measures are a limitation in this trial. There were missing data at all assessment-points and on a majority of the measures, limiting the generalizability and reliability of the results. Missing data were associated with higher anxiety scores at pre-treatment, and with less improvement and satisfaction at posttreatment, which could increase the risk for inflated effects. The amount of missing data could also be seen as a specific challenge for research in clinical settings where motivation to, and time for, datacollection is probably lower than in research settings. A large proportion of the missing data in this study were likely due to the clinicians' heavy workload and prioritizing of clinical work over research related data-collection. Although the ICBT treatment was considered to be time-effective, data-collection was considered difficult since clinicians did not systematically measure outcome in their routine work. If possible in future trials, the amount of outcome measures should be kept to a minimum, and clinicians should be assisted in collecting the data.

Another issue in this trial is that a proportion of the participants did not reach module four, where exposure training formally started, suggesting that ICBT might not be a feasible and acceptable treatment for everyone. On the other hand, 63% completed module three, which might have been sufficient information for some families. Furthermore, adherence was measured as number of competed modules in this study, which might not reflect the amount of exercises families have actually done. It would also be of clinical relevance to understand which

patients adhere to ICBT treatment and how adherence and engagement in treatment could be enhanced, such as understanding which patients need more support, what the support should include and when the support should be given.

Clinician feedback was not measured in a structured way in this trial, it was merely discussed in together and summarized afterwards. Their positive views could have been affected by the fact that they were all CBT-trained clinicians working in a rural area where access to evidence-based treatment is scarce. These are variables that have been found to be associated with positive attitudes toward ICBT (Vigerland et al., 2014), increasing the risk for positive bias. The clinicians had some previous experience of ICBT, which might also have affected their attitudes.

The small number of participants included in the trial (N=19), as well as the selective recruitment, limits the generalizability of the results. The methods chosen was due to the limited resources available at the time the trial was conducted and the purpose was to make a small and pragmatic study to evaluate the preliminary feasibility when disseminating ICBT in a clinical care setting.

5. Conclusions

This study has provided valuable information about the practical issues of implementing a 12-week, therapist-guided ICBT treatment for children with anxiety disorders in an outpatient CAMHS clinic in a rural area. Half of participants adhered to treatment working with exposure training and participants were overall content with the treatment format. Also, the clinicians were overall satisfied and provided positive feedback after the trial was completed. Furthermore, there were significant changes from pre- to post-treatment on all clinician-, child- and parent reported measures of anxiety and functional impairment with large within group effect sizes.

Given the above-mentioned limitations, more research is needed before any conclusions can be drawn about the effectiveness of ICBT in regular health care. However, the results from this trial are in accordance with previous randomized controlled trials evaluating ICBT with limited therapist-support, which suggests that ICBT is potentially transferrable from a research setting to regular outpatient clinics.

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Conflict of interest

Apart from being authors of the current paper, Maral Jolstedt, Sarah Vigerland and Eva Serlachius are also authors of the BiP-anxiety intervention, which might be a potential conflict of interest.

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