BMJ Open

Therapist-guided Internet-delivered cognitive behavioural therapy supplemented with group-exposure sessions for adolescents with social anxiety disorder: a feasibility trial

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-018345
Article Type:	Research
Date Submitted by the Author:	21-Jun-2017
Complete List of Authors:	Nordh, Martina; Karolinska Institutet Department of Clinical Neuroscience, Center for Psychiatry Research; Stockholms Lans Landsting, Stockholm health care services Vigerland, Sarah; Karolinska Institutet Department of Clinical Neuroscience, Center for Psychiatry Research; Stockholms Lans Landsting, Stockholm health care services Öst, Lars-Göran; Stockholms Universitet, Department of psychology; Karolinska Institutet Department of Clinical Neuroscience Ljótsson, Brjánn; Karolinska Institutet Department of Clinical Neuroscience, Center for Psychiatry Research; Stockholms Lans Landsting, Stockholm health care services Mataix-Cols, David; Karolinska Institutet Department of Clinical Neuroscience, Center for Psychiatry Research; Stockholms Lans Landsting, Stockholm health care services Serlachius , Eva ; Karolinska Institutet Department of Clinical Neuroscience, Center for Psychiatry Research; Stockholms Lans Landsting, Stockholm health care services Högström, Jens; Karolinska Institutet Department of Clinical Neuroscience, Center for Psychiatry Research; Stockholms Lans Landsting, Stockholm health care services
Primary Subject Heading:	Mental health
Secondary Subject Heading:	Health services research
Keywords:	Child & adolescent psychiatry < PSYCHIATRY, Anxiety disorders < PSYCHIATRY, MENTAL HEALTH

Word count
Abstract: 273
Main text: 4296
Tables: 3 Figures: 2

Therapist-guided Internet-delivered cognitive behavioural therapy supplemented with group-exposure sessions for adolescents with social anxiety disorder: a feasibility trial

Martina Nordh[1,2], Sarah Vigerland[1,2], Lars-Göran Öst[3,4], Brjánn Ljótsson[1,4], David Mataix-Cols[1,2], Eva Serlachius[1,2], Jens Högström[1,2]

Author affiliations:
[1]Centre for Psychiatry Research, Department of Clinical Neuroscience, Karolinska Institutet, Stockholm, Sweden

[2]Stockholm Health Care Services, Stockholm County Council, Stockholm, Sweden

[3]Department of psychology, Stockholm University, Stockholm, Sweden

[4]Department of Clinical Neuroscience, Division of psychology, Karolinska Institutet, Stockholm, Sweden

Correspondance to:
Martina Nordh
E-mail: martina.nord@ki.se

Address:
Child and Adolescent Psychiatry Research Center
Gävlegatan 22
113 30 Stockholm
Sweden

Phone: +46 08 514 522 15

ABSTRACT

Objectives: Social anxiety disorder (SAD) is one of the most common psychiatric disorders in youth, with a prevalence of about 3-4%, and increased risk of adverse long-term outcomes, such as depression. Cognitive behavioural therapy (CBT) is considered the first-line treatment for youth with SAD but many adolescents remain untreated due to limited accessibility to CBT. The aim of this study was to develop and evaluate the feasibility and preliminary efficacy of a therapist-guided Internet-delivered CBT treatment, supplemented with clinic-based group-exposure sessions (BIP SOFT).

Design: A proof-of-concept, open clinical trial with 6-month follow-up.

Participants: The trial was conducted at a child and adolescent psychiatric research clinic and participants (*N* = 30) were 13-17 years old (83% girls) with a principal diagnosis of SAD.

Intervention: 12 weeks of intervention, consisting of nine remote therapist-guided Internet-delivered CBT sessions and three group-exposure sessions at the clinic for the adolescents and five internet-delivered sessions for the parents.

Results: Adolescents were generally satisfied with the treatment and the completion-rate of Internet-modules, as well as attendance at group-sessions, was high. Post-treatment assessment showed a significant decrease in clinician-, adolescent-, and parent-rated social anxiety (*d* = 1.17, 0.85, and 0.79, respectively), as well as in general self- and parent-rated anxiety and depression (*d* = 0.76 and 0.51), compared with pre-treatment levels. Furthermore, 47% of participants no longer met DSM-5 criteria for SAD at post-treatment. At a 6-month follow-up, symptom reductions were maintained, or further improved, and 57% of participants no longer met criteria for SAD.

Conclusion: Therapist- and parent guided Internet-delivered CBT, supplemented with a limited number of group-exposure sessions is a feasible and promising intervention for adolescents with SAD.

Trial registration number: Clinicaltrials.gov registration ID NCT02576171

Strengths and limitations of this study

- This is the first study to investigate the feasibility and efficacy of a combined Internet-CBT and group-exposure treatment for youth with social anxiety disorder.
- Participants were followed up six months after the end of treatment.
- The study was uncontrolled which limits any causal inference about observed changes.

INTRODUCTION

Social anxiety disorder (SAD) is characterized by an intense fear of being scrutinized and negatively evaluated in social or performance situations[1]. The socially anxious individual is typically afraid of making mistakes, being embarrassed in front of others and of showing signs of anxiety, such as blushing or trembling, and may therefore avoid social and performance situations or endure them under intense distress. The disorder has a median age of onset of 9.2 years [2] and is one of the most common mental disorders among adolescents. The 12-month prevalence is 3.4% [3] and 8.6% of the adolescent population fulfill diagnostic criteria at some point between the age of 13 and 18[2]. If the disorder is left untreated it tends to follow a chronic course[2] and can lead to severe secondary consequences such as depression[4] and suicidality[5], substance and alcohol dependence[6], academic underperformance and increased social isolation[7].

Consequently, SAD causes substantial impairment as well as burden on patients' families and long-term societal costs [8 9].

Cognitive behavioural therapy (CBT) for SAD is effective for adults [10] as well as for children and adolescents [11 12] and is the first-line treatment according to international clinical guidelines (e.g., the National Institute for Health and Care Excellence; NICE) [13]. For youth, particularly face-to-face group-CBT is effective for SAD [14-19].

Despite the high level of impairment caused by the disorder, only a small proportion of adolescents with social anxiety seek help for their problems [20 21] and even fewer receive effective treatment [22]. Barriers to receiving evidence-based psychological treatment include limited availability of trained therapists, and practical issues such as long travel distances to clinics, and the requirement to take time off school or work to visit a clinic.

Internet-delivered CBT (ICBT) has been suggested as a possible solution to some of these barriers. It can provide the same treatment components as traditional CBT and allow patients to work from home (or wherever suitable), guided by an online-therapist, e.g. through e-mail or similar online communication. Treatment becomes more accessible as the therapist and patient can communicate asynchronously and it may increase treatment capacity, as therapist time per patient tends to be lower compared with face-to-face CBT[23-25]. For adults with SAD, ICBT is an evidence-based treatment [26] with at least one trial showing that ICBT is non-inferior to face-to-face CBT [27]. For youth, ICBT is effective for mixed anxiety disorders when compared to a waitlist control [28-31], with similar effects as face-to-face CBT [32], suggesting that ICBT could be a suitable treatment for adolescents with SAD. However, a recent study showed that only 12.8% and 14.6% (in the SAD specific and generic ICBT conditions, respectively) of participants

were free from their SAD diagnosis at post-treatment assessment, indicating that using the Internet, as the only modality to deliver CBT might not be sufficient[33].

The objective of the current trial is to evaluate the feasibility and efficacy of ICBT supplemented with clinic-based group-exposure sessions, for adolescents with SAD, a treatment that could potentially draw on advantages from both formats, where ICBT is a cost-effective and accessible format and group-sessions may ensure that key treatment components, such as exposure to social situations, are conveyed properly. Main research questions are: Is the treatment (BIP SOFT) feasible and acceptable with regard to adolescents' and parents' willingness to work with the Internet-modules, adolescents' attendance rates at group sessions and treatment satisfaction? Does the treatment reduce social anxiety symptoms and increase adolescents' level of functioning and quality of life?

METHOD

The study was conducted at a research unit within the Child and Adolescent Mental Health Services in Stockholm, Sweden, and was approved by the Regional Ethical Review Board in Stockholm, Sweden (2015/1383-31/2).

Participants

Participants were 30 adolescents, 13-17 years old, with a principal diagnosis of SAD, and their parents. Table 1 gives detailed information on demographic and clinical characteristics of the sample. Inclusion criteria were: a) age 13-17 years, b) principal DSM-5 diagnosis of SAD, c) ability to read and write Swedish, d) access to a computer with Internet access and e) at least one parent being able to participate in the treatment. Exclusion criteria were: f) initiation or dose modification of psychotropic drug within the past six weeks, g) ≥ 5 sessions of CBT (including exposure) within the last six

months, h) any ongoing psychological treatment for SAD, i) diagnosed with an autism spectrum disorder, current psychosis, eating disorder, severe depression, suicidal behaviour or other current severe psychiatric condition j) current substance- or alcohol abuse. Adolescents excluded due to other severe psychiatric conditions, such as severe depression or suicidality, were referred to more suitable treatments.

Participants were mainly recruited through advertisement in a local paper. The advertisement included a website address (www.bup.se/bip) where interested families could get study information and sign up. Clinicians working in the child- and adolescent health services could also refer patients to the trial.

To achieve sufficient power and to be able to detect a within-group effect size of d = 0.60 from pre to post with a power of 0.85 and $\alpha = 0.05$, allowing for a 10% drop out, we included 30 participants in the study.

Insert Table 1 here

Measures

Primary outcome measures

The Clinical Global Impression – Severity (CGI-S)[34] is a clinician rating of symptom severity, ranging from 1 ("normal, not mentally ill") to 7 ("extremely ill"). The CGI-S was administered at baseline by the treating therapist. At post-treatment and the 6-month follow-up, another clinician than the one being responsible for the treatment administered the CGIS-S.

Secondary outcome measures

Mini International Neuropsychiatric Interview for Children and Adolescents (M.I.N.I. KID) [35], was used to determine presence of SAD, as well as comorbid conditions. In addition, the SAD section of the Anxiety Disorders Interview Schedule for DSM-IV-Child Version (ADIS-C)[36] was used to further confirm SAD-diagnosis and to assess the intensity of SAD symptoms. An independent rater (a clinical psychologist, not part of the research group, blind to whether the adolescent had been included in the study or not) watched recordings of the baseline interviews and reassessed 20% of them (both included and excluded adolescents), generating an excellent inter-rater reliability at pre-treatment for SAD-diagnosis ($\kappa = 1.0$) and a fair inter-rater reliability for comorbidity ($\kappa = 0.46$, $p < .05$).

Clinical global impression – Improvement (CGI-I) [34] is a clinician rating of the participant's change in symptom severity relative to baseline, ranging from 1 ("very much improved") to 7 ("very much worse"). The Children's Global Assessment Scale (CGAS)[37] is a clinician rating of global functioning (scale 0-100), with higher rating indicating higher level of functioning. The M.I.N.I. KID and CGAS were administered at baseline, post-treatment and at the 6-month follow-up, whereas the CGI-I was administered post-treatment and at the 6-month follow-up.

Social Phobia and Anxiety Inventory - Child and Parent Version (SPAI-C/P)[38] is a 26-item self-report measure evaluating aspects of SAD on a 3-point scale, where a score of ≥18 is considered the clinical level of social anxiety. The Social Phobia Weekly Summary Scale (SPWSS) is a five-item self-report scale [39 40] measuring dimensions of SAD (social anxiety, avoidance, self-focused attention, anticipatory processing and post-event processing). The SPAI-C/P and the SPWSS were administered at baseline, every third week during treatment, post-treatment as well as at the 6-month follow-up.

The Revised Children Anxiety And Depression Scale – Child and Parent Version (RCADS-C/P) [41] is a 47-item self-report measure evaluating anxiety disorders (including one subscale for SAD) and depression on a 4-point scale, ranging from *never* to *always*. In the current trial one item regarding suicidality, with three options ("I do not think about killing myself", "I think about killing myself, but would never do it" or "I want to kill myself"), was added at the end of the RCADS-C/P. The Education, Work and Social Adjustment Scale – Child and Parent Version (EWSAS-C/P)[42 43] is a 5-item self-report scale measuring functional impairment on a 9-point scale (higher rating indicating more impairment). The RCADS-C/P and the EWSAS-C/P were administered at baseline, after six weeks of treatment, post-treatment as well as at the 6-month follow-up.

The Health related quality of life questionnaire for children, adolescents and their parents (KIDSCREEN-10)[44] is a self-report measure assessing health related quality of life. The parent-rated measure Trimbos/iMTA questionnaire for Costs associated with Psychiatric Illness – Child version (TiC-P)[45] covers e.g. production loss among parents due to health problems in the child. The KIDSCREEN-10 and the TiC-P were administered at baseline, post-treatment and at the 6-month follow-up.

Feasibility measures, adverse events and therapist time

The Technology Acceptance Scale – child and parent version (TAS-C/P) is a self-report measure adapted from Venkatesh et al. [46], which measures the usefulness, acceptability and satisfaction of the website through which the Internet-modules of the treatment were delivered. The TAS-C/P was administered after three weeks of treatment and post-treatment.

At post-treatment, adolescents and parents were asked to report any negative experiences or adverse events over the course of treatment as well as to what extent the negative event had affected the adolescent's wellbeing.

Amount of therapist time per participant was logged automatically through the Internet-treatment platform.

Procedure

Figure 1 gives an overview of inclusion procedures and assessment points. Families who applied to the study were contacted by telephone and a short screening interview was conducted. Eligible families were invited to diagnostic assessment at the clinic. After thorough information about the study, adolescents gave verbal assent to participate and written informed consent was obtained from parents. The screening interview M.I.N.I. KID (with the supplement of the SAD section of the ADIS-C) was then conducted. The therapist who conducted the baseline assessment was responsible for the treatment of the participant.

Adolescents with a principal diagnosis of SAD were included and adolescents and parents completed baseline self-report measures online through the treatment platform. In each family, one of the parents was assigned the main responsibility to respond to the parent-report measures at each assessment point throughout the study. Adolescents and parents had separate user accounts and a two-factor authentication (an individual password and a single-use code sent to the user's cellular phone) gave access to the online platform.

Self- and parent rated measures administered during the treatment (SPAI C/P, SPWSS, RCADS C/P and EWSAS C/P) were completed online.

At post-treatment and at the 6-month follow-up all participating adolescents and parents were invited back to the clinic for a diagnostic assessment. To reduce the risk of biased assessment, a clinician that had not been responsible for the participant's treatment conducted the post-treatment and follow-up assessments. All self-assessment scales were administered online post-treatment and at follow-up. Families who could not come to the clinic for post-treatment assessment (n = 1) and 6-month follow-up (n = 3) were assessed over the telephone.

Insert Figure 1 here

Intervention

The intervention was 12 weeks of ICBT supplemented with group-exposure, comprising nine Internet-delivered modules completed individually from home, and three group-exposure sessions at the clinic (Table 2). The online treatment platform used in this study was developed for delivery of ICBT and has been tested in a number of previous studies for different psychiatric disorders in youth [25 31 47-49]. The current treatment (BIP SOFT) was based on the cognitive-behavioural model by Rapee and Heimberg[50] and to some extent on the cognitive model by Clark and Wells[51] . The treatment manual was developed by the authors and contains CBT components commonly used for SAD in youth[14 18 52], such as exposure, coping strategies and social skills training. The group sessions were mostly based on the Albano and DiBartolo group-CBT manual for adolescent SAD[52]. Therapists in the study were three clinical psychologists and two master students at their final year of training in clinical psychology.

The Internet-modules included educative texts, animations, audio clips and exercises. The parental part of the intervention consisted of five Internet-modules with parent-

specific topics such as "parental traps" (e.g., compensating for the adolescent in social situations by for instance speaking for him/her) and doing functional analyses of such parental accommodation (Table 2). Parents were encouraged to be actively involved in their adolescent's treatment and discuss with the adolescent how they should support him or her throughout the treatment, e.g. during exposure exercises. Parents were also encouraged to bring up parent-specific topics with their therapist, for example how to support the adolescent before or during exposures. Parents could send messages to the therapist throughout the 12 weeks of treatment. Adolescents and parents were instructed to log in and complete one module each week. The therapists had asynchronous contact online with adolescents and parents every week, commenting on their progress on work sheets and through a built in message function. If necessary, therapists had telephone contact with families, e.g., if they hadn't logged in during the last week or if mid-treatment self-reports exceeded a cut-off for depression (>11 on RCADS-C depression subscale) or suicidality.

The group-exposure sessions (at week 4, 6 and 10) ensured that key components of the treatment were demonstrated in a correct way and that participants could practice e.g. exposure under observation of a therapist. To ensure large enough group sizes, cohorts of six participants started the treatment at the same time. The group sessions were two hours long and led by two of the clinical psychologists.

Insert Table 2 here

Statistical analysis

All analyses were conducted in SPSS Version 23.

Cohen's kappa coefficient (κ)[53] was used to calculate inter-rater reliability for SAD-diagnosis and comorbidity at pre-treatment assessment. The level of reliability is interpreted as poor when κ< 0.40, fair when κ is 0.40-0.59, good when κ is 0.60-0.74 and excellent when κ>0.74[54].

Linear mixed models were used to analyse changes from pre- to post-treatment, and from post-treatment to 6-month follow-up. Mixed model analyses use all available data and account for correlations between measurements within the same subject [55]. Thus, missing data is handled within the model. All mixed models in this study included a fixed effect for time (pre, post and 6-month follow-up) and a random effect for individual subjects. Potential missing bias was investigated using *t*-tests that compared the baseline characteristics of those who had complete data at post-treatment with those who had missing data. For SPAI C/P and SPWSS three mid-treatment (week 3, 6 and 9) time points were included in the analyses, and for RCADS C/P and EWSAS C/P one mid-treatment (week 6) time point was included in the analyses.

Effect sizes are reported as Cohen's $d = (M_1\text{-}M_2 / SD_{pooled})$. Effect sizes are defined according to Cohen's suggested levels, small ($d \geq 0.20$), moderate ($d \geq 0.50$) and large ($d \geq 0.80$) [56].

RESULTS

Response rate and feasibility

Mid-treatment measures were completed by 97% of the participating families at week three, 83% at week six and 70% at week nine. Post-treatment and 6-month follow-up measures were completed by 90% and 83% of the participating families, respectively. T-tests comparing participants with missing versus complete data points on baseline characteristics revealed no statistically significant differences.

Adolescents completed on average 5.7 (*sd* =2.1) of the nine Internet-modules and parents completed on average 4.4 (*sd* =1.0) of their five modules. Attendance at the group-sessions were 70% (session 1), 77% (session 2) and 63% (session 3) respectively. Two thirds of the participants attended two or more group sessions and only 10% attended none.

None of the adolescents meeting inclusion criteria at baseline assessment declined participation, which indicates good acceptability of the offered treatment.

Figure 2 illustrates that a majority of the adolescents were satisfied with the treatment, would recommend the treatment to a friend and found the program easy to understand.

Insert Figure 2 here

Clinician support

The average time a clinician spent giving feedback and guidance to participants (including time spent on the adolescent *and* parent) was 19.5 minutes per week for the Internet-modules. Group sessions required two hours of therapist time per participant in total during the 12 weeks, which corresponds to 10 minutes per week and participant. In total thus, each family got 29.5 minutes of therapist time, per week.

Changes in clinical outcomes from pre- to post-treatment

Means, standard deviations and effect sizes for pre to post changes, are presented in Table 3. Intention-to-treat analyses of the primary outcome measure (CGI-S) showed a significant decrease of SAD severity from pre- to post-treatment, $t(26.05) = 5.62$, $p<.001$, with a large effect size, $d = 1.17$ (*95%CI* 0.61,1.72). For all secondary outcome measures,

analyses revealed significant improvements with moderate to large effect sizes, with the exception of quality of life (KIDSCREEN-C/P) where a small effect was observed. At post-treatment, 47% of the participants (n = 14) no longer met diagnostic criteria for SAD, according to DSM-5 criteria and a CGI-rating <4 (level of severity and functional impairment below diagnostic threshold) and 30% (n = 9) scored ≤18 on SPAI-C (cut-off for clinical level of social anxiety). On the clinician rated CGI-I 8% (n=2) were "very much improved", 23% (n = 6) "much improved", 42% (n = 11) "minimally improved", 23% (n = 6) "not changed" and 4% (n = 1) "minimally worse".

Changes in clinical outcomes from post-treatment to 6-month follow-up

Table 3 gives an overview of means, standard deviations and effect sizes from post-treatment to the 6-month follow-up. The improvements seen at post-treatment were generally maintained and further augmented at the 6-month follow-up with small effect sizes, except for self-focus (SPWSS) that deteriorated slightly. The primary outcome measure (CGI-S) showed a significant decrease of SAD severity from post-treatment to 6-month follow up, $t(25.45) = 2.60$, $p<.05$, with a small effect size, $d = 0.22$ (*95%CI* -0.01, 0.45). At follow-up, 57% (n = 17) no longer met diagnostic criteria for SAD and 37% (n = 11) scored ≤18 on SPAI-C.

Comparison of pre-treatment and 6-month follow-up levels of social anxiety showed overall improvements with large effect-sizes, CGI-S: $t(27.23) = 6.24$, $p<.001$, $d = 1.36$ (*95%CI* 0.71, 2.01), SPAI-C: $t(27.63) = 5.50$, $p<.001$, $d = 0.95$ (*95%CI* 0.51, 1.39) and SPAI-P: $t(26.08) = 5.57$, $p<.001$, $d = 1.14$ (*95%CI* 0.57, 1.72). Clinician-rated CGI-I indicated that, of those who participated in the 6-month follow-up assessment, 19% (n = 5) were "very much improved", 31% (n = 8) "much improved", 38% (n = 10) "minimally

improved", 4% (*n* = 1) "not changed" and 8% (*n* = 2) "minimally worse", compared to baseline.

Post-hoc analyses

The proportion of parents reporting that they had stayed home from work during the last month due to their adolescent's health problems was 27% before treatment and 13% at 6-month follow-up. Of the adolescents, 50% had stayed home from school during the last month due to health problems before treatment and 33% at 6-month follow-up.

At 6-month follow-up, six participants reported that they had received additional treatment for social anxiety; two participants (7%) got CBT and four participants (13%) had initiated or increased SSRI medication. Half of all participants (*n*=15) reported that they had used strategies from the treatment since post-treatment assessment, referring to exposure, coping strategies (such as breathing exercises and focus shift) and cognitive techniques as the most common ones.

Adverse events

Seven adolescents (23%) reported having experienced some negative event during the course of treatment. These events included increased stress due to the limited time to work with treatment modules (*n* =4; 13%), increased social anxiety (*n*=1; 3%), increased panic anxiety (*n*=1; 3%) and increased depression and negative thoughts (*n*=1; 3%). Those who reported increased stress and anxiety associated these symptoms with the first weeks of treatment and typically described a decrease as treatment continued. Two adolescents reported that the negative event (increased negative thoughts in one case and increased panic anxiety in the other case) still had some impact on their wellbeing at the end of treatment.

DISCUSSION

To our knowledge this is the first study evaluating the feasibility and efficacy of therapist- and parent-guided, Internet-delivered cognitive behavioural therapy (ICBT), supplemented with group-exposure sessions, for adolescents with SAD. The results show that such a combined treatment format is both feasible and potentially efficacious and that the improvements are maintained at least 6 months beyond treatment termination. Feasibility was indicated by the high proportion of participants who reported satisfaction with the program, and who would recommend it to a peer, as well as by the high attendance rate at group-sessions and good completion of online-sessions. The results showed substantial reductions of social anxiety symptoms on all clinician-, adolescent- and parent-rated measures at post treatment, as well as improvements in secondary outcomes such as overall anxiety and level of functioning. These symptom reductions were maintained or further improved at the 6-month follow-up.

The adolescents completed on average nearly two thirds of the 9 online-modules which is more than in previous studies on ICBT for youth with SAD where participants have completed less than half of the modules on average[29 33]. It is possible that the face-to-face component (group-exposure sessions) in the present study influenced the working pace with the Internet-modules as participants were recommended to complete the preceding modules before attending group-exposure sessions. Even if completion of previous modules was not a prerequisite for attendance at group sessions, participants tended to complete them before attending the sessions. Participants also had peer and therapist support in the group on aspects of the Internet-delivered modules that they found difficult (e.g., designing an idiosyncratic exposure hierarchy), which might have led to more motivation to work with modules *after* group sessions. It

has been proposed that socially anxious children and adolescents have a tendency to avoid practicing skills on their own that they have learned online, such as conducting in-vivo exposure[33]. It could therefore be hypothesized that the group-sessions in this study enhanced the participants' inclination to practice skills at home as a consequence of being offered intensive therapist guidance and direct feedback during group-exposure.

Forty seven per cent of participants no longer met diagnostic criteria for SAD after treatment, a proportion that further increased to 57% at 6-month follow-up. This is in line with levels reported in studies evaluating face-to-face CBT for youth with SAD [14-16 18 57] and higher than strictly Internet-delivered CBT for youth with SAD[33]. A recent trial of ICBT for youth with SAD reported a relatively limited impact on the clinical diagnosis of SAD (in the two active treatment conditions 12.8 and 14.6% at post-treatment and 29.8% and 35.4 % at 6-month follow-up, no longer met diagnostic criteria for SAD)[33] and the authors suggest that stand-alone ICBT might not be enough for youth with SAD[33]. It is tempting to attribute the better outcomes in our trial to the addition of group-exposure sessions to the ICBT protocol, though this hypothesis remains to be formally evaluated. Discrepancies between our and previous results may also be attributable to differences in study samples, study design or other methodological aspects.

Therapists in this study spent less than 20 minutes per family and week, on the Internet-delivered treatment, which is comparable to previous ICBT trials for youth[24 25]. Although the group sessions added another 10 minutes per family and week in the present trial, group-exposure supplemented ICBT should still be considered a time-efficient intervention compared with face-to-face CBT where the therapist time per family and week usually ranges from 45-60 minutes.

Around a fifth of the participants reported a negative event during the course of the treatment. Some of the events were expected, such as increased social anxiety when exposure is initiated. Reports of increased stress were also associated with the first weeks of the treatment and can be interpreted as an initial difficulty combining treatment with other demands such as schoolwork. Two participants reported having experienced some negative events that affected their wellbeing beyond the treatment termination but these participants still benefited from treatment.

Overall, the treatment seems feasible and possibly efficacious for adolescents with SAD and their parents, but to be considered for implementation in regular care, an intervention must also be feasible from an organizational point of view. A possible drawback with the addition of group-exposure to ICBT is that it limits the flexibility of the intervention. For instance, several patients must be recruited and able to commence treatment at the same time. A possible alternative to group-exposure sessions is to add other forms of direct communication between patients and ICBT-therapists, e.g. video conferencing or equivalent, something that future studies should investigate further.

Limitations

Although this feasibility trial has several strengths, some important limitations need to be considered when interpreting the results. Causal inferences of observed changes are not possible due to lack of a control condition. Thus, improvement could be an effect of non-specific factors such as the therapist attention or of the passage of time. However, SAD has been shown to commonly follow a chronic course when left untreated[2] and it is not likely that spontaneous remission would explain a significant part of the improvements in the study. Additionally, results were maintained and slightly improved at follow-up, indicating that treatment gains were stable over time, even after the

attention from a therapist had ceased. A small proportion of the participants did seek additional care between post-treatment and 6-month follow-up, which could have affected the results. However, these participants all continued to report high levels of social anxiety at follow-up, implying that additional care had limited impact on the long-term outcome. Another limitation concerns assessment at post-treatment and follow-up. Although attempts to reduce bias were made by having these assessments conducted by clinicians not involved in the treatment, assessors were not blind to the fact that the participant had received treatment.

Conclusions

This is the first study of therapist- and parent-guided ICBT supplemented with group-exposure for adolescents with SAD. The intervention was highly acceptable to the families and significantly reduced social anxiety symptoms up to 6-month follow-up. Participants were generally satisfied with the treatment and the completion-rate of Internet-modules and attendance at group sessions were high, indicating that the treatment is feasible and acceptable to the SAD youth population. Furthermore, per-patient therapist time was limited, even considering the time spent on group-sessions; thus, ICBT supplemented with group-exposure might be cost-effective when compared to traditional face-to-face CBT. Further controlled trials are needed.

Acknowledgements The authors would like to thank Ulrika Thulin for invaluable help with writing the treatment modules, and Cornelia Hanqvist and Jon Juselius for assisting with providing the treatment.

Contributors The study was designed by MN, SV, DMC, ES and JH. MN was the project manager in collaboration with JH. MN wrote the treatment modules and provided the treatment in collaboration with JH and SV. All statistical analyses were conducted by JH and MN. MN drafted the manuscript in

collaboration with JH. The manuscript was reviewed and revised by SV, ES, DMC, BL and LGÖ. All authors have read and approved the final manuscript.

Funding This work was supported by the Stockholm County Council (PPG project 20150032; HSNV 140 99; HSN 1011-1176) and the Swedish Research Council and Swedish Research Council for Health, Working Life and Welfare (Forte 2014-4052)

Competing interests None.

Data sharing statement No additional data are available.

References

1. Association AP. Diagnostic and statistical manual of mental disorders (DSM-5®): American Psychiatric Pub 2013.
2. Burstein M, He JP, Kattan G, et al. Social phobia and subtypes in the national comorbidity survey-adolescent supplement: prevalence, correlates, and comorbidity. *J Am Acad Child Adolesc Psychiatry* 2011;50(9):870-80. doi: 10.1016/j.jaac.2011.06.005 [published Online First: 2011/08/30]
3. Lawrence D, Johnson S, Hafekost J, et al. The Mental Health of Children and Adolescents: Report on the Second Australian Child and Adolescent Survey of Mental Health and Wellbeing. 2015
4. Beesdo K, Bittner A, Pine DS, et al. Incidence of social anxiety disorder and the consistent risk for secondary depression in the first three decades of life. *Arch Gen Psychiatry* 2007;64(8):903-12.
5. Katzelnick DJ, Kobak KA, DeLeire T, et al. Impact of generalized social anxiety disorder in managed care. *Am J Psychiatry* 2001;158(12):1999-2007.
6. Buckner JD, Schmidt NB, Lang AR, et al. Specificity of social anxiety disorder as a risk factor for alcohol and cannabis dependence. *J Psychiatr Res* 2008;42(3):230-39.
7. Beidel DC, Turner SM, Morris TL. Psychopathology of childhood social phobia. *J Am Acad Child Adolesc Psychiatry* 1999;38(6):643-50. doi: 10.1097/00004583-199906000-00010 [published Online First: 1999/06/11]
8. Acarturk C, Smit F, De Graaf R, et al. Economic costs of social phobia: a population-based study. *J Affect Disord* 2009;115(3):421-29.
9. Patel A, Knapp M, Henderson J, et al. The economic consequences of social phobia. *J Affect Disord* 2002;68(2):221-33.
10. Hofmann SG, Smits JA. Cognitive-behavioral therapy for adult anxiety disorders: a meta-analysis of randomized placebo-controlled trials. *J Clin Psychiatry* 2008;69(4):621.
11. Scaini S, Belotti R, Ogliari A, et al. A comprehensive meta-analysis of cognitive-behavioral interventions for social anxiety disorder in children and adolescents. *J Anxiety Disord* 2016;42:105-12. doi: 10.1016/j.janxdis.2016.05.008
12. Segool NK, Carlson JS. Efficacy of cognitive‐behavioral and pharmacological treatments for children with social anxiety. *Depress Anxiety* 2008;25(7):620-31.
13. Pilling S, Mayo-Wilson E, Mavranezouli I, et al. Recognition, assessment and treatment of social anxiety disorder: summary of NICE guidance. *BMJ* 2013;346:f2541.
14. Albano AM, Marten PA, Holt CS, et al. Cognitive-Behavioral Group Treatment for Social Phobia in Adolescents A Preliminary Study. *J Nerv Ment Dis* 1995;183(10):649-56.
15. Hayward C, Varady S, Albano AM, et al. Cognitive-behavioral group therapy for social phobia in female adolescents: results of a pilot study. *J Am Acad Child Adolesc Psychiatry* 2000;39(6):721-26.
16. Spence SH, Donovan C, Brechman‐Toussaint M. The treatment of childhood social phobia: The effectiveness of a social skills training‐based, cognitive‐behavioural intervention, with and without parental involvement. *J Child Psychol Psychiatry* 2000;41(6):713-26.
17. Olivares J, García-López L-J, Beidel DC, et al. Results at long-term among three psychological treatments for adolescents with generalized social phobia (I): Statistical significance. *Psicología Conductual* 2002;10(1):147-66.

18. Beidel DC, Turner SM, Morris TL. Behavioral treatment of childhood social phobia. *J Consult Clin Psychol* 2000;68(6):1072-80. [published Online First: 2001/01/06]
19. Herbert JD, Gaudiano BA, Rheingold AA, et al. Cognitive behavior therapy for generalized social anxiety disorder in adolescents: A randomized controlled trial. *J Anxiety Disord* 2009;23(2):167-77.
20. Essau CA, Conradt J, Petermann F. Frequency and comorbidity of social phobia and social fears in adolescents. *Behav Res Ther* 1999;37(9):831-43. [published Online First: 1999/08/24]
21. Wittchen HU, Stein MB, Kessler RC. Social fears and social phobia in a community sample of adolescents and young adults: prevalence, risk factors and co-morbidity. *Psychol Med* 1999;29(2):309-23. doi: 10.1017/s0033291798008174
22. Merikangas KR, He J-p, Burstein M, et al. Service utilization for lifetime mental disorders in US adolescents: Results of the National Comorbidity Survey–Adolescent Supplement (NCS-A). *J Am Acad Child Adolesc Psychiatry* 2011;50(1):32-45.
23. Hedman E, Andersson E, Ljotsson B, et al. Cost-effectiveness of Internet-based cognitive behavior therapy vs. cognitive behavioral group therapy for social anxiety disorder: results from a randomized controlled trial. *Behav Res Ther* 2011;49(11):729-36. doi: 10.1016/j.brat.2011.07.009 [published Online First: 2011/08/20]
24. Lenhard F, Andersson E, Mataix-Cols D, et al. Therapist-Guided, Internet-Delivered Cognitive-Behavioral Therapy for Adolescents With Obsessive-Compulsive Disorder: A Randomized Controlled Trial. *J Am Acad Child Adolesc Psychiatry* 2017;56(1):10-19.e2. doi: 10.1016/j.jaac.2016.09.515 [published Online First: 2016/12/21]
25. Lenhard F, Vigerland S, Andersson E, et al. Internet-delivered cognitive behavior therapy for adolescents with obsessive-compulsive disorder: an open trial. *PLoS One* 2014;9(6):e100773. doi: 10.1371/journal.pone.0100773 [published Online First: 2014/06/21]
26. Hedman E, Ljótsson B, Lindefors N. Cognitive behavior therapy via the Internet: a systematic review of applications, clinical efficacy and cost–effectiveness. *Expert Rev Pharmacoecon Outcomes Res* 2012;12(6):745-64.
27. Hedman E, Andersson G, Ljotsson B, et al. Internet-based cognitive behavior therapy vs. cognitive behavioral group therapy for social anxiety disorder: a randomized controlled non-inferiority trial. *PLoS One* 2011;6(3):e18001. doi: 10.1371/journal.pone.0018001 [published Online First: 2011/04/13]
28. March S, Spence SH, Donovan CL. The efficacy of an internet-based cognitive-behavioral therapy intervention for child anxiety disorders. *J Pediatr Psychol* 2009;34(5):474-87.
29. Tillfors M, Andersson G, Ekselius L, et al. A randomized trial of Internet-delivered treatment for social anxiety disorder in high school students. *Cogn Behav Ther* 2011;40(2):147-57. doi: 10.1080/16506073.2011.555486 [published Online First: 2011/01/01]
30. Donovan CL, March S. Online CBT for preschool anxiety disorders: a randomised control trial. *Behav Res Ther* 2014;58:24-35.
31. Vigerland S, Ljótsson B, Thulin U, et al. Internet-delivered cognitive behavioural therapy for children with anxiety disorders: A randomised controlled trial. *Behav Res Ther* 2016;76:47-56.

32. Spence SH, Donovan CL, March S, et al. A randomized controlled trial of online versus clinic-based CBT for adolescent anxiety. *J Consult Clin Psychol* 2011;79(5):629-42. doi: 10.1037/a0024512 [published Online First: 2011/07/13]
33. Spence SH, Donovan CL, March S, et al. Generic versus disorder specific cognitive behavior therapy for social anxiety disorder in youth: A randomized controlled trial using internet delivery. *Behav Res Ther* 2016;90:41-57. doi: 10.1016/j.brat.2016.12.003 [published Online First: 2016/12/19]
34. Guy W. Clinical global impression scale. *The ECDEU Assessment Manual for Psychopharmacology-Revised Volume DHEW Publ No ADM* 1976;76(338):218-22.
35. Sheehan DV, Lecrubier Y, Sheehan KH, et al. The Mini-International Neuropsychiatric Interview (M.I.N.I.): the development and validation of a structured diagnostic psychiatric interview for DSM-IV and ICD-10. *J Clin Psychiatry* 1998;59 Suppl 20:22-33;quiz 34-57. [published Online First: 1999/01/09]
36. Albano A, Silverman W. The Anxiety Disorders Interview Schedule for Children for DSM-IV: clinician manual (child and parent versions). *San Antonio, TX: Psychological Corporation* 1996
37. Shaffer D, Gould MS, Brasic J, et al. A children's global assessment scale (CGAS). *Arch Gen Psychiatry* 1983;40(11):1228-31. [published Online First: 1983/11/01]
38. Beidel DC, Turner SM, Morris TL. A new inventory to assess childhood social anxiety and phobia - the social phobia and anxiety inventory for children *Psychol Assess* 1995;7(1):73-79. doi: 10.1037/1040-3590.7.1.73
39. Clark DM, Ehlers A, McManus F, et al. Cognitive therapy versus fluoxetine in generalized social phobia: a randomized placebo-controlled trial. *J Consult Clin Psychol* 2003;71(6):1058.
40. Hedman E, Mörtberg E, Hesser H, et al. Mediators in psychological treatment of social anxiety disorder: Individual cognitive therapy compared to cognitive behavioral group therapy. *Behav Res Ther* 2013;51(10):696-705.
41. Chorpita BF, Yim L, Moffitt C, et al. Assessment of symptoms of DSM-IV anxiety and depression in children: a revised child anxiety and depression scale. *Behav Res Ther* 2000;38(8):835-55. [published Online First: 2000/08/11]
42. Mundt JC, Marks IM, Shear MK, et al. The Work and Social Adjustment Scale: a simple measure of impairment in functioning. *Br J Psychiatry* 2002;180:461-4. [published Online First: 2002/05/02]
43. Mataix-Cols D, Cowley AJ, Hankins M, et al. Reliability and validity of the Work and Social Adjustment Scale in phobic disorders. *Compr Psychiatry* 2005;46(3):223-28.
44. Ravens-Sieberer U, Gosch A, Rajmil L, et al. KIDSCREEN-52 quality-of-life measure for children and adolescents. *Expert Rev Pharmacoecon Outcomes Res* 2005;5(3):353-64.
45. Bouwmans C, De Jong K, Timman R, et al. Feasibility, reliability and validity of a questionnaire on healthcare consumption and productivity loss in patients with a psychiatric disorder (TiC-P). *BMC Health Serv Res* 2013;13(1):1.
46. Venkatesh V, Morris MG, Davis GB, et al. User acceptance of information technology: Toward a unified view. *MIS quarterly* 2003:425-78.
47. Bonnert M, Olen O, Lalouni M, et al. Internet-Delivered Cognitive Behavior Therapy for Adolescents With Irritable Bowel Syndrome: A Randomized Controlled Trial. *Am J Gastroenterol* 2016 doi: 10.1038/ajg.2016.503 [published Online First: 2016/11/16]

48. Lenhard F, Vigerland S, Andersson E, et al. Internet-delivered cognitive behavior therapy for adolescents with obsessive-compulsive disorder: an open trial. *PLoS One* 2014;9(6):e100773.
49. Vigerland S, Thulin U, Ljotsson B, et al. Internet-delivered CBT for children with specific phobia: a pilot study. *Cogn Behav Ther* 2013;42(4):303-14. doi: 10.1080/16506073.2013.844201 [published Online First: 2013/11/20]
50. Rapee RM, Heimberg RG. A cognitive-behavioral model of anxiety in social phobia. *Behav Res Ther* 1997;35(8):741-56. [published Online First: 1997/08/01]
51. Clark DM, Wells A. A cognitive model of social phobia. *Social phobia: Diagnosis, assessment, and treatment* 1995;41(68):00022-3.
52. Albano AM, DiBartolo PM. Cognitive-Behavioral Therapy for Social Phobia in Adolescents: Stand Up, Speak Out Therapist Guide: Oxford University Press 2007.
53. Cohen J. A coefficient of agreement for nominal scales. Educational and Psychosocial Measurement, 20, 37-46, 1960.
54. Mannuzza S, Fyer AJ, Martin LY, et al. Reliability of anxiety assessment. I. Diagnostic agreement. *Arch Gen Psychiatry* 1989;46(12):1093-101. [published Online First: 1989/12/01]
55. Gueorguieva R, Krystal JH. Move over ANOVA: progress in analyzing repeated-measures data and its reflection in papers published in the Archives of General Psychiatry. *Arch Gen Psychiatry* 2004;61(3):310-7. doi: 10.1001/archpsyc.61.3.310 [published Online First: 2004/03/03]
56. Cohen J. A power primer. *Psychol Bull* 1992;112(1):155.
57. Öst L-G, Cederlund R, Reuterskiöld L. Behavioral treatment of social phobia in youth: Does parent education training improve the outcome? *Behav Res Ther* 2015;67:19-29.

Table 1. Demographic and clinical features of study participants (*N* = 30)

Variables		*N*	%
Age (years)	*M (SD)*	15 (1.22)	
	min-max	13-17	
Gender	Girls	25	83
	Boys	5	17
Country of birth, adolescent	Sweden	29	97
	Other	1	3
Country of birth, parents	Both in Sweden	20	67
	One in Sweden	7	23
	None in Sweden	3	10
Education, responding parent	Primary	14	47
	Higher	16	53
Employment, responding parent	Working	25	83
	Unemployed	4	13
	Retired	1	3
Psychotropic medication pre-treatment	None	27	90
	SSRI	3	10
Prior psychological treatment	None	11	37
	Primary care, counseling or equivalent	4	13
	Psychiatric specialist care or equivalent	14	47
Referred from child health services		6	20
Comorbid diagnoses	Specific Phobia	8	26.7
	GAD	5	16.7
	ADD	3	10
	Depression	2	6.7
	OCD	2	6.7
	Panic disorder	1	3.3
	Tics/Tourette	1	3.3
	Separation anxiety	1	3.3
	Trichotillomania	1	3.3
Frequency of comorbid diagnoses	None	13	43.3
	One	11	36.7
	Two	3	10
	Three or more	3	10
Onset (age in years)	M (SD)	8.9 (4.29)	
Duration of SAD (years)	M (SD)	6.2 (4.05)	

Note: Primary education ≤12. Higher education >12 years.
Abbreviations: GAD = generalized anxiety disorder; ADD = attention deficit disorder; OCD = obsessive compulsive disorder.

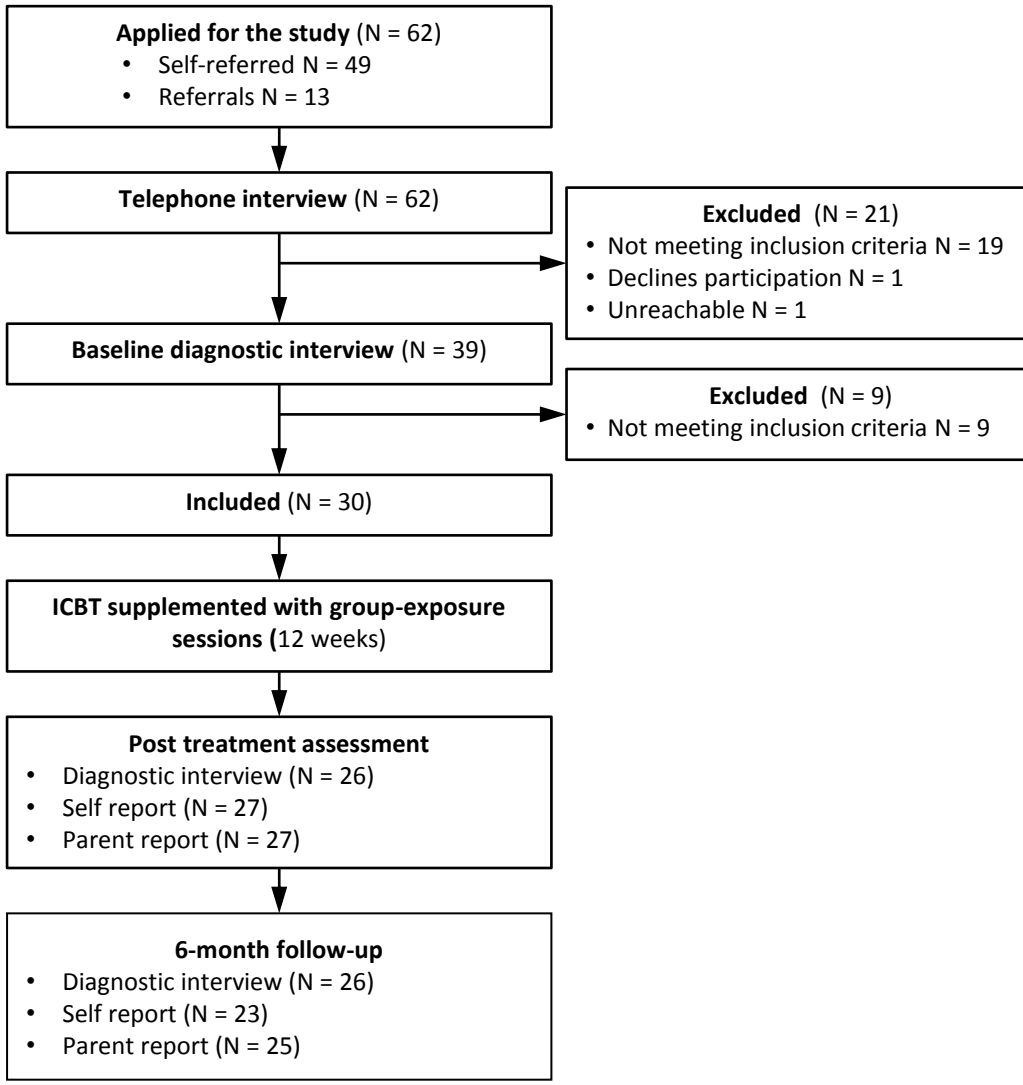
Table 2. An overview of the content of the ICBT protocol and group-exposure sessions

Chapter	Adolescent	Parent	Group-exposure sessions
1	Introduction to ICBT, Learn about emotions, fear and social anxiety. How to do functional analyses of my own behavior	Introduction to ICBT. Learn about emotions, fear and social anxiety. How to do functional analyses of my teenager's behavior and my own reactions.	
2	More about social anxiety disorder. Learn to reduce self-focus and safety behaviors. Improve coping strategies.	Suggest treatment goals. Plan the treatment. Learn about exposure and how to be a co-therapist during exposure.	
3	Map the social anxiety. Learn about exposure to social situations. Set treatment goals and build an individual exposure hierarchy.	Learn about common parental challenges. How to reward my adolescent. Problem solving.	
4		How to handle negative thoughts. Learn about social skills.	Modelling and practice of social skills. Modelling and mapping of safety behaviors and how to reduce them. Set an individual exposure hierarchy. Exposure in vivo. Summary with parents.
5	Exposure follow-up. Learn about negative thoughts and how to handle them.	Prepare relapse prevention. Evaluation of parent modules and treatment.	
6			Repetition of treatment components. Exposure in vivo. Summary with parents.
7	Exposure follow-up. Extended practice of focus shift.		
8	Exposure follow-up. Negative thoughts follow-up. Problem solving.		
9	Exposure follow-up. Learn how to say no and other self-assertive behaviors.		
10			Exposure in vivo. Social mishaps in public environment. Summary with parents.
11	Exposure follow-up. Last sprint: how to get the most out of the last exposures.		
12	Make a plan for relapse prevention. What did I learn? What do I want to practice further? Make an evaluation of the treatment.		

Table 3 Means, standard deviations, pre- to post and post to 6-month follow-up comparisons, and effect sizes of all outcome measures

	Pre		Post		Pre to post comparison		6-month follow-up		Post to follow-up comparison	
Measure	**M**	**SD**	**M**	**SD**	***p***	***d* (95% CI)**	**M**	**SD**	***p***	***d* (95%CI)**
Clinician-rated										
CGI-S	4.6	0.72	3.3	1.3	<.001	1.17 (0.61,1.72)	3.0	1.43	.015	0.22 (-0.01, 0.45)
C-GAS	55.5	6.68	62.0	8.85	<.001	0.80 (0.40, 1.21)	65.4	11.14	<.001	0.30 (0.13, 0.46)
Self- and parent rated social anixety										
SPAI-C	33.4	9.32	24.5	11.31	<.001	0.85 (0.36, 1.34)	21.5	11.24	.023	0.27 (0.02, 0.51)
SPAI-P	35.3	8.46	27.2	11.55	<.001	0.79 (0.29, 1.28)	25.7	11.01	n.s.	
SPWSS avoid	4.0	2.38	1.9	2.22	<.001	0.91 (0.36, 1.47)	1.8	1.81	<.001	0.05 (-0.4, 0.5)
SPWSS s-f	4.9	1.74	2.8	1.44	<.001	1.31 (0.61, 2.02)	3.3	2.03	<.001	-0.28 (-0.83-0.26)
SPWSS a a	4.9	1.85	3.0	2.19	<.001	0.94 (0.32, 1.55)	2.4	1.92	<.001	0.29 (-0.18-0.76)
SPWSS pep	4.8	2.29	3.6	1.77	<.001	0.58 (0.02-1.15)	3.3	2.30	<.001	0.14 (-0.36-0.65)
Other self- and parent rated measures										
RCADS-C SAD	18.5	5.69	14.2	5.87	<.001	0.74 (0.36, 1.13)	12.4	6.16	.018	0.30(0.05, 0.55)
RCADS-P SAD	16.4	5.88	13.2	5.70	.006	0.55 (0.09, 1.01)	12.3	6.07	n.s.	
RCADS-C	60.0	24.77	42.1	21.74	<.001	0.76 (0.32, 1.21)	38.4	25.92	n.s.	
RCADS-P	46.2	23.39	35.2	19.13	.005	0.51 (0.11, 0.91)	31.8	22.31	n.s.	
KIDSCREEN-C	32.2	5.59	34.1	6.07	.036	0.32 (0.06, 0.59)	35.7	6.93	n.s.	
KIDSCREEN-P	33.1	4.50	35.5	5.98	.025	0.44 (0.06, 0.82)	35.8	5.85	n.s.	
EWSAS-C	15.0	7.47	10.9	6.69	.006	0.58 (0.14, 1.01)	7.8	5.28	.004	0.50 (0.1, 0.91)
EWSAS-P	14.6	6.51	11.4	6.88	.002	0.48 (0.13, 0.83)	9.1	7.44	.002	0.31 (0.1, 0.54)

Abbreviations: CGI-S = The Clinical Global Impression – Severity, C-GAS = Children's Global Assessment Scale, SPAI-C/P = Social Phobia and Anxiety Inventory - Child and Parent Version, SPWSS = The Social Phobia Weekly Summary Scale, SPWSS avoid = avoidance, s-f = self-focus, a.a = anticipatory anxiety, pep = post event-processing, RCADS-C/P = The Revised Children Anxiety And Depression Scale – Child and Parent Version, RCADS-C/P SAD = The Revised Children Anxiety And Depression Scale – Child and Parent Version, SAD subscale, KIDSCREEN-C/P = The Health related quality of life questionnaire for children, adolescents and their parents, EWSAS-C/P = The Education, Work and Social Adjustment Scale – Child and Parent Version


Applied for the study (N = 62)
Self-referred N = 49
Referrals N = 13
Telephone interview (N = 62)
Excluded (N = 21)
Not meeting inclusion criteria N = 19
Declines participation N = 1
Unreachable N = 1
Baseline diagnostic interview (N = 39)
Excluded (N = 9)
Not meeting inclusion criteria N = 9
Included (N = 30)
ICBT supplemented with group-exposure sessions (12 weeks)
Post treatment assessment
Diagnostic interview (N = 26)
Self report (N = 27)
Parent report (N = 27)
6-month follow-up
Diagnostic interview (N = 26)
Self report (N = 23)
Parent report (N = 25)

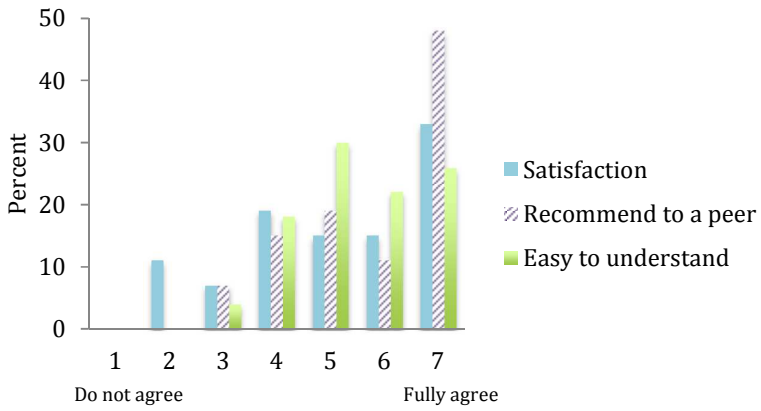


Figure 2. Adolescents' evaluation of BIP SOFT

BMJ Open

Therapist-guided Internet-delivered cognitive behavioural therapy supplemented with group-exposure sessions for adolescents with social anxiety disorder: a feasibility trial

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-018345.R1
Article Type:	Research
Date Submitted by the Author:	21-Aug-2017
Complete List of Authors:	Nordh, Martina; Karolinska Institutet Department of Clinical Neuroscience, Center for Psychiatry Research; Stockholms Lans Landsting, Stockholm health care services Vigerland, Sarah; Karolinska Institutet Department of Clinical Neuroscience, Center for Psychiatry Research; Stockholms Lans Landsting, Stockholm health care services Öst, Lars-Göran; Stockholms Universitet, Department of psychology; Karolinska Institutet Department of Clinical Neuroscience Ljótsson, Brjánn; Karolinska Institutet Department of Clinical Neuroscience, Center for Psychiatry Research; Stockholms Lans Landsting, Stockholm health care services Mataix-Cols, David; Karolinska Institutet Department of Clinical Neuroscience, Center for Psychiatry Research; Stockholms Lans Landsting, Stockholm health care services Serlachius , Eva ; Karolinska Institutet Department of Clinical Neuroscience, Center for Psychiatry Research; Stockholms Lans Landsting, Stockholm health care services Högström, Jens; Karolinska Institutet Department of Clinical Neuroscience, Center for Psychiatry Research; Stockholms Lans Landsting, Stockholm health care services
Primary Subject Heading:	Mental health
Secondary Subject Heading:	Health services research
Keywords:	Child & adolescent psychiatry < PSYCHIATRY, Anxiety disorders < PSYCHIATRY, MENTAL HEALTH

Word count
Abstract: 273
Main text: 4604
Tables: 3 Figures: 2

Therapist-guided Internet-delivered cognitive behavioural therapy supplemented with group-exposure sessions for adolescents with social anxiety disorder: a feasibility trial

Martina Nordh[1,2], Sarah Vigerland[1,2], Lars-Göran Öst[3,4], Brjánn Ljótsson[1,4], David Mataix-Cols[1,2], Eva Serlachius[1,2], Jens Högström[1,2]

Author affiliations:
[1]Centre for Psychiatry Research, Department of Clinical Neuroscience, Karolinska Institutet, Stockholm, Sweden

[2]Stockholm Health Care Services, Stockholm County Council, Stockholm, Sweden

[3]Department of psychology, Stockholm University, Stockholm, Sweden

[4]Department of Clinical Neuroscience, Division of psychology, Karolinska Institutet, Stockholm, Sweden

Correspondance to:
Martina Nordh
E-mail: martina.nord@ki.se

Address:
Child and Adolescent Psychiatry Research Center
Gävlegatan 22
113 30 Stockholm
Sweden

Phone: +46 08 514 522 15

ABSTRACT

Objectives: Social anxiety disorder (SAD) is one of the most common psychiatric disorders in youth, with a prevalence of about 3-4%, and increased risk of adverse long-term outcomes, such as depression. Cognitive behavioural therapy (CBT) is considered the first-line treatment for youth with SAD but many adolescents remain untreated due to limited accessibility to CBT. The aim of this study was to develop and evaluate the feasibility and preliminary efficacy of a therapist-guided Internet-delivered CBT treatment, supplemented with clinic-based group-exposure sessions (BIP SOFT).

Design: A proof-of-concept, open clinical trial with 6-month follow-up.

Participants: The trial was conducted at a child and adolescent psychiatric research clinic and participants (*N* = 30) were 13-17 years old (83% girls) with a principal diagnosis of SAD.

Intervention: 12 weeks of intervention, consisting of nine remote therapist-guided Internet-delivered CBT sessions and three group-exposure sessions at the clinic for the adolescents and five internet-delivered sessions for the parents.

Results: Adolescents were generally satisfied with the treatment and the completion-rate of Internet-modules, as well as attendance at group-sessions, was high. Post-treatment assessment showed a significant decrease in clinician-, adolescent-, and parent-rated social anxiety (*d* = 1.17, 0.85, and 0.79, respectively), as well as in general self- and parent-rated anxiety and depression (*d* = 0.76 and 0.51), compared with pre-treatment levels. Furthermore, 47% of participants no longer met DSM-5 criteria for SAD at post-treatment. At a 6-month follow-up, symptom reductions were maintained, or further improved, and 57% of participants no longer met criteria for SAD.

Conclusion: Therapist- and parent guided Internet-delivered CBT, supplemented with a limited number of group-exposure sessions is a feasible and promising intervention for adolescents with SAD.

Trial registration number: Clinicaltrials.gov registration ID NCT02576171

Strengths and limitations of this study

- This is the first study to investigate the feasibility and efficacy of a combined Internet-CBT and group-exposure treatment for youth with social anxiety disorder.
- Participants were followed up six months after the end of treatment.
- The study was uncontrolled which limits any causal inference about observed changes.

INTRODUCTION

Social anxiety disorder (SAD) is characterized by an intense fear of being scrutinized and negatively evaluated in social or performance situations[1]. The socially anxious individual is typically afraid of making mistakes, being embarrassed in front of others and of showing signs of anxiety, such as blushing or trembling, and may therefore avoid social and performance situations or endure them under intense distress. The disorder has a median age of onset of 9.2 years [2] and is one of the most common mental disorders among adolescents. SAD is more common in adolescent girls than in adolescent boys with a female to male odds ratio of 1.58 (*95%CI*: 1.18-2.12)[2]. The 12-month prevalence is 3.4% [3] and 8.6% of the adolescent population fulfill diagnostic criteria at some point between the age of 13 and 18[2]. If the disorder is left untreated it tends to follow a chronic course[2] and can lead to severe secondary consequences such as depression[4] and

suicidality[5], substance and alcohol dependence[6], academic underperformance and increased social isolation[7]. Consequently, SAD causes substantial impairment as well as burden on patients' families and long-term societal costs [8 9].

Cognitive behavioural therapy (CBT) for SAD is effective for adults [10] as well as for children and adolescents [11 12] and is the first-line treatment according to international clinical guidelines (e.g., the National Institute for Health and Care Excellence; NICE) [13]. In face-to-face treatment, generic CBT has shown poorer outcomes for youth with SAD compared to other anxiety disorders[14], but when treatments have been tailored to include SAD-specific components, such as social skills training, the reported effects have been larger[15 16].

Despite the high level of impairment caused by the disorder, only a small proportion of adolescents with social anxiety seek help for their problems [17 18] and even fewer receive effective treatment [19]. Barriers to receiving evidence-based psychological treatment include limited availability of trained therapists, and practical issues such as long travel distances to clinics, and the requirement to take time off school or work to visit a clinic.

Internet-delivered CBT (ICBT) has been suggested as a possible solution to some of these barriers. It can provide the same treatment components as traditional CBT and allow patients to work from home (or wherever suitable), guided by an online-therapist, e.g. through e-mail or similar online communication. Treatment becomes more accessible as the therapist and patient can communicate asynchronously and it may increase treatment capacity, as therapist time per patient tends to be lower compared with face-to-face CBT[20-22]. For adults with SAD, ICBT is an evidence-based treatment [23] with at least one trial showing that ICBT is non-inferior to face-to-face CBT [24]. For youth, ICBT is effective for mixed anxiety disorders when compared to a waitlist control [25-28],

with similar effects as face-to-face CBT [29], suggesting that ICBT could be a suitable treatment for adolescents with SAD. However, a recent study showed that only 12.8% and 14.6% (in the SAD specific and generic ICBT conditions, respectively) of participants were free from their SAD diagnosis at post-treatment assessment, indicating that using the Internet, as the only modality to deliver CBT might not be sufficient[30].

The objective of the current trial is to evaluate the feasibility and efficacy of ICBT supplemented with clinic-based group-exposure sessions, for adolescents with SAD, a treatment that could potentially draw on advantages from both formats, where ICBT is a cost-effective and accessible format and group-sessions may ensure that key treatment components, such as exposure to social situations and social skills training, are conveyed properly. Main research questions are: Is the treatment (BIP SOFT) feasible and acceptable with regard to adolescents' and parents' willingness to work with the Internet-modules, adolescents' attendance rates at group sessions and treatment satisfaction? Does the treatment reduce social anxiety symptoms and increase adolescents' level of functioning and quality of life?

METHOD

The study was conducted at a research unit within the Child and Adolescent Mental Health Services in Stockholm, Sweden, and was approved by the Regional Ethical Review Board in Stockholm, Sweden (2015/1383-31/2). Participants were recruited and treated between October 2015 and May 2016.

Participants

Participants were 30 adolescents, 13-17 years old, with a principal diagnosis of SAD, and their parents. Table 1 gives detailed information on demographic and clinical characteristics of the sample. Inclusion criteria were: a) age 13-17 years, b) principal

DSM-5 diagnosis of SAD, c) ability to read and write Swedish, d) access to a computer with Internet access and e) at least one parent being able to participate in the treatment. Exclusion criteria were: f) initiation or dose modification of psychotropic drug within the past six weeks, g) ≥ 5 sessions of CBT (including exposure) within the last six months, h) any ongoing psychological treatment for SAD, i) diagnosed with an autism spectrum disorder, current psychosis, eating disorder, severe depression, suicidal behaviour or other current severe psychiatric condition j) current substance- or alcohol abuse. Adolescents excluded due to other severe psychiatric conditions, such as severe depression or suicidality, were referred to more suitable treatments.

Participants were mainly recruited through advertisement in a local paper. The advertisement included a website address (www.bup.se/bip) where interested families could get study information and sign up. Clinicians working in the child- and adolescent health services could also refer patients to the trial.

To achieve sufficient power and to be able to detect a within-group effect size of d = 0.60 from pre to post with a power of 0.85 and $\alpha = 0.05$, allowing for a 10% drop out, we included 30 participants in the study.

Insert Table 1 here

Measures

Primary outcome measures

The Clinical Global Impression – Severity (CGI-S)[31] is a clinician rating of symptom severity, ranging from 1 ("normal, not mentally ill") to 7 ("extremely ill"). The CGI-S was administered at baseline by the treating therapist. At post-treatment and the 6-month follow-up, another clinician than the one being responsible for the treatment

administered the CGIS-S.

Secondary outcome measures

Mini International Neuropsychiatric Interview for Children and Adolescents (M.I.N.I. KID) [32], was used to determine presence of SAD, as well as comorbid conditions. In addition, the SAD section of the Anxiety Disorders Interview Schedule for DSM-IV-Child Version (ADIS-C)[33] was used to further confirm SAD-diagnosis and to assess the intensity of SAD symptoms. An independent rater (a clinical psychologist, not part of the research group, blind to whether the adolescent had been included in the study or not) watched recordings of the baseline interviews and reassessed 20% of them (both included and excluded adolescents), generating an excellent inter-rater reliability at pre-treatment for SAD-diagnosis ($\kappa = 1.0$) and a fair inter-rater reliability for comorbidity ($\kappa = 0.46$, $p < .05$).

Clinical global impression – Improvement (CGI-I) [31] is a clinician rating of the participant's change in symptom severity relative to baseline, ranging from 1 ("very much improved") to 7 ("very much worse"). The Children's Global Assessment Scale (CGAS)[34] is a clinician rating of global functioning (scale 0-100), with higher rating indicating higher level of functioning. The M.I.N.I. KID and CGAS were administered at baseline, post-treatment and at the 6-month follow-up, whereas the CGI-I was administered post-treatment and at the 6-month follow-up.

Social Phobia and Anxiety Inventory - Child and Parent Version (SPAI-C/P)[35] is a 26-item self-report measure evaluating aspects of SAD on a 3-point scale, where a score of ≥18 is considered the clinical level of social anxiety. The Social Phobia Weekly Summary Scale (SPWSS) is a five-item self-report scale [36 37] measuring dimensions of SAD (social anxiety, avoidance, self-focused attention, anticipatory processing and post-event

processing). The SPAI-C/P and the SPWSS were administered at baseline, every third week during treatment, post-treatment as well as at the 6-month follow-up.

The Revised Children Anxiety And Depression Scale – Child and Parent Version (RCADS-C/P) [38] is a 47-item self-report measure evaluating anxiety disorders (including one subscale for SAD) and depression on a 4-point scale, ranging from *never* to *always*. In the current trial one item regarding suicidality, with three options ("I do not think about killing myself", "I think about killing myself, but would never do it" or "I want to kill myself"), was added at the end of the RCADS-C/P. The Education, Work and Social Adjustment Scale – Child and Parent Version (EWSAS-C/P)[39 40] is a 5-item self-report scale measuring functional impairment on a 9-point scale (higher rating indicating more impairment). The RCADS-C/P and the EWSAS-C/P were administered at baseline, after six weeks of treatment, post-treatment as well as at the 6-month follow-up.

The Health related quality of life questionnaire for children, adolescents and their parents (KIDSCREEN-10)[41] is a self-report measure assessing health related quality of life. The parent-rated measure Trimbos/iMTA questionnaire for Costs associated with Psychiatric Illness – Child version (TiC-P)[42] covers e.g. production loss among parents due to health problems in the child. The KIDSCREEN-10 and the TiC-P were administered at baseline, post-treatment and at the 6-month follow-up.

Feasibility measures, adverse events and therapist time

The Technology Acceptance Scale – child and parent version (TAS-C/P) is a self-report measure adapted from Venkatesh et al. [43], which measures the usefulness, acceptability and satisfaction of the website through which the Internet-modules of the treatment were delivered. The TAS-C/P was administered after three weeks of treatment and post-treatment.

At post-treatment, adolescents and parents were asked to report any negative experiences or adverse events over the course of treatment as well as to what extent the negative event had affected the adolescent's wellbeing.

Amount of therapist time per participant was logged automatically through the Internet-treatment platform.

Procedure

Figure 1 gives an overview of inclusion procedures and assessment points. Families who applied to the study were contacted by telephone and a short screening interview was conducted. Eligible families were invited to diagnostic assessment at the clinic. After thorough information about the study, adolescents gave verbal assent to participate and written informed consent was obtained from parents. The screening interview M.I.N.I. KID (with the supplement of the SAD section of the ADIS-C) was then conducted. The therapist who conducted the baseline assessment was responsible for the treatment of the participant.

Adolescents with a principal diagnosis of SAD were included and adolescents and parents completed baseline self-report measures online through the treatment platform. In each family, one of the parents was assigned the main responsibility to respond to the parent-report measures at each assessment point throughout the study. Adolescents and parents had separate user accounts and a two-factor authentication (an individual password and a single-use code sent to the user's cellular phone) gave access to the online platform.

Self- and parent rated measures administered during the treatment (SPAI C/P, SPWSS, RCADS C/P and EWSAS C/P) were completed online.

At post-treatment and at the 6-month follow-up all participating adolescents and parents were invited back to the clinic for a diagnostic assessment. To reduce the risk of biased assessment, a clinician that had not been responsible for the participant's treatment conducted the post-treatment and follow-up assessments. All self-assessment scales were administered online post-treatment and at follow-up. Families who could not come to the clinic for post-treatment assessment (n = 1) and 6-month follow-up (n = 3) were assessed over the telephone.

Insert Figure 1 here

Intervention

The intervention was 12 weeks of ICBT supplemented with group-exposure, comprising nine Internet-delivered modules completed individually from home, and three group-exposure sessions at the clinic (Table 2). The online treatment platform used in this study was developed for delivery of ICBT and has been tested in a number of previous studies for different psychiatric disorders in youth [22 28 44-46]. The current treatment (BIP SOFT) was based on the cognitive-behavioural model by Rapee and Heimberg[47] and to some extent on the cognitive model by Clark and Wells[48] . The treatment manual was developed by the authors and contains CBT components commonly used for SAD in youth[15 49 50], such as exposure, coping strategies and social skills training. The group sessions were mostly based on the Albano and DiBartolo group-CBT manual for adolescent SAD[50]. Therapists in the study were three clinical psychologists and two master students at their final year of training in clinical psychology.

The Internet-modules included educative texts, animations, audio clips and exercises. The parental part of the intervention consisted of five Internet-modules with parent-

specific topics such as “parental traps” (e.g., compensating for the adolescent in social situations by for instance speaking for him/her) and doing functional analyses of such parental accommodation (Table 2). Parents were encouraged to be actively involved in their adolescent’s treatment and discuss with the adolescent how they should support him or her throughout the treatment, e.g. during exposure exercises. Parents were also encouraged to bring up parent-specific topics with their therapist, for example how to support the adolescent before or during exposures. Parents could send messages to the therapist throughout the 12 weeks of treatment. Adolescents and parents were instructed to log in and complete one module each week. The modules were assigned in a predetermined order and therefore, all modules but the first were initially locked. Once the participant completed a module, the therapist made the next one available.

The therapists had asynchronous contact online with adolescents and parents every week, commenting on their progress on work sheets and through a built in message function. Therapists were instructed to log in and provide feedback to their families three times per week. If necessary, therapists had telephone contact with families, e.g., if they hadn’t logged in during the last week or if mid-treatment self-reports exceeded a cut-off for depression (>11 on RCADS-C depression subscale) or suicidality.

The group-exposure sessions (at week 4, 6 and 10) ensured that key components of the treatment were demonstrated in a correct way and that participants could practice e.g. exposure under observation of a therapist. To ensure large enough group sizes, cohorts of six participants started the treatment at the same time. The group sessions were two hours long and led by two of the clinical psychologists.

Insert Table 2 here

Statistical analysis

All analyses were conducted in SPSS Version 23.

Cohen's kappa coefficient (κ)[51] was used to calculate inter-rater reliability for SAD-diagnosis and comorbidity at pre-treatment assessment. The level of reliability is interpreted as poor when κ< 0.40, fair when κ is 0.40-0.59, good when κ is 0.60-0.74 and excellent when κ>0.74[52].

Linear mixed models were used to analyse changes from pre- to post-treatment, and from post-treatment to 6-month follow-up. Mixed model analyses use all available data and account for correlations between measurements within the same subject [53]. Thus, missing data is handled within the model. All mixed models in this study included a fixed effect for time (pre, post and 6-month follow-up) and a random effect for individual subjects. Potential missing bias was investigated using *t*-tests that compared the baseline characteristics of those who had complete data at post-treatment with those who had missing data. For SPAI C/P and SPWSS three mid-treatment (week 3, 6 and 9) time points were included in the analyses, and for RCADS C/P and EWSAS C/P one mid-treatment (week 6) time point was included in the analyses.

Effect sizes are reported as Cohen's $d = (M_1\text{-}M_2 / SD_{pooled})$. Effect sizes are defined according to Cohen's suggested levels, small ($d \geq 0.20$), moderate ($d \geq 0.50$) and large ($d \geq 0.80$) [54].

RESULTS

Response rate and feasibility

Mid-treatment measures were completed by 97% of the participating families at week three, 83% at week six and 70% at week nine. Post-treatment and 6-month follow-up measures were completed by 90% and 83% of the participating families, respectively. T-

tests comparing participants with missing versus complete data points on baseline characteristics revealed no statistically significant differences.

Adolescents completed on average 5.7 (*sd* =2.1) of the nine Internet-modules and parents completed on average 4.4 (*sd* =1.0) of their five modules. The frequency of completed modules by the adolescents was distributed as follows: 20% (n = 6) completed 2-3 modules, 43% (n = 13) completed 4-6 modules and 37% (n = 11) completed 7-9 modules. None completed fewer than two modules.

Attendance at the group-sessions were 70% (session 1), 77% (session 2) and 63% (session 3) respectively. Two thirds of the participants attended two or more group sessions and only 10% attended none.

None of the adolescents meeting inclusion criteria at baseline assessment declined participation, which indicates good acceptability of the offered treatment.

Figure 2 illustrates that a majority of the adolescents were satisfied with the treatment, would recommend the treatment to a friend and found the program easy to understand. Furthermore, most of the participating adolescents found the treatment's online platform easy to use, with a mean rating of 5.6 (range 4-7) on the 7-point TAS scale item (were 7 indicates full agreement with the statement "The program was easy to use").

Insert Figure 2 here

Clinician support

The average time a clinician spent giving feedback and guidance to participants (including time spent on the adolescent *and* parent) was 19.5 minutes per week for the Internet-modules. Group sessions required two hours of therapist time per participant

in total during the 12 weeks, which corresponds to 10 minutes per week and participant. In total thus, each family got 29.5 minutes of therapist time, per week.

Changes in clinical outcomes from pre- to post-treatment

Means, standard deviations and effect sizes for pre to post changes, are presented in Table 3. Intention-to-treat analyses of the primary outcome measure (CGI-S) showed a significant decrease of SAD severity from pre- to post-treatment, $t(26.05) = 5.62$, $p<.001$, with a large effect size, $d = 1.17$ (*95%CI* 0.61,1.72). For all secondary outcome measures, analyses revealed significant improvements with moderate to large effect sizes, with the exception of quality of life (KIDSCREEN-C/P) where a small effect was observed. At post-treatment, 47% of the participants ($n = 14$) no longer met diagnostic criteria for SAD, according to DSM-5 criteria and a CGI-rating <4 (level of severity and functional impairment below diagnostic threshold) and 30% ($n = 9$) scored ≤18 on SPAI-C (cut-off for clinical level of social anxiety). On the clinician rated CGI-I 8% ($n=2$) were "very much improved", 23% ($n = 6$) "much improved", 42% ($n = 11$) "minimally improved", 23% ($n = 6$) "not changed" and 4% ($n = 1$) "minimally worse".

Changes in clinical outcomes from post-treatment to 6-month follow-up

Table 3 gives an overview of means, standard deviations and effect sizes from post-treatment to the 6-month follow-up. The improvements seen at post-treatment were generally maintained and further augmented at the 6-month follow-up with small effect sizes, except for self-focus (SPWSS) that deteriorated slightly. The primary outcome measure (CGI-S) showed a significant decrease of SAD severity from post-treatment to 6-month follow up, $t(25.45) = 2.60$, $p<.05$, with a small effect size, $d = 0.22$ (*95%CI* -0.01,

0.45). At follow-up, 57% (*n* = 17) no longer met diagnostic criteria for SAD and 37% (*n* = 11) scored ≤18 on SPAI-C.

Comparison of pre-treatment and 6-month follow-up levels of social anxiety showed overall improvements with large effect-sizes, CGI-S: $t(27.23) = 6.24$, $p<.001$, $d = 1.36$ (*95%CI* 0.71, 2.01), SPAI-C: $t(27.63) = 5.50$, $p<.001$, $d = 0.95$ (*95%CI* 0.51, 1.39) and SPAI-P: $t(26.08) = 5.57$, $p<.001$, $d = 1.14$ (*95%CI* 0.57, 1.72). Clinician-rated CGI-I indicated that, of those who participated in the 6-month follow-up assessment, 19% (*n* = 5) were "very much improved", 31% (*n* = 8) "much improved", 38% (*n* = 10) "minimally improved", 4% (*n* = 1) "not changed" and 8% (*n* = 2) "minimally worse", compared to baseline.

Post-hoc analyses

The proportion of parents reporting that they had stayed home from work during the last month due to their adolescent's health problems was 27% before treatment and 13% at 6-month follow-up. Of the adolescents, 50% had stayed home from school during the last month due to health problems before treatment and 33% at 6-month follow-up. At 6-month follow-up, six participants reported that they had received additional treatment for social anxiety; two participants (7%) got CBT and four participants (13%) had initiated or increased SSRI medication. All these participants fulfilled diagnostic criteria for SAD at post treatment assessment and five out of six still fulfilled diagnostic criteria for SAD at follow-up.

Half of all participants (*n*=15) reported that they had used strategies from the treatment since post-treatment assessment, referring to exposure, coping strategies (such as breathing exercises and focus shift) and cognitive techniques as the most common ones.

Adverse events

Seven adolescents (23%) reported having experienced some negative event during the course of treatment. These events included increased stress due to the limited time to work with treatment modules (*n* =4; 13%), increased social anxiety (*n*=1; 3%), increased panic anxiety (*n*=1; 3%) and increased depression and negative thoughts (*n*=1; 3%). Those who reported increased stress and anxiety associated these symptoms with the first weeks of treatment and typically described a decrease as treatment continued. Two adolescents reported that the negative event (increased negative thoughts in one case and increased panic anxiety in the other case) still had some impact on their wellbeing at the end of treatment.

DISCUSSION

To our knowledge this is the first study evaluating the feasibility and efficacy of therapist- and parent-guided, Internet-delivered cognitive behavioural therapy (ICBT), supplemented with group-exposure sessions, for adolescents with SAD. The results suggest that such a combined treatment format is both feasible and potentially efficacious and that the improvements are maintained at least 6 months beyond treatment termination. Feasibility was indicated by the high proportion of participants who reported satisfaction with the program, and who would recommend it to a peer, as well as by the high attendance rate at group-sessions and good completion of online-sessions. The results showed substantial reductions of social anxiety symptoms on all clinician-, adolescent- and parent-rated measures at post treatment, as well as improvements in secondary outcomes such as overall anxiety and level of functioning. These symptom reductions were maintained or further improved at the 6-month follow-up.

The adolescents completed on average nearly two thirds of the 9 online-modules which is more than in previous studies on ICBT for youth with SAD where participants completed less than half of the modules on average[26 30]. It is possible that the face-to-face component (group-based exposure sessions) in the present study influenced the working pace with the Internet-modules as participants were recommended to complete the preceding modules before attending group sessions. Even if completion of previous modules was not a prerequisite for attendance at group sessions, participants tended to complete them before attending the sessions. Participants also had peer and therapist support in the group on aspects of the Internet-delivered modules that they found difficult (e.g., designing an idiosyncratic exposure hierarchy), which might have led to more motivation to work with modules *after* group sessions. It has been proposed that socially anxious children and adolescents have a tendency to avoid practicing skills on their own that they have learned online, such as conducting in-vivo exposure[30]. It could therefore be hypothesized that the group-sessions in this study enhanced the participants' inclination to practice skills at home as a consequence of being offered intensive therapist guidance and direct feedback during group-based exposure.

Forty seven per cent of participants no longer met diagnostic criteria for SAD after treatment, a proportion that further increased to 57% at 6-month follow-up. This is in line with levels reported in studies evaluating face-to-face CBT for youth with SAD [15 49 55-57] and higher than strictly Internet-delivered CBT for youth with SAD[30]. A recent trial of ICBT for youth with SAD reported a relatively limited impact on the clinical diagnosis of SAD (in the two active treatment conditions 12.8 and 14.6% at post-treatment and 29.8% and 35.4 % at 6-month follow-up, no longer met diagnostic criteria for SAD)[30] and the authors suggest that stand-alone ICBT might not be enough for youth with SAD[30]. It is tempting to attribute the better outcomes in our trial to the addition of

group-based exposure sessions to the ICBT protocol, though this hypothesis remains to be formally evaluated. Discrepancies between our and previous results may also be attributable to differences in study samples, study design or other methodological aspects.

Therapists in this study spent less than 20 minutes per family and week, on the Internet-delivered treatment, which is comparable to previous ICBT trials for youth[21 22]. Although the group sessions added another 10 minutes per family and week in the present trial, group-exposure supplemented ICBT should still be considered a time-efficient intervention compared with face-to-face CBT where the therapist time per family and week usually ranges from 45-60 minutes.

Around a fifth of the participants reported a negative event during the course of the treatment. Some of the events were expected, such as increased social anxiety when exposure was initiated. Reports of increased stress were also associated with the first weeks of the treatment and can be interpreted as an initial difficulty combining treatment with other demands such as schoolwork. Two participants reported having experienced some negative events that affected their wellbeing beyond the treatment termination but these participants still benefited from treatment.

Overall, the treatment seems feasible and possibly efficacious for adolescents with SAD and their parents, but to be considered for implementation in regular care, an intervention must also be feasible from an organizational point of view. A possible drawback with the addition of group-exposure to ICBT is that it limits the flexibility of the intervention. For instance, several patients must be recruited and able to commence treatment at the same time. SAD is a challenging disorder to treat and interventions aspiring to be effective may need to include direct and frequent therapist guidance. On the other hand, development of new treatments should not only consider treatment

efficacy, but also accessibility, flexibility and cost effectiveness. A possible alternative to group-based exposure sessions is to add other forms of direct communication between patients and ICBT-therapists, e.g. video conferencing or equivalent, something that future studies should investigate further.

Limitations

Although this feasibility trial has several strengths, some important limitations need to be considered when interpreting the results. Causal inferences of observed changes are not possible due to lack of a control condition. Thus, improvement could be an effect of non-specific factors such as the therapist attention or of the passage of time. However, SAD has been shown to commonly follow a chronic course when left untreated[2] and it is not likely that spontaneous remission would explain a significant part of the improvements in the study. Additionally, results were maintained and slightly improved at follow-up, indicating that treatment gains were stable over time, even after the attention from a therapist had ceased. A small proportion of the participants did seek additional care between post-treatment and 6-month follow-up, which could have affected the results. However, these participants continued to report high levels of social anxiety at follow-up, implying that additional care had limited impact on the long-term outcome. Although social anxiety is generally more common among women, the current sample had an overrepresentation of girls. The effect of gender on the results in this trial is unclear and may be further analyzed in future trials with larger samples.

Another limitation concerns assessment at post-treatment and follow-up. Although attempts to reduce bias were made by having these assessments conducted by clinicians not involved in the treatment, assessors were not blind to the fact that the participant had received treatment.

Conclusions

This is the first study of therapist- and parent-guided ICBT supplemented with group-exposure for adolescents with SAD. The intervention was highly acceptable to the families and significantly reduced social anxiety symptoms up to 6-month follow-up. Participants were generally satisfied with the treatment and the completion-rate of Internet-modules and attendance at group sessions were high, indicating that the treatment is feasible and acceptable to the SAD youth population. Furthermore, per-patient therapist time was limited, even considering the time spent on group-sessions; thus, ICBT supplemented with group-based exposure sessions might be cost-effective when compared to traditional face-to-face CBT. Further controlled trials are needed.

Acknowledgements The authors would like to thank Ulrika Thulin for invaluable help with writing the treatment modules, and Cornelia Hanqvist and Jon Juselius for assisting with providing the treatment.

Contributors The study was designed by MN, SV, DMC, ES and JH. MN was the project manager in collaboration with JH. MN wrote the treatment modules and provided the treatment in collaboration with JH and SV. All statistical analyses were conducted by JH and MN. MN drafted the manuscript in collaboration with JH. The manuscript was reviewed and revised by SV, ES, DMC, BL and LGÖ. All authors have read and approved the final manuscript.

Funding This work was supported by the Stockholm County Council (PPG project 20150032; HSNV 140 99; HSN 1011-1176) and the Swedish Research Council and Swedish Research Council for Health, Working Life and Welfare (Forte 2014-4052)

Competing interests None.

Data sharing statement No additional data are available.

References

1. Association AP. Diagnostic and statistical manual of mental disorders (DSM-5®): American Psychiatric Pub 2013.
2. Burstein M, He JP, Kattan G, et al. Social phobia and subtypes in the national comorbidity survey-adolescent supplement: prevalence, correlates, and comorbidity. *J Am Acad Child Adolesc Psychiatry* 2011;50(9):870-80. doi: 10.1016/j.jaac.2011.06.005
3. Lawrence D, Johnson S, Hafekost J, et al. The Mental Health of Children and Adolescents: Report on the Second Australian Child and Adolescent Survey of Mental Health and Wellbeing. 2015
4. Beesdo K, Bittner A, Pine DS, et al. Incidence of social anxiety disorder and the consistent risk for secondary depression in the first three decades of life. *Arch Gen Psychiatry* 2007;64(8):903-12.
5. Katzelnick DJ, Kobak KA, DeLeire T, et al. Impact of generalized social anxiety disorder in managed care. *Am J Psychiatry* 2001;158(12):1999-2007.
6. Buckner JD, Schmidt NB, Lang AR, et al. Specificity of social anxiety disorder as a risk factor for alcohol and cannabis dependence. *J Psychiatr Res* 2008;42(3):230-39.
7. Beidel DC, Turner SM, Morris TL. Psychopathology of childhood social phobia. *J Am Acad Child Adolesc Psychiatry* 1999;38(6):643-50. doi: 10.1097/00004583-199906000-00010
8. Acarturk C, Smit F, De Graaf R, et al. Economic costs of social phobia: a population-based study. *J Affect Disord* 2009;115(3):421-29.
9. Patel A, Knapp M, Henderson J, et al. The economic consequences of social phobia. *J Affect Disord* 2002;68(2):221-33.
10. Hofmann SG, Smits JA. Cognitive-behavioral therapy for adult anxiety disorders: a meta-analysis of randomized placebo-controlled trials. *J Clin Psychiatry* 2008;69(4):621.
11. Scaini S, Belotti R, Ogliari A, et al. A comprehensive meta-analysis of cognitive-behavioral interventions for social anxiety disorder in children and adolescents. *J Anxiety Disord* 2016;42:105-12. doi: 10.1016/j.janxdis.2016.05.008
12. Segool NK, Carlson JS. Efficacy of cognitive‐behavioral and pharmacological treatments for children with social anxiety. *Depress Anxiety* 2008;25(7):620-31.
13. Pilling S, Mayo-Wilson E, Mavranezouli I, et al. Recognition, assessment and treatment of social anxiety disorder: summary of NICE guidance. *BMJ* 2013;346:f2541.
14. Hudson JL, Rapee RM, Lyneham HJ, et al. Comparing outcomes for children with different anxiety disorders following cognitive behavioural therapy. *Behav Res Ther* 2015;72:30-37. doi: http://dx.doi.org/10.1016/j.brat.2015.06.007
15. Beidel DC, Turner SM, Morris TL. Behavioral treatment of childhood social phobia. *J Consult Clin Psychol* 2000;68(6):1072-80.
16. Beidel DC, Turner SM, Sallee FR, et al. SET-C versus fluoxetine in the treatment of childhood social phobia. *J Am Acad Child Adolesc Psychiatry* 2007;46(12):1622-32. doi: 10.1097/chi.0b013e318154bb57
17. Essau CA, Conradt J, Petermann F. Frequency and comorbidity of social phobia and social fears in adolescents. *Behav Res Ther* 1999;37(9):831-43.
18. Wittchen HU, Stein MB, Kessler RC. Social fears and social phobia in a community sample of adolescents and young adults: prevalence, risk factors and co-morbidity. *Psychol Med* 1999;29(2):309-23. doi: 10.1017/s0033291798008174

19. Merikangas KR, He J-p, Burstein M, et al. Service utilization for lifetime mental disorders in US adolescents: Results of the National Comorbidity Survey–Adolescent Supplement (NCS-A). *J Am Acad Child Adolesc Psychiatry* 2011;50(1):32-45.
20. Hedman E, Andersson E, Ljotsson B, et al. Cost-effectiveness of Internet-based cognitive behavior therapy vs. cognitive behavioral group therapy for social anxiety disorder: results from a randomized controlled trial. *Behav Res Ther* 2011;49(11):729-36. doi: 10.1016/j.brat.2011.07.009
21. Lenhard F, Andersson E, Mataix-Cols D, et al. Therapist-Guided, Internet-Delivered Cognitive-Behavioral Therapy for Adolescents With Obsessive-Compulsive Disorder: A Randomized Controlled Trial. *J Am Acad Child Adolesc Psychiatry* 2017;56(1):10-19.e2. doi: 10.1016/j.jaac.2016.09.515
22. Lenhard F, Vigerland S, Andersson E, et al. Internet-delivered cognitive behavior therapy for adolescents with obsessive-compulsive disorder: an open trial. *PLoS One* 2014;9(6):e100773. doi: 10.1371/journal.pone.0100773
23. Hedman E, Ljótsson B, Lindefors N. Cognitive behavior therapy via the Internet: a systematic review of applications, clinical efficacy and cost–effectiveness. *Expert Rev Pharmacoecon Outcomes Res* 2012;12(6):745-64.
24. Hedman E, Andersson G, Ljotsson B, et al. Internet-based cognitive behavior therapy vs. cognitive behavioral group therapy for social anxiety disorder: a randomized controlled non-inferiority trial. *PLoS One* 2011;6(3):e18001. doi: 10.1371/journal.pone.0018001
25. March S, Spence SH, Donovan CL. The efficacy of an internet-based cognitive-behavioral therapy intervention for child anxiety disorders. *J Pediatr Psychol* 2009;34(5):474-87.
26. Tillfors M, Andersson G, Ekselius L, et al. A randomized trial of Internet-delivered treatment for social anxiety disorder in high school students. *Cogn Behav Ther* 2011;40(2):147-57. doi: 10.1080/16506073.2011.555486
27. Donovan CL, March S. Online CBT for preschool anxiety disorders: a randomised control trial. *Behav Res Ther* 2014;58:24-35.
28. Vigerland S, Ljótsson B, Thulin U, et al. Internet-delivered cognitive behavioural therapy for children with anxiety disorders: A randomised controlled trial. *Behav Res Ther* 2016;76:47-56.
29. Spence SH, Donovan CL, March S, et al. A randomized controlled trial of online versus clinic-based CBT for adolescent anxiety. *J Consult Clin Psychol* 2011;79(5):629-42. doi: 10.1037/a0024512
30. Spence SH, Donovan CL, March S, et al. Generic versus disorder specific cognitive behavior therapy for social anxiety disorder in youth: A randomized controlled trial using internet delivery. *Behav Res Ther* 2017;90:41-57. doi: 10.1016/j.brat.2016.12.003
31. Guy W. Clinical global impression scale. *The ECDEU Assessment Manual for Psychopharmacology-Revised Volume DHEW Publ No ADM* 1976;76(338):218-22.
32. Sheehan DV, Lecrubier Y, Sheehan KH, et al. The Mini-International Neuropsychiatric Interview (M.I.N.I.): the development and validation of a structured diagnostic psychiatric interview for DSM-IV and ICD-10. *J Clin Psychiatry* 1998;59 Suppl 20:22-33;quiz 34-57.
33. Albano A, Silverman W. The Anxiety Disorders Interview Schedule for Children for DSM-IV: clinician manual (child and parent versions). *San Antonio, TX: Psychological Corporation* 1996

34. Shaffer D, Gould MS, Brasic J, et al. A children's global assessment scale (CGAS). *Arch Gen Psychiatry* 1983;40(11):1228-31.
35. Beidel DC, Turner SM, Morris TL. A new inventory to assess childhood social anxiety and phobia - the social phobia and anxiety inventory for children *Psychol Assess* 1995;7(1):73-79. doi: 10.1037/1040-3590.7.1.73
36. Clark DM, Ehlers A, McManus F, et al. Cognitive therapy versus fluoxetine in generalized social phobia: a randomized placebo-controlled trial. *J Consult Clin Psychol* 2003;71(6):1058.
37. Hedman E, Mörtberg E, Hesser H, et al. Mediators in psychological treatment of social anxiety disorder: Individual cognitive therapy compared to cognitive behavioral group therapy. *Behav Res Ther* 2013;51(10):696-705.
38. Chorpita BF, Yim L, Moffitt C, et al. Assessment of symptoms of DSM-IV anxiety and depression in children: a revised child anxiety and depression scale. *Behav Res Ther* 2000;38(8):835-55.
39. Mundt JC, Marks IM, Shear MK, et al. The Work and Social Adjustment Scale: a simple measure of impairment in functioning. *Br J Psychiatry* 2002;180:461-4.
40. Mataix-Cols D, Cowley AJ, Hankins M, et al. Reliability and validity of the Work and Social Adjustment Scale in phobic disorders. *Compr Psychiatry* 2005;46(3):223-28.
41. Ravens-Sieberer U, Gosch A, Rajmil L, et al. KIDSCREEN-52 quality-of-life measure for children and adolescents. *Expert Rev Pharmacoecon Outcomes Res* 2005;5(3):353-64.
42. Bouwmans C, De Jong K, Timman R, et al. Feasibility, reliability and validity of a questionnaire on healthcare consumption and productivity loss in patients with a psychiatric disorder (TiC-P). *BMC Health Serv Res* 2013;13(1):1.
43. Venkatesh V, Morris MG, Davis GB, et al. User acceptance of information technology: Toward a unified view. *MIS quarterly* 2003:425-78.
44. Bonnert M, Olen O, Lalouni M, et al. Internet-Delivered Cognitive Behavior Therapy for Adolescents With Irritable Bowel Syndrome: A Randomized Controlled Trial. *Am J Gastroenterol* 2016 doi: 10.1038/ajg.2016.503
45. Lenhard F, Vigerland S, Andersson E, et al. Internet-delivered cognitive behavior therapy for adolescents with obsessive-compulsive disorder: an open trial. *PLoS One* 2014;9(6):e100773.
46. Vigerland S, Thulin U, Ljotsson B, et al. Internet-delivered CBT for children with specific phobia: a pilot study. *Cogn Behav Ther* 2013;42(4):303-14. doi: 10.1080/16506073.2013.844201
47. Rapee RM, Heimberg RG. A cognitive-behavioral model of anxiety in social phobia. *Behav Res Ther* 1997;35(8):741-56.
48. Clark DM, Wells A. A cognitive model of social phobia. *Social phobia: Diagnosis, assessment, and treatment* 1995;41(68):00022-3.
49. Albano AM, Marten PA, Holt CS, et al. Cognitive-Behavioral Group Treatment for Social Phobia in Adolescents A Preliminary Study. *J Nerv Ment Dis* 1995;183(10):649-56.
50. Albano AM, DiBartolo PM. Cognitive-Behavioral Therapy for Social Phobia in Adolescents: Stand Up, Speak Out Therapist Guide: Oxford University Press 2007.
51. Cohen J. A coefficient of agreement for nominal scales. Educational and Psychosocial Measurement, 20, 37-46, 1960.
52. Mannuzza S, Fyer AJ, Martin LY, et al. Reliability of anxiety assessment. I. Diagnostic agreement. *Arch Gen Psychiatry* 1989;46(12):1093-101.

53. Gueorguieva R, Krystal JH. Move over ANOVA: progress in analyzing repeated-measures data and its reflection in papers published in the Archives of General Psychiatry. *Arch Gen Psychiatry* 2004;61(3):310-7. doi: 10.1001/archpsyc.61.3.310
54. Cohen J. A power primer. *Psychol Bull* 1992;112(1):155.
55. Hayward C, Varady S, Albano AM, et al. Cognitive-behavioral group therapy for social phobia in female adolescents: results of a pilot study. *J Am Acad Child Adolesc Psychiatry* 2000;39(6):721-26.
56. Spence SH, Donovan C, Brechman‐Toussaint M. The treatment of childhood social phobia: The effectiveness of a social skills training‐based, cognitive‐behavioural intervention, with and without parental involvement. *J Child Psychol Psychiatry* 2000;41(6):713-26.
57. Öst L-G, Cederlund R, Reuterskiöld L. Behavioral treatment of social phobia in youth: Does parent education training improve the outcome? *Behav Res Ther* 2015;67:19-29.

Table 1. Demographic and clinical features of study participants (*N* = 30)

Variables		*N*	%
Age (years)	*M (SD)*	15 (1.22)	
	min-max	13-17	
Gender	Girls	25	83
	Boys	5	17
Country of birth, adolescent	Sweden	29	97
	Other	1	3
Country of birth, parents	Both in Sweden	20	67
	One in Sweden	7	23
	None in Sweden	3	10
Education, responding parent	Primary	14	47
	Higher	16	53
Employment, responding parent	Working	25	83
	Unemployed	4	13
	Retired	1	3
Psychotropic medication pre-treatment	None	27	90
	SSRI	3	10
Prior psychological treatment	None	11	37
	Primary care, counseling or equivalent	4	13
	Psychiatric specialist care or equivalent	14	47
Referred from child health services		6	20
Comorbid diagnoses	Specific Phobia	8	26.7
	GAD	5	16.7
	ADD	3	10
	Depression	2	6.7
	OCD	2	6.7
	Panic disorder	1	3.3
	Tics/Tourette	1	3.3
	Separation anxiety	1	3.3
	Trichotillomania	1	3.3
Frequency of comorbid diagnoses	None	13	43.3
	One	11	36.7
	Two	3	10
	Three or more	3	10
Onset (age in years)	M (SD)	8.9 (4.29)	
Duration of SAD (years)	M (SD)	6.2 (4.05)	

Note: Primary education ≤12. Higher education >12 years.
Abbreviations: GAD = generalized anxiety disorder; ADD = attention deficit disorder; OCD = obsessive compulsive disorder.

Table 2. An overview of the content of the ICBT protocol and group-exposure sessions

Chapter	Adolescent	Parent	Group-exposure sessions
1	Introduction to ICBT, Learn about emotions, fear and social anxiety. How to do functional analyses of my own behavior	Introduction to ICBT. Learn about emotions, fear and social anxiety. How to do functional analyses of my teenager's behavior and my own reactions.	
2	More about social anxiety disorder. Learn to reduce self-focus and safety behaviors. Improve coping strategies.	Suggest treatment goals. Plan the treatment. Learn about exposure and how to be a co-therapist during exposure.	
3	Map the social anxiety. Learn about exposure to social situations. Set treatment goals and build an individual exposure hierarchy.	Learn about common parental challenges. How to reward my adolescent. Problem solving.	
4		How to handle negative thoughts. Learn about social skills.	Modelling and practice of social skills. Modelling and mapping of safety behaviors and how to reduce them. Set an individual exposure hierarchy. Exposure in vivo. Summary with parents.
5	Exposure follow-up. Learn about negative thoughts and how to handle them.	Prepare relapse prevention. Evaluation of parent modules and treatment.	
6			Repetition of treatment components. Exposure in vivo. Summary with parents.
7	Exposure follow-up. Extended practice of focus shift.		
8	Exposure follow-up. Negative thoughts follow-up. Problem solving.		
9	Exposure follow-up. Learn how to say no and other self-assertive behaviors.		
10			Exposure in vivo. Social mishaps in public environment. Summary with parents.
11	Exposure follow-up. Last sprint: how to get the most out of the last exposures.		
12	Make a plan for relapse prevention. What did I learn? What do I want to practice further? Make an evaluation of the treatment.		

Table 3 Means, standard deviations, pre- to post and post to 6-month follow-up comparisons, and effect sizes of all outcome measures

	Pre		Post		Pre to post comparison		6-month follow-up		Post to follow-up comparison	
Measure	**M**	**SD**	**M**	**SD**	***p***	***d* (95% CI)**	**M**	**SD**	***p***	***d* (95%CI)**
Clinician-rated										
CGI-S	4.6	0.72	3.3	1.3	<.001	1.17 (0.61,1.72)	3.0	1.43	.015	0.22 (-0.01, 0.45)
C-GAS	55.5	6.68	62.0	8.85	<.001	0.80 (0.40, 1.21)	65.4	11.14	<.001	0.30 (0.13, 0.46)
Self- and parent rated social anixety										
SPAI-C	33.4	9.32	24.5	11.31	<.001	0.85 (0.36, 1.34)	21.5	11.24	.023	0.27 (0.02, 0.51)
SPAI-P	35.3	8.46	27.2	11.55	<.001	0.79 (0.29, 1.28)	25.7	11.01	n.s.	
SPWSS avoid	4.0	2.38	1.9	2.22	<.001	0.91 (0.36, 1.47)	1.8	1.81	<.001	0.05 (-0.4, 0.5)
SPWSS s-f	4.9	1.74	2.8	1.44	<.001	1.31 (0.61, 2.02)	3.3	2.03	<.001	-0.28 (-0.83-0.26)
SPWSS a a	4.9	1.85	3.0	2.19	<.001	0.94 (0.32, 1.55)	2.4	1.92	<.001	0.29 (-0.18-0.76)
SPWSS pep	4.8	2.29	3.6	1.77	<.001	0.58 (0.02-1.15)	3.3	2.30	<.001	0.14 (-0.36-0.65)
Other self- and parent rated measures										
RCADS-C SAD	18.5	5.69	14.2	5.87	<.001	0.74 (0.36, 1.13)	12.4	6.16	.018	0.30(0.05, 0.55)
RCADS-P SAD	16.4	5.88	13.2	5.70	.006	0.55 (0.09, 1.01)	12.3	6.07	n.s.	
RCADS-C	60.0	24.77	42.1	21.74	<.001	0.76 (0.32, 1.21)	38.4	25.92	n.s.	
RCADS-P	46.2	23.39	35.2	19.13	.005	0.51 (0.11, 0.91)	31.8	22.31	n.s.	
KIDSCREEN-C	32.2	5.59	34.1	6.07	.036	0.32 (0.06, 0.59)	35.7	6.93	n.s.	
KIDSCREEN-P	33.1	4.50	35.5	5.98	.025	0.44 (0.06, 0.82)	35.8	5.85	n.s.	
EWSAS-C	15.0	7.47	10.9	6.69	.006	0.58 (0.14, 1.01)	7.8	5.28	.004	0.50 (0.1, 0.91)
EWSAS-P	14.6	6.51	11.4	6.88	.002	0.48 (0.13, 0.83)	9.1	7.44	.002	0.31 (0.1, 0.54)

Abbreviations: CGI-S = The Clinical Global Impression – Severity, C-GAS = Children's Global Assessment Scale, SPAI-C/P = Social Phobia and Anxiety Inventory - Child and Parent Version, SPWSS = The Social Phobia Weekly Summary Scale, SPWSS avoid = avoidance, s-f = self-focus, a.a = anticipatory anxiety, pep = post event-processing, RCADS-C/P = The Revised Children Anxiety And Depression Scale – Child and Parent Version, RCADS-C/P SAD = The Revised Children Anxiety And Depression Scale – Child and Parent Version, SAD subscale, KIDSCREEN-C/P = The Health related quality of life questionnaire for children, adolescents and their parents, EWSAS-C/P = The Education, Work and Social Adjustment Scale – Child and Parent Version

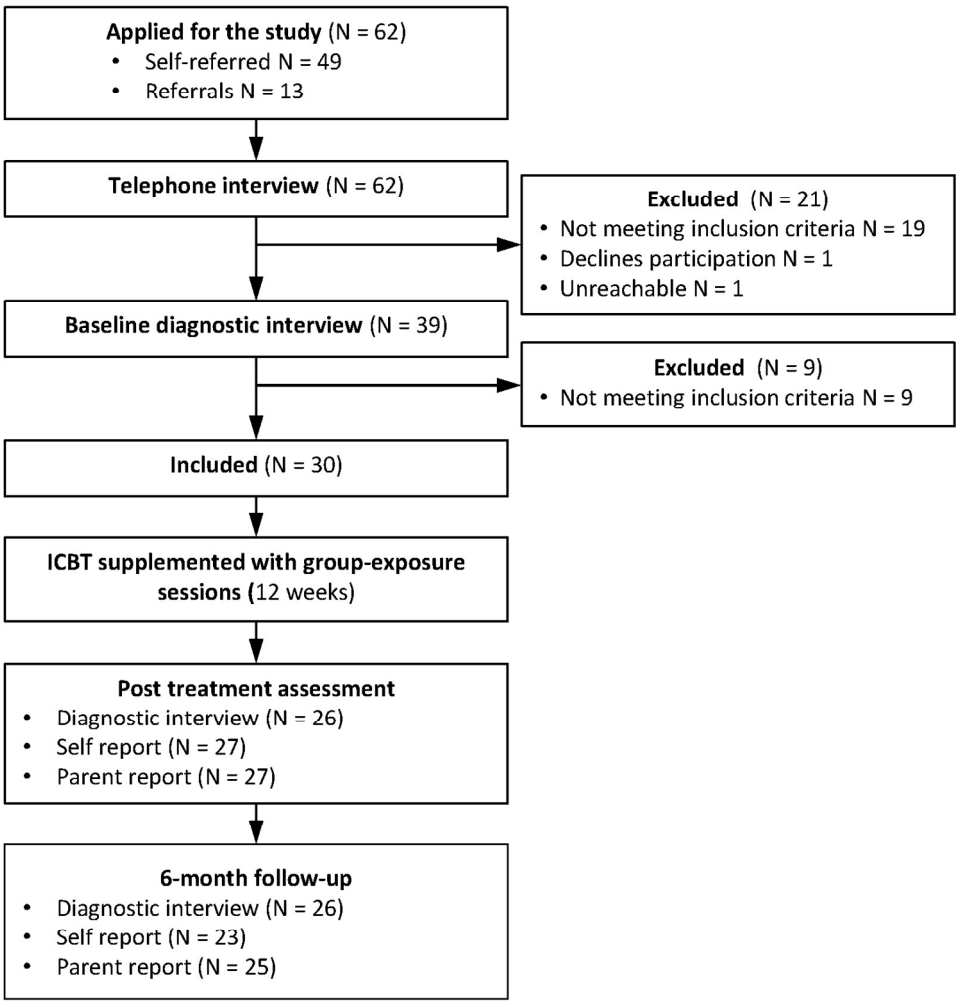


Figure 1. Study flow chart

143x149mm (300 x 300 DPI)

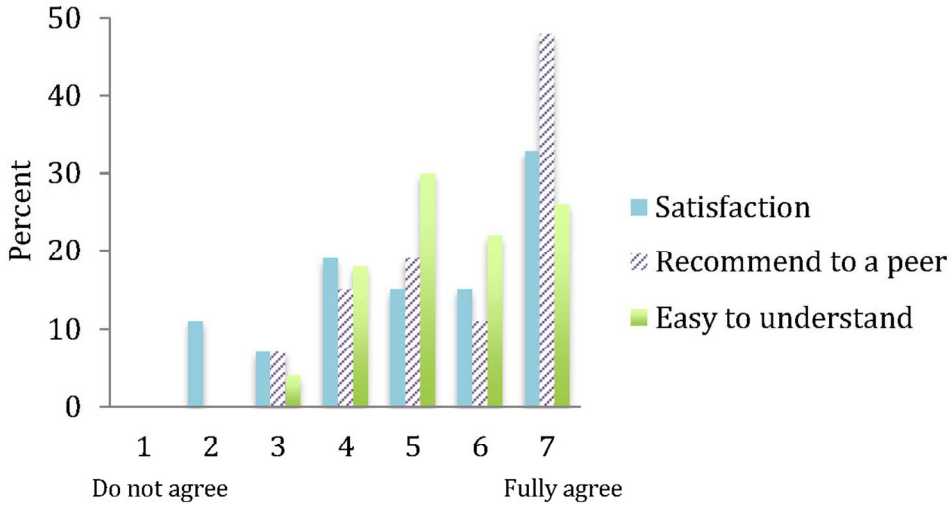


Figure 2. Adolescents' evaluation of BIP SOFT

112x64mm (300 x 300 DPI)

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
Title and abstract			
1a	Identification as a randomised trial in the title	Identification as a pilot or feasibility randomised trial in the title	1
1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	2-3
Introduction			
Background and objectives:			
2a	Scientific background and explanation of rationale	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	3-5
2b	Specific objectives or hypotheses	Specific objectives or research questions for pilot trial	5
Methods			
Trial design:			

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
3a	Description of trial design (such as parallel, factorial) including allocation ratio	Description of pilot trial design (such as parallel, factorial) including allocation ratio	2
3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	NA
Participants:			
4a	Eligibility criteria for participants		5-6
4b	Settings and locations where the data were collected		5
4c		How participants were identified and consented	6,9
Interventions:			
5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered		10-11
Outcomes:			

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	6-9
6b	Any changes to trial outcomes after the trial commenced, with reasons	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	NA
6c		If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	NA
Sample size:			
7a	How sample size was determined	Rationale for numbers in the pilot trial	6
7b	When applicable, explanation of any interim analyses and stopping guidelines		NA
Randomisation:			

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
Sequence generation:			
8a	Method used to generate the random allocation sequence		NA
8b	Type of randomisation; details of any restriction (such as blocking and block size)	Type of randomisation(s); details of any restriction (such as blocking and block size)	NA
Allocation concealment mechanism:			
9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned		NA
Implementation:			
10	Who generated the random allocation sequence, enrolled participants, and assigned participants to interventions		NA
Blinding:			

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
11a	If done, who was blinded after assignment to interventions (eg, participants, care providers, those assessing outcomes) and how		NA
11b	If relevant, description of the similarity of interventions		NA
Analytical methods:			
12a	Statistical methods used to compare groups for primary and secondary outcomes	Methods used to address each pilot trial objective whether qualitative or quantitative	12
12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Not applicable	NA
Results			
Participant flow (a diagram is strongly recommended):			
13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received	10

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
	primary outcome	intended treatment, and were assessed for each objective	
13b	For each group, losses and exclusions after randomisation, together with reasons		NA
Recruitment:			
14a	Dates defining the periods of recruitment and follow-up		5
14b	Why the trial ended or was stopped	Why the pilot trial ended or was stopped	NA
Baseline data:			
15	A table showing baseline demographic and clinical characteristics for each group		6
Numbers analysed:			
16	For each group, number of participants (denominator) included in each analysis and whether the	For each objective, number of participants (denominator) included in each analysis. If relevant, these	12

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
	analysis was by original assigned groups	numbers should be by randomised group	
Outcomes and estimation:			
17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	27
17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not applicable	NA
Ancillary analyses:			
18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory	Results of any other analyses performed that could be used to inform the future definitive trial	15
Harms:			
19	All important harms or unintended		16

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
	effects in each group (for specific guidance see CONSORT for harms)		
19a		If relevant, other important unintended consequences	NA
Discussion			
Limitations:			
20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	19
Generalisability:			
21	Generalisability (external validity, applicability) of the trial findings	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	19
Interpretation:			
22	Interpretation consistent with results, balancing benefits and harms, and	Interpretation consistent with pilot trial objectives and findings,	20

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
	considering other relevant evidence	balancing potential benefits and harms, and considering other relevant evidence	
22a		Implications for progression from pilot to future definitive trial, including any proposed amendments	18-19
Other information			
Registration:			
23	Registration number and name of trial registry	Registration number for pilot trial and name of trial registry	3
Protocol:			
24	Where the full trial protocol can be accessed, if available	Where the pilot trial protocol can be accessed, if available	NA
Funding:			
25	Sources of funding and other support (such as supply of drugs), role of funders		20
26		Ethical approval or approval by	5

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
		research review committee, confirmed with reference number	

BMJ Open

Therapist-guided Internet-delivered cognitive behavioural therapy supplemented with group-exposure sessions for adolescents with social anxiety disorder: a feasibility trial

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2017-018345.R2
Article Type:	Research
Date Submitted by the Author:	04-Oct-2017
Complete List of Authors:	Nordh, Martina; Karolinska Institutet Department of Clinical Neuroscience, Center for Psychiatry Research; Stockholms Lans Landsting, Stockholm health care services Vigerland, Sarah; Karolinska Institutet Department of Clinical Neuroscience, Center for Psychiatry Research; Stockholms Lans Landsting, Stockholm health care services Öst, Lars-Göran; Stockholms Universitet, Department of psychology; Karolinska Institutet Department of Clinical Neuroscience Ljótsson, Brjánn; Karolinska Institutet Department of Clinical Neuroscience, Center for Psychiatry Research; Stockholms Lans Landsting, Stockholm health care services Mataix-Cols, David; Karolinska Institutet Department of Clinical Neuroscience, Center for Psychiatry Research; Stockholms Lans Landsting, Stockholm health care services Serlachius , Eva ; Karolinska Institutet Department of Clinical Neuroscience, Center for Psychiatry Research; Stockholms Lans Landsting, Stockholm health care services Högström, Jens; Karolinska Institutet Department of Clinical Neuroscience, Center for Psychiatry Research; Stockholms Lans Landsting, Stockholm health care services
Primary Subject Heading:	Mental health
Secondary Subject Heading:	Health services research
Keywords:	Child & adolescent psychiatry < PSYCHIATRY, Anxiety disorders < PSYCHIATRY, MENTAL HEALTH

Word count
Abstract: 273
Main text: 4820
Tables: 3 Figures: 2

Therapist-guided Internet-delivered cognitive behavioural therapy supplemented with group-exposure sessions for adolescents with social anxiety disorder: a feasibility trial

Martina Nordh[1,2], Sarah Vigerland[1,2], Lars-Göran Öst[3,4], Brjánn Ljótsson[1,4], David Mataix-Cols[1,2], Eva Serlachius[1,2], Jens Högström[1,2]

Author affiliations:
[1]Centre for Psychiatry Research, Department of Clinical Neuroscience, Karolinska Institutet, Stockholm, Sweden

[2]Stockholm Health Care Services, Stockholm County Council, Stockholm, Sweden

[3]Department of psychology, Stockholm University, Stockholm, Sweden

[4]Department of Clinical Neuroscience, Division of psychology, Karolinska Institutet, Stockholm, Sweden

Correspondance to:
Martina Nordh
E-mail: martina.nord@ki.se

Address:
Child and Adolescent Psychiatry Research Center
Gävlegatan 22
113 30 Stockholm
Sweden

Phone: +46 08 514 522 15

ABSTRACT

Objectives: Social anxiety disorder (SAD) is one of the most common psychiatric disorders in youth, with a prevalence of about 3-4%, and increased risk of adverse long-term outcomes, such as depression. Cognitive behavioural therapy (CBT) is considered the first-line treatment for youth with SAD but many adolescents remain untreated due to limited accessibility to CBT. The aim of this study was to develop and evaluate the feasibility and preliminary efficacy of a therapist-guided Internet-delivered CBT treatment, supplemented with clinic-based group-exposure sessions (BIP SOFT).

Design: A proof-of-concept, open clinical trial with 6-month follow-up.

Participants: The trial was conducted at a child and adolescent psychiatric research clinic and participants (*N* = 30) were 13-17 years old (83% girls) with a principal diagnosis of SAD.

Intervention: 12 weeks of intervention, consisting of nine remote therapist-guided Internet-delivered CBT sessions and three group-exposure sessions at the clinic for the adolescents and five internet-delivered sessions for the parents.

Results: Adolescents were generally satisfied with the treatment and the completion-rate of Internet-modules, as well as attendance at group-sessions, was high. Post-treatment assessment showed a significant decrease in clinician-, adolescent-, and parent-rated social anxiety (*d* = 1.17, 0.85, and 0.79, respectively), as well as in general self- and parent-rated anxiety and depression (*d* = 0.76 and 0.51), compared with pre-treatment levels. Furthermore, 47% of participants no longer met DSM-5 criteria for SAD at post-treatment. At a 6-month follow-up, symptom reductions were maintained, or further improved, and 57% of participants no longer met criteria for SAD.

Conclusion: Therapist- and parent guided Internet-delivered CBT, supplemented with a limited number of group-exposure sessions is a feasible and promising intervention for adolescents with SAD.

Trial registration number: Clinicaltrials.gov registration ID NCT02576171

Strengths and limitations of this study

- This is the first study to investigate the feasibility and efficacy of a combined Internet-CBT and group-exposure treatment for youth with social anxiety disorder.
- Participants were followed up six months after the end of treatment.
- The study was uncontrolled which limits any causal inference about observed changes.

INTRODUCTION

Social anxiety disorder (SAD) is characterized by an intense fear of being scrutinized and negatively evaluated in social or performance situations[1]. The socially anxious individual is typically afraid of making mistakes, being embarrassed in front of others and of showing signs of anxiety, such as blushing or trembling, and may therefore avoid social and performance situations or endure them under intense distress. The disorder has a median age of onset of 9.2 years [2] and is one of the most common mental disorders among adolescents. SAD is more common in adolescent girls than in adolescent boys with a female to male odds ratio of 1.58 (*95%CI*: 1.18-2.12)[2]. The 12-month prevalence is 3.4% [3] and 8.6% of the adolescent population fulfill diagnostic criteria at some point between the age of 13 and 18[2]. If the disorder is left untreated it tends to follow a chronic course[2] and can lead to severe secondary consequences such as depression[4] and

suicidality[5], substance and alcohol dependence[6], academic underperformance and increased social isolation[7]. Consequently, SAD causes substantial impairment as well as burden on patients' families and long-term societal costs [8 9].

Cognitive behavioural therapy (CBT) for SAD is effective for adults [10] as well as for children and adolescents [11 12] and is the first-line treatment according to international clinical guidelines (e.g., the National Institute for Health and Care Excellence; NICE) [13]. In face-to-face treatment, generic CBT has shown poorer outcomes for youth with SAD compared to other anxiety disorders[14], but when treatments have been tailored to include SAD-specific components, such as social skills training, the reported effects have been larger[15 16].

Despite the high level of impairment caused by the disorder, only a small proportion of adolescents with social anxiety seek help for their problems [17 18] and even fewer receive effective treatment [19]. Barriers to receiving evidence-based psychological treatment include limited availability of trained therapists, and practical issues such as long travel distances to clinics, and the requirement to take time off school or work to visit a clinic.

Internet-delivered CBT (ICBT) has been suggested as a possible solution to some of these barriers. It can provide the same treatment components as traditional CBT and allow patients to work from home (or wherever suitable), guided by an online-therapist, e.g. through e-mail or similar online communication. Treatment becomes more accessible as the therapist and patient can communicate asynchronously and it may increase treatment capacity, as therapist time per patient tends to be lower compared with face-to-face CBT[20-22]. For adults with SAD, ICBT is an evidence-based treatment [23] with at least one trial showing that ICBT is non-inferior to face-to-face CBT [24]. For youth, ICBT is effective for mixed anxiety disorders when compared to a waitlist control [25-28],

with similar effects as face-to-face CBT [29], suggesting that ICBT could be a suitable treatment for adolescents with SAD. However, a recent study showed that only 12.8% and 14.6% (in the SAD specific and generic ICBT conditions, respectively) of participants were free from their SAD diagnosis at post-treatment assessment, indicating that using the Internet, as the only modality to deliver CBT might not be sufficient[30]. Earlier findings suggest that face-to-face CBT supported by computerized CBT may be more effective than stand-alone ICBT for adolescents and young adults with anxiety disorders[31 32]. Furthermore, it has been suggested that ICBT combined with face-to-face CBT may be beneficial for adult patients with SAD[33] and depression[34]. Such a treatment has, however, never been developed for adolescents with SAD before and the objective of the current trial is to evaluate the feasibility and efficacy of ICBT supplemented with clinic-based group-exposure sessions for adolescents with SAD. This treatment could potentially draw on advantages from both formats, where ICBT is a cost-effective and accessible format and group-sessions may ensure that key treatment components, such as exposure to social situations and social skills training, are conveyed properly. Main research questions are: Is the treatment (BIP SOFT) feasible and acceptable with regard to adolescents' and parents' willingness to work with the Internet-modules, adolescents' attendance rates at group sessions and treatment satisfaction? Does the treatment reduce social anxiety symptoms and increase adolescents' level of functioning and quality of life?

METHOD

The study was conducted at a research unit within the Child and Adolescent Mental Health Services in Stockholm, Sweden, and was approved by the Regional Ethical Review

Board in Stockholm, Sweden (2015/1383-31/2). Participants were recruited and treated between October 2015 and May 2016.

Participants

Participants were 30 adolescents, 13-17 years old, with a principal diagnosis of SAD, and their parents. Table 1 gives detailed information on demographic and clinical characteristics of the sample. Inclusion criteria were: a) age 13-17 years, b) principal DSM-5 diagnosis of SAD, c) ability to read and write Swedish, d) access to a computer with Internet access and e) at least one parent being able to participate in the treatment. Exclusion criteria were: f) initiation or dose modification of psychotropic drug within the past six weeks, g) ≥ 5 sessions of CBT (including exposure) within the last six months, h) any ongoing psychological treatment for SAD, i) diagnosed with an autism spectrum disorder, current psychosis, eating disorder, severe depression, suicidal behaviour or other current severe psychiatric condition j) current substance- or alcohol abuse. Most participants that were excluded at the initial screening fulfilled an exclusion criterion, due to having either initiated SSRI medication (or modified the dose) recently, for having received CBT within the last six months or for being diagnosed with an autism spectrum disorder. Adolescents excluded due to other severe psychiatric conditions, such as severe depression or suicidality, were referred to more suitable treatments.

Participants were mainly recruited through advertisement in a local paper. The advertisement included a website address (www.bup.se/bip) where interested families could get study information and sign up. Clinicians working in the child- and adolescent health services could also refer patients to the trial.

To achieve sufficient power and to be able to detect a within-group effect size of *d* = 0.60 from pre to post with a power of 0.85 and α = 0.05, allowing for a 10% drop out, we included 30 participants in the study.

Insert Table 1 here

Measures

Primary outcome measures

The Clinical Global Impression – Severity (CGI-S)[35] is a clinician rating of symptom severity, ranging from 1 ("normal, not mentally ill") to 7 ("extremely ill"). The CGI-S was administered at baseline by the treating therapist. At post-treatment and the 6-month follow-up, another clinician than the one being responsible for the treatment administered the CGIS-S.

Secondary outcome measures

Mini International Neuropsychiatric Interview for Children and Adolescents (M.I.N.I. KID) [36], was used to determine presence of SAD, as well as comorbid conditions. In addition, the SAD section of the Anxiety Disorders Interview Schedule for DSM-IV-Child Version (ADIS-C)[37] was used to further confirm SAD-diagnosis and to assess the intensity of SAD symptoms. An independent rater (a clinical psychologist, not part of the research group, blind to whether the adolescent had been included in the study or not) watched recordings of the baseline interviews and reassessed 20% of them (both included and excluded adolescents), generating an excellent inter-rater reliability at pre-treatment for SAD-diagnosis (κ = 1.0) and a fair inter-rater reliability for comorbidity (κ = 0.46, $p < .05$).

Clinical global impression – Improvement (CGI-I) [35] is a clinician rating of the participant's change in symptom severity relative to baseline, ranging from 1 ("very much improved") to 7 ("very much worse"). The Children's Global Assessment Scale (CGAS)[38] is a clinician rating of global functioning (scale 0-100), with higher rating indicating higher level of functioning. The M.I.N.I. KID and CGAS were administered at baseline, post-treatment and at the 6-month follow-up, whereas the CGI-I was administered post-treatment and at the 6-month follow-up.

Social Phobia and Anxiety Inventory - Child and Parent Version (SPAI-C/P)[39] is a 26-item self-report measure evaluating aspects of SAD on a 3-point scale, where a score of ≥18 is considered the clinical level of social anxiety. The Social Phobia Weekly Summary Scale (SPWSS) is a five-item self-report scale [40 41] measuring dimensions of SAD (social anxiety, avoidance, self-focused attention, anticipatory processing and post-event processing). The SPAI-C/P and the SPWSS were administered at baseline, every third week during treatment, post-treatment as well as at the 6-month follow-up.

The Revised Children Anxiety And Depression Scale – Child and Parent Version (RCADS-C/P) [42] is a 47-item self-report measure evaluating anxiety disorders (including one subscale for SAD) and depression on a 4-point scale, ranging from *never* to *always*. In the current trial one item regarding suicidality, with three options ("I do not think about killing myself", "I think about killing myself, but would never do it" or "I want to kill myself"), was added at the end of the RCADS-C/P. The Education, Work and Social Adjustment Scale – Child and Parent Version (EWSAS-C/P)[43 44] is a 5-item self-report scale measuring functional impairment on a 9-point scale (higher rating indicating more impairment). The RCADS-C/P and the EWSAS-C/P were administered at baseline, after six weeks of treatment, post-treatment as well as at the 6-month follow-up.

The Health related quality of life questionnaire for children, adolescents and their parents (KIDSCREEN-10)[45] is a self-report measure assessing health related quality of life. The parent-rated measure Trimbos/iMTA questionnaire for Costs associated with Psychiatric Illness – Child version (TiC-P)[46] covers e.g. production loss among parents due to health problems in the child. The KIDSCREEN-10 and the TiC-P were administered at baseline, post-treatment and at the 6-month follow-up.

Feasibility measures, adverse events and therapist time

The Technology Acceptance Scale – child and parent version (TAS-C/P) is a self-report measure adapted from Venkatesh et al. [47], which measures the usefulness, acceptability and satisfaction of the website through which the Internet-modules of the treatment were delivered. The TAS-C/P was administered after three weeks of treatment and post-treatment.

At post-treatment, adolescents and parents were asked to report any negative experiences or adverse events over the course of treatment as well as to what extent the negative event had affected the adolescent's wellbeing.

Amount of therapist time per participant was logged automatically through the Internet-treatment platform.

Procedure

Figure 1 gives an overview of inclusion procedures and assessment points. Families who applied to the study were contacted by telephone and a short screening interview was conducted. Eligible families were invited to diagnostic assessment at the clinic. After thorough information about the study, adolescents gave verbal assent to participate and written informed consent was obtained from parents. The screening interview M.I.N.I.

KID (with the supplement of the SAD section of the ADIS-C) was then conducted. The therapist who conducted the baseline assessment was responsible for the treatment of the participant.

Adolescents with a principal diagnosis of SAD were included and adolescents and parents completed baseline self-report measures online through the treatment platform. In each family, one of the parents was assigned the main responsibility to respond to the parent-report measures at each assessment point throughout the study. Adolescents and parents had separate user accounts and a two-factor authentication (an individual password and a single-use code sent to the user's cellular phone) gave access to the online platform.

Self- and parent rated measures administered during the treatment (SPAI C/P, SPWSS, RCADS C/P and EWSAS C/P) were completed online.

At post-treatment and at the 6-month follow-up all participating adolescents and parents were invited back to the clinic for a diagnostic assessment. To reduce the risk of biased assessment, a clinician that had not been responsible for the participant's treatment conducted the post-treatment and follow-up assessments. All self-assessment scales were administered online post-treatment and at follow-up. Families who could not come to the clinic for post-treatment assessment (n = 1) and 6-month follow-up (n = 3) were assessed over the telephone.

Insert Figure 1 here

Intervention

The intervention was 12 weeks of ICBT supplemented with group-exposure, comprising nine Internet-delivered modules completed individually from home, and three group-

exposure sessions at the clinic (Table 2). The online treatment platform used in this study was developed for delivery of ICBT and has been tested in a number of previous studies for different psychiatric disorders in youth [22 28 48-50]. The current treatment (BIP SOFT) was based on the cognitive-behavioural model by Rapee and Heimberg[51] and to some extent on the cognitive model by Clark and Wells[52] . The treatment manual was developed by the authors and contains CBT components commonly used for SAD in youth[15 53 54], such as exposure, coping strategies and social skills training. The group sessions were mostly based on the Albano and DiBartolo group-CBT manual for adolescent SAD[54]. Therapists in the study were three clinical psychologists and two master students at their final year of training in clinical psychology.

The Internet-modules included educative texts, animations, audio clips and exercises. The parental part of the intervention consisted of five Internet-modules with parent-specific topics such as "parental traps" (e.g., compensating for the adolescent in social situations by for instance speaking for him/her) and doing functional analyses of such parental accommodation (Table 2). Parents were encouraged to be actively involved in their adolescent's treatment and discuss with the adolescent how they should support him or her throughout the treatment, e.g. during exposure exercises. Parents were also encouraged to bring up parent-specific topics with their therapist, for example how to support the adolescent before or during exposures. Parents could send messages to the therapist throughout the 12 weeks of treatment with the purpose to keep parents active as co-therapists. Therapists were instructed to only give support on actual treatment content and to only answer messages about the adolescents (or about parents' relationship with the adolescents) and not regarding parents' own difficulties.

Adolescents and parents were instructed to log in and complete one module each week. The modules were assigned in a predetermined order and therefore, all modules but the

first were initially locked. Once the participant completed a module, the therapist made the next one available.

The therapists had asynchronous contact online with adolescents and parents every week, commenting on their progress on work sheets and through a built in message function. Therapists were instructed to log in and provide feedback to their families three times per week. If necessary, therapists had telephone contact with families, e.g., if they hadn't logged in during the last week or if mid-treatment self-reports exceeded a cut-off for depression (>11 on RCADS-C depression subscale) or suicidality.

The group-exposure sessions (at week 4, 6 and 10) ensured that key components of the treatment were demonstrated in a correct way and that participants could practice e.g. exposure under observation of a therapist. To ensure large enough group sizes, cohorts of six participants started the treatment at the same time. The group sessions were two hours long and led by two of the clinical psychologists.

Insert Table 2 here

Statistical analysis

All analyses were conducted in SPSS Version 23.

Cohen's kappa coefficient (κ)[55] was used to calculate inter-rater reliability for SAD-diagnosis and comorbidity at pre-treatment assessment. The level of reliability is interpreted as poor when κ< 0.40, fair when κ is 0.40-0.59, good when κ is 0.60-0.74 and excellent when κ>0.74[56].

Linear mixed models were used to analyse changes from pre- to post-treatment, and from post-treatment to 6-month follow-up. Mixed model analyses use all available data and account for correlations between measurements within the same subject [57]. Thus,

missing data is handled within the model. All mixed models in this study included a fixed effect for time (pre, post and 6-month follow-up) and a random effect for individual subjects. Potential missing bias was investigated using *t*-tests that compared the baseline characteristics of those who had complete data at post-treatment with those who had missing data. For SPAI C/P and SPWSS three mid-treatment (week 3, 6 and 9) time points were included in the analyses, and for RCADS C/P and EWSAS C/P one mid-treatment (week 6) time point was included in the analyses.

Effect sizes are reported as Cohen's $d = (M_1\text{-}M_2 / SD_{pooled})$. Effect sizes are defined according to Cohen's suggested levels, small ($d \geq 0.20$), moderate ($d \geq 0.50$) and large ($d \geq 0.80$) [58].

RESULTS

Response rate and feasibility

Mid-treatment measures were completed by 97% of the participating families at week three, 83% at week six and 70% at week nine. Post-treatment and 6-month follow-up measures were completed by 90% and 83% of the participating families, respectively. T-tests comparing participants with missing versus complete data points on baseline characteristics revealed no statistically significant differences.

Adolescents completed on average 5.7 (*sd* =2.1) of the nine Internet-modules and parents completed on average 4.4 (*sd* =1.0) of their five modules. The frequency of completed modules by the adolescents was distributed as follows: 20% (n = 6) completed 2-3 modules, 43% (n = 13) completed 4-6 modules and 37% (n = 11) completed 7-9 modules. None completed fewer than two modules.

Attendance at the group-sessions were 70% (session 1), 77% (session 2) and 63% (session 3) respectively. Two thirds of the participants attended two or more group sessions and only 10% attended none.

None of the adolescents meeting inclusion criteria at baseline assessment declined participation, which indicates good acceptability of the offered treatment.

Figure 2 illustrates that a majority of the adolescents were satisfied with the treatment, would recommend the treatment to a friend and found the program easy to understand. Furthermore, most of the participating adolescents found the treatment's online platform easy to use, with a mean rating of 5.6 (range 4-7) on the 7-point TAS scale item (were 7 indicates full agreement with the statement "The program was easy to use").

Insert Figure 2 here

Clinician support

The average time a clinician spent giving feedback and guidance to participants (including time spent on the adolescent *and* parent) was 19.5 minutes per week for the Internet-modules. Group sessions required two hours of therapist time per participant in total during the 12 weeks, which corresponds to 10 minutes per week and participant. In total thus, each family got 29.5 minutes of therapist time, per week.

Changes in clinical outcomes from pre- to post-treatment

Means, standard deviations and effect sizes for pre to post changes, are presented in Table 3. Intention-to-treat analyses of the primary outcome measure (CGI-S) showed a significant decrease of SAD severity from pre- to post-treatment, $t(26.05) = 5.62$, $p<.001$, with a large effect size, $d = 1.17$ (*95%CI* 0.61,1.72). For all secondary outcome measures, analyses revealed significant improvements with moderate to large effect sizes, with the exception of quality of life (KIDSCREEN-C/P) where a small effect was observed. At post-

treatment, 47% of the participants (*n* = 14) no longer met diagnostic criteria for SAD, according to DSM-5 criteria and a CGI-rating <4 (level of severity and functional impairment below diagnostic threshold) and 30% (*n* = 9) scored ≤18 on SPAI-C (cut-off for clinical level of social anxiety). On the clinician rated CGI-I 8% (*n*=2) were "very much improved", 23% (*n* = 6) "much improved", 42% (*n* = 11) "minimally improved", 23% (*n* = 6) "not changed" and 4% (*n* = 1) "minimally worse".

Changes in clinical outcomes from post-treatment to 6-month follow-up

Table 3 gives an overview of means, standard deviations and effect sizes from post-treatment to the 6-month follow-up. The improvements seen at post-treatment were generally maintained and further augmented at the 6-month follow-up with small effect sizes, except for self-focus (SPWSS) that deteriorated slightly. The primary outcome measure (CGI-S) showed a significant decrease of SAD severity from post-treatment to 6-month follow up, $t(25.45) = 2.60$, $p<.05$, with a small effect size, $d = 0.22$ (*95%CI* -0.01, 0.45). At follow-up, 57% (*n* = 17) no longer met diagnostic criteria for SAD and 37% (*n* = 11) scored ≤18 on SPAI-C.

Comparison of pre-treatment and 6-month follow-up levels of social anxiety showed overall improvements with large effect-sizes, CGI-S: $t(27.23) = 6.24$, $p<.001$, $d = 1.36$ (*95%CI* 0.71, 2.01), SPAI-C: $t(27.63) = 5.50$, $p<.001$, $d = 0.95$ (*95%CI* 0.51, 1.39) and SPAI-P: $t(26.08) = 5.57$, $p<.001$, $d = 1.14$ (*95%CI* 0.57, 1.72). Clinician-rated CGI-I indicated that, of those who participated in the 6-month follow-up assessment, 19% (*n* = 5) were "very much improved", 31% (*n* = 8) "much improved", 38% (*n* = 10) "minimally improved", 4% (*n* = 1) "not changed" and 8% (*n* = 2) "minimally worse", compared to baseline.

Post-hoc analyses

The proportion of parents reporting that they had stayed home from work during the last month due to their adolescent's health problems was 27% before treatment and 13% at 6-month follow-up. Of the adolescents, 50% had stayed home from school during the last month due to health problems before treatment and 33% at 6-month follow-up. At 6-month follow-up, six participants reported that they had received additional treatment for social anxiety; two participants (7%) got CBT and four participants (13%) had initiated or increased SSRI medication. All these participants fulfilled diagnostic criteria for SAD at post treatment assessment and five out of six still fulfilled diagnostic criteria for SAD at follow-up.

Half of all participants (*n*=15) reported that they had used strategies from the treatment since post-treatment assessment, referring to exposure, coping strategies (such as breathing exercises and focus shift) and cognitive techniques as the most common ones.

Adverse events

Seven adolescents (23%) reported having experienced some negative event during the course of treatment. These events included increased stress due to the limited time to work with treatment modules (*n* =4; 13%), increased social anxiety (*n*=1; 3%), increased panic anxiety (*n*=1; 3%) and increased depression and negative thoughts (*n*=1; 3%). Those who reported increased stress and anxiety associated these symptoms with the first weeks of treatment and typically described a decrease as treatment continued. Two adolescents reported that the negative event (increased negative thoughts in one case and increased panic anxiety in the other case) still had some impact on their wellbeing at the end of treatment.

DISCUSSION

To our knowledge this is the first study evaluating the feasibility and efficacy of therapist- and parent-guided, Internet-delivered cognitive behavioural therapy (ICBT), supplemented with group-exposure sessions, for adolescents with SAD. The results suggest that such a combined treatment format is both feasible and potentially efficacious and that the improvements are maintained at least 6 months beyond treatment termination. Feasibility was indicated by the high proportion of participants who reported satisfaction with the program, and who would recommend it to a peer, as well as by the high attendance rate at group-sessions and good completion of online-sessions. The results showed substantial reductions of social anxiety symptoms on all clinician-, adolescent- and parent-rated measures at post treatment, as well as improvements in secondary outcomes such as overall anxiety and level of functioning. These symptom reductions were maintained or further improved at the 6-month follow-up.

The adolescents completed on average nearly two thirds of the 9 online-modules which is more than in previous studies on ICBT for youth with SAD where participants completed less than half of the modules on average[26 30]. It is possible that the face-to-face component (group-based exposure sessions) in the present study influenced the working pace with the Internet-modules as participants were recommended to complete the preceding modules before attending group sessions. Even if completion of previous modules was not a prerequisite for attendance at group sessions, participants tended to complete them before attending the sessions. Participants also had peer and therapist support in the group on aspects of the Internet-delivered modules that they found difficult (e.g., designing an idiosyncratic exposure hierarchy), which might have led to more motivation to work with modules *after* group sessions. It has been proposed

that socially anxious children and adolescents have a tendency to avoid practicing skills on their own that they have learned online, such as conducting in-vivo exposure[30]. It could therefore be hypothesized that the group-sessions in this study enhanced the participants' inclination to practice skills at home as a consequence of being offered intensive therapist guidance and direct feedback during group-based exposure. A majority of the participants completed a large number of online treatment modules and group sessions, which gave them time to conduct a significant amount of exposure (introduced in online module 3) and social skills training (introduced in group session 1 at week four). However, we did not track the number of completed exposure- and social skills training exercises in other ways than by proxy, through measuring module completion and group attendance.

Forty seven per cent of participants no longer met diagnostic criteria for SAD after treatment, a proportion that further increased to 57% at 6-month follow-up. This is in line with levels reported in studies evaluating face-to-face CBT for youth with SAD [15 53 59-61] and higher than strictly Internet-delivered CBT for youth with SAD[30]. A recent trial of ICBT for youth with SAD reported a relatively limited impact on the clinical diagnosis of SAD (in the two active treatment conditions 12.8 and 14.6% at post-treatment and 29.8% and 35.4 % at 6-month follow-up, no longer met diagnostic criteria for SAD)[30] and the authors suggest that stand-alone ICBT might not be enough for youth with SAD[30]. It is tempting to attribute the better outcomes in our trial to the addition of group-based exposure sessions to the ICBT protocol, though this hypothesis remains to be formally evaluated. Discrepancies between our and previous results may also be attributable to differences in study samples, study design or other methodological aspects.

Therapists in this study spent less than 20 minutes per family and week, on the Internet-delivered treatment, which is comparable to previous ICBT trials for youth[21 22]. Although the group sessions added another 10 minutes per family and week in the present trial, group-exposure supplemented ICBT should still be considered a time-efficient intervention compared with face-to-face CBT where the therapist time per family and week usually ranges from 45-60 minutes.

Around a fifth of the participants reported a negative event during the course of the treatment. Some of the events were expected, such as increased social anxiety when exposure was initiated. Reports of increased stress were also associated with the first weeks of the treatment and can be interpreted as an initial difficulty combining treatment with other demands such as schoolwork. Two participants reported having experienced some negative events that affected their wellbeing beyond the treatment termination but these participants still benefited from treatment.

Overall, the treatment seems feasible and possibly efficacious for adolescents with SAD and their parents, but to be considered for implementation in regular care, an intervention must also be feasible from an organizational point of view. A possible drawback with the addition of group-exposure to ICBT is that it limits the flexibility of the intervention. For instance, several patients must be recruited and able to commence treatment at the same time. SAD is a challenging disorder to treat and interventions aspiring to be effective may need to include direct and frequent therapist guidance. On the other hand, development of new treatments should not only consider treatment efficacy, but also accessibility, flexibility and cost effectiveness. A possible alternative to group-based exposure sessions is to add other forms of direct communication between patients and ICBT-therapists, e.g. video conferencing or equivalent, something that future studies should investigate further.

Limitations

Although this feasibility trial has several strengths, some important limitations need to be considered when interpreting the results. Causal inferences of observed changes are not possible due to lack of a control condition. Thus, improvement could be an effect of non-specific factors such as the therapist attention or of the passage of time. However, SAD has been shown to commonly follow a chronic course when left untreated[2] and it is not likely that spontaneous remission would explain a significant part of the improvements in the study. Additionally, results were maintained and slightly improved at follow-up, indicating that treatment gains were stable over time, even after the attention from a therapist had ceased. A small proportion of the participants did seek additional care between post-treatment and 6-month follow-up, which could have affected the results. However, these participants continued to report high levels of social anxiety at follow-up, implying that additional care had limited impact on the long-term outcome. Although social anxiety is generally more common among women, the current sample had an overrepresentation of girls. The effect of gender on the results in this trial is unclear and may be further analyzed in future trials with larger samples.

Another limitation concerns assessment at post-treatment and follow-up. Although attempts to reduce bias were made by having these assessments conducted by clinicians not involved in the treatment, assessors were not blind to the fact that the participant had received treatment.

Conclusions

This is the first study of therapist- and parent-guided ICBT supplemented with group-exposure for adolescents with SAD. The intervention was highly acceptable to the

families and significantly reduced social anxiety symptoms up to 6-month follow-up. Participants were generally satisfied with the treatment and the completion-rate of Internet-modules and attendance at group sessions were high, indicating that the treatment is feasible and acceptable to the SAD youth population. Furthermore, per-patient therapist time was limited, even considering the time spent on group-sessions; thus, ICBT supplemented with group-based exposure sessions might be cost-effective when compared to traditional face-to-face CBT. Further controlled trials are needed.

Acknowledgements The authors would like to thank Ulrika Thulin for invaluable help with writing the treatment modules, and Cornelia Hanqvist and Jon Juselius for assisting with providing the treatment.

Contributors The study was designed by MN, SV, DMC, ES and JH. MN was the project manager in collaboration with JH. MN wrote the treatment modules and provided the treatment in collaboration with JH and SV. All statistical analyses were conducted by JH and MN. MN drafted the manuscript in collaboration with JH. The manuscript was reviewed and revised by SV, ES, DMC, BL and LGÖ. All authors have read and approved the final manuscript.

Funding This work was supported by the Stockholm County Council (PPG project 20150032; HSNV 140 99; HSN 1011-1176) and the Swedish Research Council and Swedish Research Council for Health, Working Life and Welfare (Forte 2014-4052)

Competing interests None.

Data sharing statement No additional data are available.

References

1. Association AP. Diagnostic and statistical manual of mental disorders (DSM-5®): American Psychiatric Pub 2013.
2. Burstein M, He JP, Kattan G, et al. Social phobia and subtypes in the national comorbidity survey-adolescent supplement: prevalence, correlates, and comorbidity. *J Am Acad Child Adolesc Psychiatry* 2011;50(9):870-80. doi: 10.1016/j.jaac.2011.06.005
3. Lawrence D, Johnson S, Hafekost J, et al. The Mental Health of Children and Adolescents: Report on the Second Australian Child and Adolescent Survey of Mental Health and Wellbeing. 2015
4. Beesdo K, Bittner A, Pine DS, et al. Incidence of social anxiety disorder and the consistent risk for secondary depression in the first three decades of life. *Arch Gen Psychiatry* 2007;64(8):903-12.
5. Katzelnick DJ, Kobak KA, DeLeire T, et al. Impact of generalized social anxiety disorder in managed care. *Am J Psychiatry* 2001;158(12):1999-2007.
6. Buckner JD, Schmidt NB, Lang AR, et al. Specificity of social anxiety disorder as a risk factor for alcohol and cannabis dependence. *J Psychiatr Res* 2008;42(3):230-39.
7. Beidel DC, Turner SM, Morris TL. Psychopathology of childhood social phobia. *J Am Acad Child Adolesc Psychiatry* 1999;38(6):643-50. doi: 10.1097/00004583-199906000-00010
8. Acarturk C, Smit F, De Graaf R, et al. Economic costs of social phobia: a population-based study. *J Affect Disord* 2009;115(3):421-29.
9. Patel A, Knapp M, Henderson J, et al. The economic consequences of social phobia. *J Affect Disord* 2002;68(2):221-33.
10. Hofmann SG, Smits JA. Cognitive-behavioral therapy for adult anxiety disorders: a meta-analysis of randomized placebo-controlled trials. *J Clin Psychiatry* 2008;69(4):621.
11. Scaini S, Belotti R, Ogliari A, et al. A comprehensive meta-analysis of cognitive-behavioral interventions for social anxiety disorder in children and adolescents. *J Anxiety Disord* 2016;42:105-12. doi: 10.1016/j.janxdis.2016.05.008
12. Segool NK, Carlson JS. Efficacy of cognitive‐behavioral and pharmacological treatments for children with social anxiety. *Depress Anxiety* 2008;25(7):620-31.
13. Pilling S, Mayo-Wilson E, Mavranezouli I, et al. Recognition, assessment and treatment of social anxiety disorder: summary of NICE guidance. *BMJ* 2013;346:f2541.
14. Hudson JL, Rapee RM, Lyneham HJ, et al. Comparing outcomes for children with different anxiety disorders following cognitive behavioural therapy. *Behav Res Ther* 2015;72:30-37. doi: http://dx.doi.org/10.1016/j.brat.2015.06.007
15. Beidel DC, Turner SM, Morris TL. Behavioral treatment of childhood social phobia. *J Consult Clin Psychol* 2000;68(6):1072-80.
16. Beidel DC, Turner SM, Sallee FR, et al. SET-C versus fluoxetine in the treatment of childhood social phobia. *J Am Acad Child Adolesc Psychiatry* 2007;46(12):1622-32. doi: 10.1097/chi.0b013e318154bb57
17. Essau CA, Conradt J, Petermann F. Frequency and comorbidity of social phobia and social fears in adolescents. *Behav Res Ther* 1999;37(9):831-43.
18. Wittchen HU, Stein MB, Kessler RC. Social fears and social phobia in a community sample of adolescents and young adults: prevalence, risk factors and co-morbidity. *Psychol Med* 1999;29(2):309-23. doi: 10.1017/s0033291798008174

19. Merikangas KR, He J-p, Burstein M, et al. Service utilization for lifetime mental disorders in US adolescents: Results of the National Comorbidity Survey–Adolescent Supplement (NCS-A). *J Am Acad Child Adolesc Psychiatry* 2011;50(1):32-45.
20. Hedman E, Andersson E, Ljotsson B, et al. Cost-effectiveness of Internet-based cognitive behavior therapy vs. cognitive behavioral group therapy for social anxiety disorder: results from a randomized controlled trial. *Behav Res Ther* 2011;49(11):729-36. doi: 10.1016/j.brat.2011.07.009
21. Lenhard F, Andersson E, Mataix-Cols D, et al. Therapist-Guided, Internet-Delivered Cognitive-Behavioral Therapy for Adolescents With Obsessive-Compulsive Disorder: A Randomized Controlled Trial. *J Am Acad Child Adolesc Psychiatry* 2017;56(1):10-19.e2. doi: 10.1016/j.jaac.2016.09.515
22. Lenhard F, Vigerland S, Andersson E, et al. Internet-delivered cognitive behavior therapy for adolescents with obsessive-compulsive disorder: an open trial. *PLoS One* 2014;9(6):e100773. doi: 10.1371/journal.pone.0100773
23. Hedman E, Ljótsson B, Lindefors N. Cognitive behavior therapy via the Internet: a systematic review of applications, clinical efficacy and cost–effectiveness. *Expert Rev Pharmacoecon Outcomes Res* 2012;12(6):745-64.
24. Hedman E, Andersson G, Ljotsson B, et al. Internet-based cognitive behavior therapy vs. cognitive behavioral group therapy for social anxiety disorder: a randomized controlled non-inferiority trial. *PLoS One* 2011;6(3):e18001. doi: 10.1371/journal.pone.0018001
25. March S, Spence SH, Donovan CL. The efficacy of an internet-based cognitive-behavioral therapy intervention for child anxiety disorders. *J Pediatr Psychol* 2009;34(5):474-87.
26. Tillfors M, Andersson G, Ekselius L, et al. A randomized trial of Internet-delivered treatment for social anxiety disorder in high school students. *Cogn Behav Ther* 2011;40(2):147-57. doi: 10.1080/16506073.2011.555486
27. Donovan CL, March S. Online CBT for preschool anxiety disorders: a randomised control trial. *Behav Res Ther* 2014;58:24-35.
28. Vigerland S, Ljótsson B, Thulin U, et al. Internet-delivered cognitive behavioural therapy for children with anxiety disorders: A randomised controlled trial. *Behav Res Ther* 2016;76:47-56.
29. Spence SH, Donovan CL, March S, et al. A randomized controlled trial of online versus clinic-based CBT for adolescent anxiety. *J Consult Clin Psychol* 2011;79(5):629-42. doi: 10.1037/a0024512
30. Spence SH, Donovan CL, March S, et al. Generic versus disorder specific cognitive behavior therapy for social anxiety disorder in youth: A randomized controlled trial using internet delivery. *Behav Res Ther* 2017;90:41-57. doi: 10.1016/j.brat.2016.12.003
31. Sethi S. Treating Youth Depression and Anxiety: A Randomised Controlled Trial Examining the Efficacy of Computerised versus Face-to-face Cognitive Behaviour Therapy. *Aust Psychol* 2013;48(4):249-57. doi: 10.1111/ap.12006
32. Sethi S, Campbell AJ, Ellis LA. The Use of Computerized Self-Help Packages to Treat Adolescent Depression and Anxiety. *Journal of Technology in Human Services* 2010;28(3):144-60. doi: 10.1080/15228835.2010.508317
33. Andersson G, Carlbring P, Holmström A, et al. Internet-Based Self-Help With Therapist Feedback and In Vivo Group Exposure for Social Phobia: A Randomized

Controlled Trial. *J Consult Clin Psychol* 2006;74(4):677-86. doi: 10.1037/0022-006X.74.4.677
34. Mathiasen K, Andersen TE, Riper H, et al. Blended CBT versus face-to-face CBT: a randomised non-inferiority trial. *BMC Psychiatry* 2016;16(1):432. doi: 10.1186/s12888-016-1140-y
35. Guy W. Clinical global impression scale. *The ECDEU Assessment Manual for Psychopharmacology-Revised Volume DHEW Publ No ADM* 1976;76(338):218-22.
36. Sheehan DV, Lecrubier Y, Sheehan KH, et al. The Mini-International Neuropsychiatric Interview (M.I.N.I.): the development and validation of a structured diagnostic psychiatric interview for DSM-IV and ICD-10. *J Clin Psychiatry* 1998;59 Suppl 20:22-33;quiz 34-57.
37. Albano A, Silverman W. The Anxiety Disorders Interview Schedule for Children for DSM-IV: clinician manual (child and parent versions). *San Antonio, TX: Psychological Corporation* 1996
38. Shaffer D, Gould MS, Brasic J, et al. A children's global assessment scale (CGAS). *Arch Gen Psychiatry* 1983;40(11):1228-31.
39. Beidel DC, Turner SM, Morris TL. A new inventory to assess childhood social anxiety and phobia - the social phobia and anxiety inventory for children *Psychol Assess* 1995;7(1):73-79. doi: 10.1037/1040-3590.7.1.73
40. Clark DM, Ehlers A, McManus F, et al. Cognitive therapy versus fluoxetine in generalized social phobia: a randomized placebo-controlled trial. *J Consult Clin Psychol* 2003;71(6):1058.
41. Hedman E, Mörtberg E, Hesser H, et al. Mediators in psychological treatment of social anxiety disorder: Individual cognitive therapy compared to cognitive behavioral group therapy. *Behav Res Ther* 2013;51(10):696-705.
42. Chorpita BF, Yim L, Moffitt C, et al. Assessment of symptoms of DSM-IV anxiety and depression in children: a revised child anxiety and depression scale. *Behav Res Ther* 2000;38(8):835-55.
43. Mundt JC, Marks IM, Shear MK, et al. The Work and Social Adjustment Scale: a simple measure of impairment in functioning. *Br J Psychiatry* 2002;180:461-4.
44. Mataix-Cols D, Cowley AJ, Hankins M, et al. Reliability and validity of the Work and Social Adjustment Scale in phobic disorders. *Compr Psychiatry* 2005;46(3):223-28.
45. Ravens-Sieberer U, Gosch A, Rajmil L, et al. KIDSCREEN-52 quality-of-life measure for children and adolescents. *Expert Rev Pharmacoecon Outcomes Res* 2005;5(3):353-64.
46. Bouwmans C, De Jong K, Timman R, et al. Feasibility, reliability and validity of a questionnaire on healthcare consumption and productivity loss in patients with a psychiatric disorder (TiC-P). *BMC Health Serv Res* 2013;13(1):1.
47. Venkatesh V, Morris MG, Davis GB, et al. User acceptance of information technology: Toward a unified view. *MIS quarterly* 2003:425-78.
48. Bonnert M, Olen O, Lalouni M, et al. Internet-Delivered Cognitive Behavior Therapy for Adolescents With Irritable Bowel Syndrome: A Randomized Controlled Trial. *Am J Gastroenterol* 2016 doi: 10.1038/ajg.2016.503
49. Lenhard F, Vigerland S, Andersson E, et al. Internet-delivered cognitive behavior therapy for adolescents with obsessive-compulsive disorder: an open trial. *PLoS One* 2014;9(6):e100773.

50. Vigerland S, Thulin U, Ljotsson B, et al. Internet-delivered CBT for children with specific phobia: a pilot study. *Cogn Behav Ther* 2013;42(4):303-14. doi: 10.1080/16506073.2013.844201
51. Rapee RM, Heimberg RG. A cognitive-behavioral model of anxiety in social phobia. *Behav Res Ther* 1997;35(8):741-56.
52. Clark DM, Wells A. A cognitive model of social phobia. *Social phobia: Diagnosis, assessment, and treatment* 1995;41(68):00022-3.
53. Albano AM, Marten PA, Holt CS, et al. Cognitive-Behavioral Group Treatment for Social Phobia in Adolescents A Preliminary Study. *J Nerv Ment Dis* 1995;183(10):649-56.
54. Albano AM, DiBartolo PM. Cognitive-Behavioral Therapy for Social Phobia in Adolescents: Stand Up, Speak Out Therapist Guide: Oxford University Press 2007.
55. Cohen J. A coefficient of agreement for nominal scales. Educational and Psychosocial Measurement, 20, 37-46, 1960.
56. Mannuzza S, Fyer AJ, Martin LY, et al. Reliability of anxiety assessment. I. Diagnostic agreement. *Arch Gen Psychiatry* 1989;46(12):1093-101.
57. Gueorguieva R, Krystal JH. Move over ANOVA: progress in analyzing repeated-measures data and its reflection in papers published in the Archives of General Psychiatry. *Arch Gen Psychiatry* 2004;61(3):310-7. doi: 10.1001/archpsyc.61.3.310
58. Cohen J. A power primer. *Psychol Bull* 1992;112(1):155.
59. Hayward C, Varady S, Albano AM, et al. Cognitive-behavioral group therapy for social phobia in female adolescents: results of a pilot study. *J Am Acad Child Adolesc Psychiatry* 2000;39(6):721-26.
60. Spence SH, Donovan C, Brechman‐Toussaint M. The treatment of childhood social phobia: The effectiveness of a social skills training‐based, cognitive‐behavioural intervention, with and without parental involvement. *J Child Psychol Psychiatry* 2000;41(6):713-26.
61. Öst L-G, Cederlund R, Reuterskiöld L. Behavioral treatment of social phobia in youth: Does parent education training improve the outcome? *Behav Res Ther* 2015;67:19-29.

Table 1. Demographic and clinical features of study participants (*N* = 30)

Variables		*N*	%
Age (years)	*M (SD)*	15 (1.22)	
	min-max	13-17	
Gender	Girls	25	83
	Boys	5	17
Country of birth, adolescent	Sweden	29	97
	Other	1	3
Country of birth, parents	Both in Sweden	20	67
	One in Sweden	7	23
	None in Sweden	3	10
Education, responding parent	Primary	14	47
	Higher	16	53
Employment, responding parent	Working	25	83
	Unemployed	4	13
	Retired	1	3
Psychotropic medication pre-treatment	None	27	90
	SSRI	3	10
Prior psychological treatment	None	11	37
	Primary care, counseling or equivalent	4	13
	Psychiatric specialist care or equivalent	14	47
Referred from child health services		6	20
Comorbid diagnoses	Specific Phobia	8	26.7
	GAD	5	16.7
	ADD	3	10
	Depression	2	6.7
	OCD	2	6.7
	Panic disorder	1	3.3
	Tics/Tourette	1	3.3
	Separation anxiety	1	3.3
	Trichotillomania	1	3.3
Frequency of comorbid diagnoses	None	13	43.3
	One	11	36.7
	Two	3	10
	Three or more	3	10
Onset (age in years)	M (SD)	8.9 (4.29)	
Duration of SAD (years)	M (SD)	6.2 (4.05)	

Note: Primary education ≤12. Higher education >12 years.
Abbreviations: GAD = generalized anxiety disorder; ADD = attention deficit disorder; OCD = obsessive compulsive disorder.

Table 2. An overview of the content of the ICBT protocol and group-exposure sessions

Chapter	Adolescent	Parent	Group-exposure sessions
1	Introduction to ICBT, Learn about emotions, fear and social anxiety. How to do functional analyses of my own behavior	Introduction to ICBT. Learn about emotions, fear and social anxiety. How to do functional analyses of my teenager's behavior and my own reactions.	
2	More about social anxiety disorder. Learn to reduce self-focus and safety behaviors. Improve coping strategies.	Suggest treatment goals. Plan the treatment. Learn about exposure and how to be a co-therapist during exposure.	
3	Map the social anxiety. Learn about exposure to social situations. Set treatment goals and build an individual exposure hierarchy.	Learn about common parental challenges. How to reward my adolescent. Problem solving.	
4		How to handle negative thoughts. Learn about social skills.	Modelling and practice of social skills. Modelling and mapping of safety behaviors and how to reduce them. Set an individual exposure hierarchy. Exposure in vivo. Summary with parents.
5	Exposure follow-up. Learn about negative thoughts and how to handle them.	Prepare relapse prevention. Evaluation of parent modules and treatment.	
6			Repetition of treatment components. Exposure in vivo. Summary with parents.
7	Exposure follow-up. Extended practice of focus shift.		
8	Exposure follow-up. Negative thoughts follow-up. Problem solving.		
9	Exposure follow-up. Learn how to say no and other self-assertive behaviors.		
10			Exposure in vivo. Social mishaps in public environment. Summary with parents.
11	Exposure follow-up. Last sprint: how to get the most out of the last exposures.		
12	Make a plan for relapse prevention. What did I learn? What do I want to practice further? Make an evaluation of the treatment.		

Table 3 Means, standard deviations, pre- to post and post to 6-month follow-up comparisons, and effect sizes of all outcome measures

	Pre		Post		Pre to post comparison		6-month follow-up		Post to follow-up comparison	
Measure	**M**	**SD**	**M**	**SD**	***p***	***d* (95% CI)**	**M**	**SD**	***p***	***d* (95%CI)**
Clinician-rated										
CGI-S	4.6	0.72	3.3	1.3	<.001	1.17 (0.61,1.72)	3.0	1.43	.015	0.22 (-0.01, 0.45)
C-GAS	55.5	6.68	62.0	8.85	<.001	0.80 (0.40, 1.21)	65.4	11.14	<.001	0.30 (0.13, 0.46)
Self- and parent rated social anixety										
SPAI-C	33.4	9.32	24.5	11.31	<.001	0.85 (0.36, 1.34)	21.5	11.24	.023	0.27 (0.02, 0.51)
SPAI-P	35.3	8.46	27.2	11.55	<.001	0.79 (0.29, 1.28)	25.7	11.01	n.s.	
SPWSS avoid	4.0	2.38	1.9	2.22	<.001	0.91 (0.36, 1.47)	1.8	1.81	<.001	0.05 (-0.4, 0.5)
SPWSS s-f	4.9	1.74	2.8	1.44	<.001	1.31 (0.61, 2.02)	3.3	2.03	<.001	-0.28 (-0.83-0.26)
SPWSS a a	4.9	1.85	3.0	2.19	<.001	0.94 (0.32, 1.55)	2.4	1.92	<.001	0.29 (-0.18-0.76)
SPWSS pep	4.8	2.29	3.6	1.77	<.001	0.58 (0.02-1.15)	3.3	2.30	<.001	0.14 (-0.36-0.65)
Other self- and parent rated measures										
RCADS-C SAD	18.5	5.69	14.2	5.87	<.001	0.74 (0.36, 1.13)	12.4	6.16	.018	0.30(0.05, 0.55)
RCADS-P SAD	16.4	5.88	13.2	5.70	.006	0.55 (0.09, 1.01)	12.3	6.07	n.s.	
RCADS-C	60.0	24.77	42.1	21.74	<.001	0.76 (0.32, 1.21)	38.4	25.92	n.s.	
RCADS-P	46.2	23.39	35.2	19.13	.005	0.51 (0.11, 0.91)	31.8	22.31	n.s.	
KIDSCREEN-C	32.2	5.59	34.1	6.07	.036	0.32 (0.06, 0.59)	35.7	6.93	n.s.	
KIDSCREEN-P	33.1	4.50	35.5	5.98	.025	0.44 (0.06, 0.82)	35.8	5.85	n.s.	
EWSAS-C	15.0	7.47	10.9	6.69	.006	0.58 (0.14, 1.01)	7.8	5.28	.004	0.50 (0.1, 0.91)
EWSAS-P	14.6	6.51	11.4	6.88	.002	0.48 (0.13, 0.83)	9.1	7.44	.002	0.31 (0.1, 0.54)

Abbreviations: CGI-S = The Clinical Global Impression – Severity, C-GAS = Children's Global Assessment Scale, SPAI-C/P = Social Phobia and Anxiety Inventory - Child and Parent Version, SPWSS = The Social Phobia Weekly Summary Scale, SPWSS avoid = avoidance, s-f = self-focus, a.a = anticipatory anxiety, pep = post event-processing, RCADS-C/P = The Revised Children Anxiety And Depression Scale – Child and Parent Version, RCADS-C/P SAD = The Revised Children Anxiety And Depression Scale – Child and Parent Version, SAD subscale, KIDSCREEN-C/P = The Health related quality of life questionnaire for children, adolescents and their parents, EWSAS-C/P = The Education, Work and Social Adjustment Scale – Child and Parent Version

Figure 1. Study flow chart

Figure 2. Adolescents' evaluation of BIP SOFT

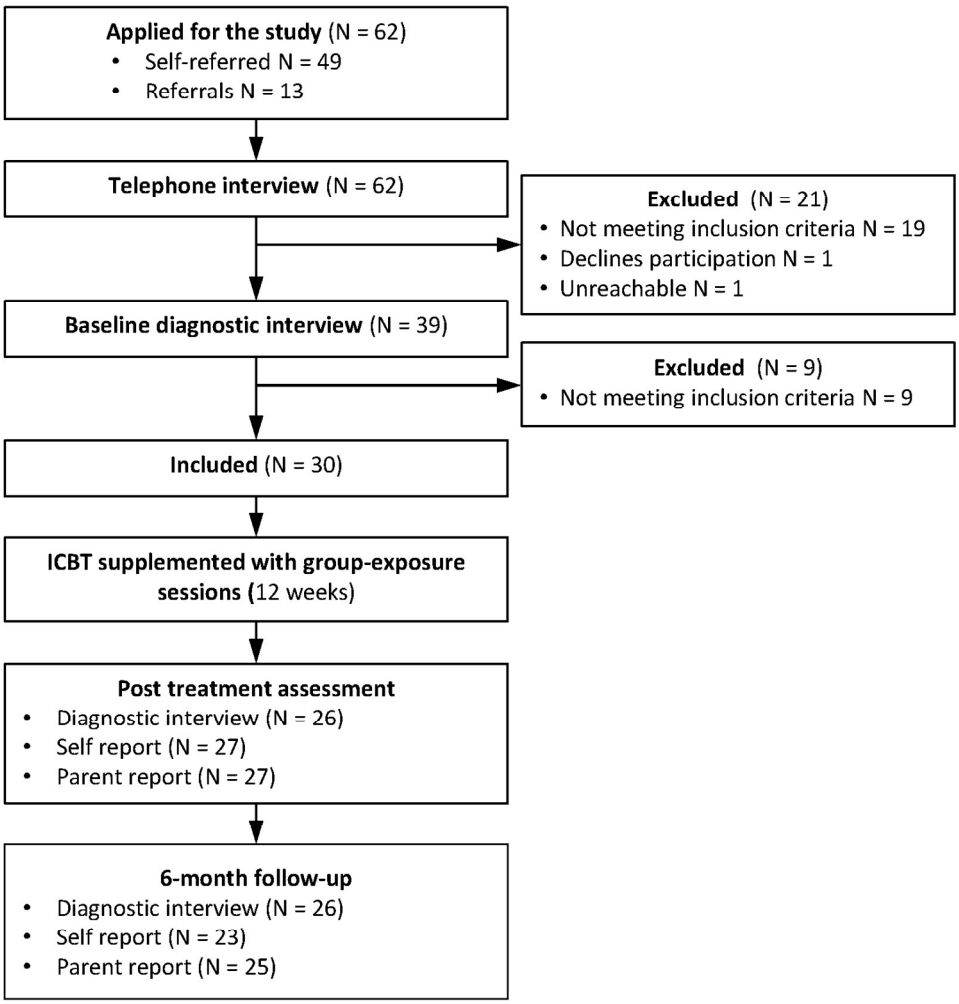


Figure 1. Study flow chart

143x149mm (300 x 300 DPI)

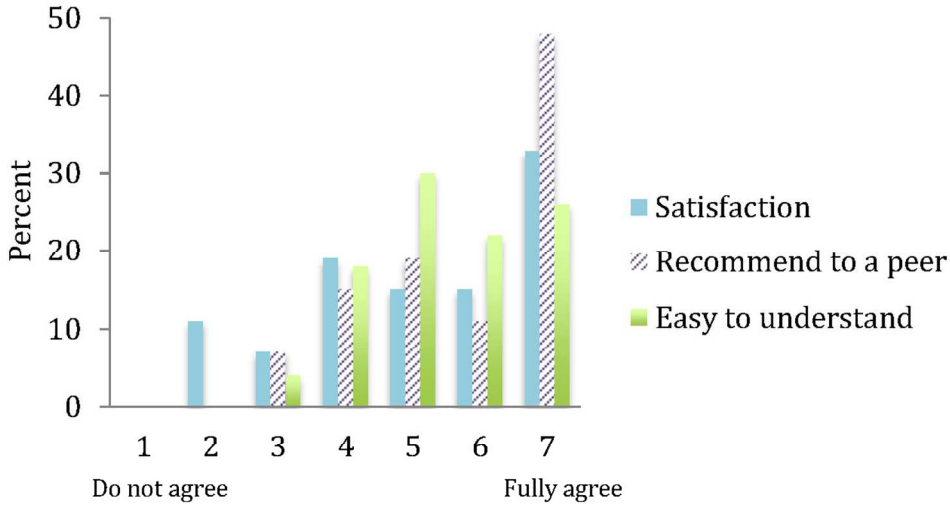


Figure 2. Adolescents' evaluation of BIP SOFT

112x64mm (300 x 300 DPI)

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
Title and abstract			
1a	Identification as a randomised trial in the title	Identification as a pilot or feasibility randomised trial in the title	1
1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	Structured summary of pilot trial design, methods, results, and conclusions (for specific guidance see CONSORT abstract extension for pilot trials)	2-3
Introduction			
Background and objectives:			
2a	Scientific background and explanation of rationale	Scientific background and explanation of rationale for future definitive trial, and reasons for randomised pilot trial	3-5
2b	Specific objectives or hypotheses	Specific objectives or research questions for pilot trial	5
Methods			
Trial design:			

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
3a	Description of trial design (such as parallel, factorial) including allocation ratio	Description of pilot trial design (such as parallel, factorial) including allocation ratio	2
3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Important changes to methods after pilot trial commencement (such as eligibility criteria), with reasons	NA
Participants:			
4a	Eligibility criteria for participants		5-6
4b	Settings and locations where the data were collected		5
4c		How participants were identified and consented	6,9
Interventions:			
5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered		10-11
Outcomes:			

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	Completely defined prespecified assessments or measurements to address each pilot trial objective specified in 2b, including how and when they were assessed	6-9
6b	Any changes to trial outcomes after the trial commenced, with reasons	Any changes to pilot trial assessments or measurements after the pilot trial commenced, with reasons	NA
6c		If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	NA
Sample size:			
7a	How sample size was determined	Rationale for numbers in the pilot trial	6
7b	When applicable, explanation of any interim analyses and stopping guidelines		NA
Randomisation:			

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
Sequence generation:			
8a	Method used to generate the random allocation sequence		NA
8b	Type of randomisation; details of any restriction (such as blocking and block size)	Type of randomisation(s); details of any restriction (such as blocking and block size)	NA
Allocation concealment mechanism:			
9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned		NA
Implementation:			
10	Who generated the random allocation sequence, enrolled participants, and assigned participants to interventions		NA
Blinding:			

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
11a	If done, who was blinded after assignment to interventions (eg, participants, care providers, those assessing outcomes) and how		NA
11b	If relevant, description of the similarity of interventions		NA
Analytical methods:			
12a	Statistical methods used to compare groups for primary and secondary outcomes	Methods used to address each pilot trial objective whether qualitative or quantitative	12
12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Not applicable	NA
Results			
Participant flow (a diagram is strongly recommended):			
13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received	10

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
	primary outcome	intended treatment, and were assessed for each objective	
13b	For each group, losses and exclusions after randomisation, together with reasons		NA
Recruitment:			
14a	Dates defining the periods of recruitment and follow-up		5
14b	Why the trial ended or was stopped	Why the pilot trial ended or was stopped	NA
Baseline data:			
15	A table showing baseline demographic and clinical characteristics for each group		6
Numbers analysed:			
16	For each group, number of participants (denominator) included in each analysis and whether the	For each objective, number of participants (denominator) included in each analysis. If relevant, these	12

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
	analysis was by original assigned groups	numbers should be by randomised group	
Outcomes and estimation:			
17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	For each objective, results including expressions of uncertainty (such as 95% confidence interval) for any estimates. If relevant, these results should be by randomised group	27
17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not applicable	NA
Ancillary analyses:			
18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory	Results of any other analyses performed that could be used to inform the future definitive trial	15
Harms:			
19	All important harms or unintended		16

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
	effects in each group (for specific guidance see CONSORT for harms)		
19a		If relevant, other important unintended consequences	NA
Discussion			
Limitations:			
20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Pilot trial limitations, addressing sources of potential bias and remaining uncertainty about feasibility	19
Generalisability:			
21	Generalisability (external validity, applicability) of the trial findings	Generalisability (applicability) of pilot trial methods and findings to future definitive trial and other studies	19
Interpretation:			
22	Interpretation consistent with results, balancing benefits and harms, and	Interpretation consistent with pilot trial objectives and findings,	20

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
	considering other relevant evidence	balancing potential benefits and harms, and considering other relevant evidence	
22a		Implications for progression from pilot to future definitive trial, including any proposed amendments	18-19
Other information			
Registration:			
23	Registration number and name of trial registry	Registration number for pilot trial and name of trial registry	3
Protocol:			
24	Where the full trial protocol can be accessed, if available	Where the pilot trial protocol can be accessed, if available	NA
Funding:			
25	Sources of funding and other support (such as supply of drugs), role of funders		20
26		Ethical approval or approval by	5

Section/topic and item No	Standard checklist item	Extension for pilot trials	Page No where item is reported
		research review committee, confirmed with reference number	