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

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

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Manuscripts

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

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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 ($d = 1.17, 0.85, \text{ and } 0.79$, respectively), as well as in general self- and parent-rated anxiety and depression ($d = 0.76 \text{ and } 0.51$), 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.

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2
3 **Conclusion:** Therapist- and parent guided Internet-delivered CBT, supplemented
4
5 with a limited number of group-exposure sessions is a feasible and promising
6
7 intervention for adolescents with SAD.
8

9
10 **Trial registration number:** Clinicaltrials.gov registration ID NCT02576171
11

12 13 14 Strengths and limitations of this study

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

33
34 Social anxiety disorder (SAD) is characterized by an intense fear of being scrutinized and
35 negatively evaluated in social or performance situations¹. The socially anxious
36 individual is typically afraid of making mistakes, being embarrassed in front of others
37 and of showing signs of anxiety, such as blushing or trembling, and may therefore avoid
38 social and performance situations or endure them under intense distress. The disorder
39 has a median age of onset of 9.2 years ² and is one of the most common mental disorders
40 among adolescents. The 12-month prevalence is 3.4% ³ and 8.6% of the adolescent
41 population fulfill diagnostic criteria at some point between the age of 13 and 18². If the
42 disorder is left untreated it tends to follow a chronic course² and can lead to severe
43 secondary consequences such as depression⁴ and suicidality⁵, substance and alcohol
44 dependence⁶, academic underperformance and increased social isolation⁷.
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3 Consequently, SAD causes substantial impairment as well as burden on patients' families
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5 and long-term societal costs ^{8 9}.

7 Cognitive behavioural therapy (CBT) for SAD is effective for adults ¹⁰ as well as for
8
9 children and adolescents ^{11 12} and is the first-line treatment according to international
10
11 clinical guidelines (e.g., the National Institute for Health and Care Excellence; NICE) ¹³.
12
13 For youth, particularly face-to-face group-CBT is effective for SAD ¹⁴⁻¹⁹.

16 Despite the high level of impairment caused by the disorder, only a small proportion
17
18 of adolescents with social anxiety seek help for their problems ^{20 21} and even fewer
19
20 receive effective treatment ²². Barriers to receiving evidence-based psychological
21
22 treatment include limited availability of trained therapists, and practical issues such as
23
24 long travel distances to clinics, and the requirement to take time off school or work to
25
26 visit a clinic.
27
28

30 Internet-delivered CBT (ICBT) has been suggested as a possible solution to some of
31
32 these barriers. It can provide the same treatment components as traditional CBT and
33
34 allow patients to work from home (or wherever suitable), guided by an online-therapist,
35
36 e.g. through e-mail or similar online communication. Treatment becomes more
37
38 accessible as the therapist and patient can communicate asynchronously and it may
39
40 increase treatment capacity, as therapist time per patient tends to be lower compared
41
42 with face-to-face CBT²³⁻²⁵. For adults with SAD, ICBT is an evidence-based treatment ²⁶
43
44 with at least one trial showing that ICBT is non-inferior to face-to-face CBT ²⁷. For youth,
45
46 ICBT is effective for mixed anxiety disorders when compared to a waitlist control ²⁸⁻³¹,
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48 with similar effects as face-to-face CBT ³², suggesting that ICBT could be a suitable
49
50 treatment for adolescents with SAD. However, a recent study showed that only 12.8%
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52 and 14.6% (in the SAD specific and generic ICBT conditions, respectively) of participants
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3 were free from their SAD diagnosis at post-treatment assessment, indicating that using
4
5 the Internet, as the only modality to deliver CBT might not be sufficient³³.
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8 The objective of the current trial is to evaluate the feasibility and efficacy of ICBT
9
10 supplemented with clinic-based group-exposure sessions, for adolescents with SAD, a
11
12 treatment that could potentially draw on advantages from both formats, where ICBT is a
13
14 cost-effective and accessible format and group-sessions may ensure that key treatment
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16 components, such as exposure to social situations, are conveyed properly. Main research
17
18 questions are: Is the treatment (BIP SOFT) feasible and acceptable with regard to
19
20 adolescents' and parents' willingness to work with the Internet-modules, adolescents'
21
22 attendance rates at group sessions and treatment satisfaction? Does the treatment
23
24 reduce social anxiety symptoms and increase adolescents' level of functioning and
25
26 quality of life?
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32 **METHOD**

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34
35 The study was conducted at a research unit within the Child and Adolescent Mental
36
37 Health Services in Stockholm, Sweden, and was approved by the Regional Ethical Review
38
39 Board in Stockholm, Sweden (2015/1383-31/2).
40

41 **Participants**

42
43 Participants were 30 adolescents, 13-17 years old, with a principal diagnosis of SAD, and
44
45 their parents. Table 1 gives detailed information on demographic and clinical
46
47 characteristics of the sample. Inclusion criteria were: a) age 13-17 years, b) principal
48
49 DSM-5 diagnosis of SAD, c) ability to read and write Swedish, d) access to a computer
50
51 with Internet access and e) at least one parent being able to participate in the treatment.
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53 Exclusion criteria were: f) initiation or dose modification of psychotropic drug within
54
55 the past six weeks, g) ≥ 5 sessions of CBT (including exposure) within the last six
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3 months, h) any ongoing psychological treatment for SAD, i) diagnosed with an autism
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5 spectrum disorder, current psychosis, eating disorder, severe depression, suicidal
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7 behaviour or other current severe psychiatric condition j) current substance- or alcohol
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9 abuse. Adolescents excluded due to other severe psychiatric conditions, such as severe
10
11 depression or suicidality, were referred to more suitable treatments.
12
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14
15 Participants were mainly recruited through advertisement in a local paper. The
16
17 advertisement included a website address (www.bup.se/bip) where interested families
18
19 could get study information and sign up. Clinicians working in the child- and adolescent
20
21 health services could also refer patients to the trial.
22
23

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25 To achieve sufficient power and to be able to detect a within-group effect size of $d =$
26
27 0.60 from pre to post with a power of 0.85 and $\alpha = 0.05$, allowing for a 10% drop out, we
28
29 included 30 participants in the study.
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35 Insert Table 1 here
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38 39 **Measures**

40 41 *Primary outcome measures*

42
43 The Clinical Global Impression – Severity (CGI-S)³⁴ is a clinician rating of symptom
44
45 severity, ranging from 1 (“normal, not mentally ill”) to 7 (“extremely ill”). The CGI-S
46
47 was administered at baseline by the treating therapist. At post-treatment and the 6-
48
49 month follow-up, another clinician than the one being responsible for the treatment
50
51 administered the CGIS-S.
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54 55 *Secondary outcome measures*

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3 Mini International Neuropsychiatric Interview for Children and Adolescents (M.I.N.I.
4 KID)³⁵, was used to determine presence of SAD, as well as comorbid conditions. In
5
6
7 addition, the SAD section of the Anxiety Disorders Interview Schedule for DSM-IV-Child
8
9
10 Version (ADIS-C)³⁶ was used to further confirm SAD-diagnosis and to assess the
11
12 intensity of SAD symptoms. An independent rater (a clinical psychologist, not part of the
13
14 research group, blind to whether the adolescent had been included in the study or not)
15
16 watched recordings of the baseline interviews and reassessed 20% of them (both
17
18 included and excluded adolescents), generating an excellent inter-rater reliability at pre-
19
20 treatment for SAD-diagnosis ($\kappa = 1.0$) and a fair inter-rater reliability for comorbidity (κ
21
22 = 0.46, $p < .05$).
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24

25
26 Clinical global impression – Improvement (CGI-I)³⁴ is a clinician rating of the
27
28 participant's change in symptom severity relative to baseline, ranging from 1 ("very
29
30 much improved") to 7 ("very much worse"). The Children's Global Assessment Scale
31
32 (CGAS)³⁷ is a clinician rating of global functioning (scale 0-100), with higher rating
33
34 indicating higher level of functioning. The M.I.N.I. KID and CGAS were administered at
35
36 baseline, post-treatment and at the 6-month follow-up, whereas the CGI-I was
37
38 administered post-treatment and at the 6-month follow-up.
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41
42 Social Phobia and Anxiety Inventory - Child and Parent Version (SPAI-C/P)³⁸ is a 26-
43
44 item self-report measure evaluating aspects of SAD on a 3-point scale, where a score of
45
46 ≥ 18 is considered the clinical level of social anxiety. The Social Phobia Weekly Summary
47
48 Scale (SPWSS) is a five-item self-report scale^{39 40} measuring dimensions of SAD (social
49
50 anxiety, avoidance, self-focused attention, anticipatory processing and post-event
51
52 processing). The SPAI-C/P and the SPWSS were administered at baseline, every third
53
54 week during treatment, post-treatment as well as at the 6-month follow-up.
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3 The Revised Children Anxiety And Depression Scale – Child and Parent Version
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5 (RCADS-C/P)⁴¹ is a 47-item self-report measure evaluating anxiety disorders (including
6
7 one subscale for SAD) and depression on a 4-point scale, ranging from *never* to *always*.
8
9 In the current trial one item regarding suicidality, with three options (“I do not think
10
11 about killing myself”, “I think about killing myself, but would never do it” or “I want to
12
13 kill myself”), was added at the end of the RCADS-C/P. The Education, Work and Social
14
15 Adjustment Scale – Child and Parent Version (EWSAS-C/P)^{42 43} is a 5-item self-report
16
17 scale measuring functional impairment on a 9-point scale (higher rating indicating more
18
19 impairment). The RCADS-C/P and the EWSAS-C/P were administered at baseline, after
20
21 six weeks of treatment, post-treatment as well as at the 6-month follow-up.
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26 The Health related quality of life questionnaire for children, adolescents and their
27
28 parents (KIDSCREEN-10)⁴⁴ is a self-report measure assessing health related quality of
29
30 life. The parent-rated measure Trimbos/iMTA questionnaire for Costs associated with
31
32 Psychiatric Illness – Child version (TiC-P)⁴⁵ covers e.g. production loss among parents
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34 due to health problems in the child. The KIDSCREEN-10 and the TiC-P were
35
36 administered at baseline, post-treatment and at the 6-month follow-up.
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41 *Feasibility measures, adverse events and therapist time*

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43 The Technology Acceptance Scale – child and parent version (TAS-C/P) is a self-report
44
45 measure adapted from Venkatesh et al.⁴⁶, which measures the usefulness, acceptability
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47 and satisfaction of the website through which the Internet-modules of the treatment
48
49 were delivered. The TAS-C/P was administered after three weeks of treatment and post-
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51 treatment.
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3 At post-treatment, adolescents and parents were asked to report any negative
4 experiences or adverse events over the course of treatment as well as to what extent the
5 negative event had affected the adolescent's wellbeing.
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10 Amount of therapist time per participant was logged automatically through the
11 Internet-treatment platform.
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14 15 16 **Procedure**

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18 Figure 1 gives an overview of inclusion procedures and assessment points. Families who
19 applied to the study were contacted by telephone and a short screening interview was
20 conducted. Eligible families were invited to diagnostic assessment at the clinic. After
21 thorough information about the study, adolescents gave verbal assent to participate and
22 written informed consent was obtained from parents. The screening interview M.I.N.I.
23 KID (with the supplement of the SAD section of the ADIS-C) was then conducted. The
24 therapist who conducted the baseline assessment was responsible for the treatment of
25 the participant.
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37 Adolescents with a principal diagnosis of SAD were included and adolescents and
38 parents completed baseline self-report measures online through the treatment platform.
39 In each family, one of the parents was assigned the main responsibility to respond to the
40 parent-report measures at each assessment point throughout the study. Adolescents and
41 parents had separate user accounts and a two-factor authentication (an individual
42 password and a single-use code sent to the user's cellular phone) gave access to the
43 online platform.
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53 Self- and parent rated measures administered during the treatment (SPAI C/P,
54 SPWSS, RCADS C/P and EWSAS C/P) were completed online.
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3 At post-treatment and at the 6-month follow-up all participating adolescents and
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5 parents were invited back to the clinic for a diagnostic assessment. To reduce the risk of
6
7 biased assessment, a clinician that had not been responsible for the participant's
8
9 treatment conducted the post-treatment and follow-up assessments. All self-assessment
10
11 scales were administered online post-treatment and at follow-up. Families who could
12
13 not come to the clinic for post-treatment assessment (n = 1) and 6-month follow-up (n =
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15 3) were assessed over the telephone.
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25 **Intervention**

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27 The intervention was 12 weeks of ICBT supplemented with group-exposure, comprising
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29 nine Internet-delivered modules completed individually from home, and three group-
30
31 exposure sessions at the clinic (Table 2). The online treatment platform used in this
32
33 study was developed for delivery of ICBT and has been tested in a number of previous
34
35 studies for different psychiatric disorders in youth^{25 31 47-49}. The current treatment (BIP
36
37 SOFT) was based on the cognitive-behavioural model by Rapee and Heimberg⁵⁰ and to
38
39 some extent on the cognitive model by Clark and Wells⁵¹. The treatment manual was
40
41 developed by the authors and contains CBT components commonly used for SAD in
42
43 youth^{14 18 52}, such as exposure, coping strategies and social skills training. The group
44
45 sessions were mostly based on the Albano and DiBartolo group-CBT manual for
46
47 adolescent SAD⁵². Therapists in the study were three clinical psychologists and two
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49 master students at their final year of training in clinical psychology.
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55 The Internet-modules included educative texts, animations, audio clips and exercises.
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57 The parental part of the intervention consisted of five Internet-modules with parent-
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3 specific topics such as “parental traps” (e.g., compensating for the adolescent in social
4 situations by for instance speaking for him/her) and doing functional analyses of such
5 parental accommodation (Table 2). Parents were encouraged to be actively involved in
6 their adolescent’s treatment and discuss with the adolescent how they should support
7 him or her throughout the treatment, e.g. during exposure exercises. Parents were also
8 encouraged to bring up parent-specific topics with their therapist, for example how to
9 support the adolescent before or during exposures. Parents could send messages to the
10 therapist throughout the 12 weeks of treatment. Adolescents and parents were
11 instructed to log in and complete one module each week. The therapists had
12 asynchronous contact online with adolescents and parents every week, commenting on
13 their progress on work sheets and through a built in message function. If necessary,
14 therapists had telephone contact with families, e.g., if they hadn’t logged in during the
15 last week or if mid-treatment self-reports exceeded a cut-off for depression (>11 on
16 RCADS-C depression subscale) or suicidality.
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34 The group-exposure sessions (at week 4, 6 and 10) ensured that key components of
35 the treatment were demonstrated in a correct way and that participants could practice
36 e.g. exposure under observation of a therapist. To ensure large enough group sizes,
37 cohorts of six participants started the treatment at the same time. The group sessions
38 were two hours long and led by two of the clinical psychologists.
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52 **Statistical analysis**

53 All analyses were conducted in SPSS Version 23.
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3 Cohen's kappa coefficient (κ)⁵³ was used to calculate inter-rater reliability for SAD-
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5 diagnosis and comorbidity at pre-treatment assessment. The level of reliability is
6
7 interpreted as poor when $\kappa < 0.40$, fair when κ is 0.40-0.59, good when κ is 0.60-0.74 and
8
9 excellent when $\kappa > 0.74$ ⁵⁴.

10
11 Linear mixed models were used to analyse changes from pre- to post-treatment, and
12
13 from post-treatment to 6-month follow-up. Mixed model analyses use all available data
14
15 and account for correlations between measurements within the same subject⁵⁵. Thus,
16
17 missing data is handled within the model. All mixed models in this study included a fixed
18
19 effect for time (pre, post and 6-month follow-up) and a random effect for individual
20
21 subjects. Potential missing bias was investigated using *t*-tests that compared the
22
23 baseline characteristics of those who had complete data at post-treatment with those
24
25 who had missing data. For SPAI C/P and SPWSS three mid-treatment (week 3, 6 and 9)
26
27 time points were included in the analyses, and for RCADS C/P and EWSAS C/P one mid-
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29 treatment (week 6) time point was included in the analyses.
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35 Effect sizes are reported as Cohen's $d = (M_1 - M_2 / SD_{\text{pooled}})$. Effect sizes are defined
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37 according to Cohen's suggested levels, small ($d \geq 0.20$), moderate ($d \geq 0.50$) and large (d
38
39 ≥ 0.80)⁵⁶.

40 41 **RESULTS**

42 43 **Response rate and feasibility**

44
45 Mid-treatment measures were completed by 97% of the participating families at week
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47 three, 83% at week six and 70% at week nine. Post-treatment and 6-month follow-up
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49 measures were completed by 90% and 83% of the participating families, respectively. T-
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51 tests comparing participants with missing versus complete data points on baseline
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53 characteristics revealed no statistically significant differences.
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3 Adolescents completed on average 5.7 ($sd = 2.1$) of the nine Internet-modules and
4
5 parents completed on average 4.4 ($sd = 1.0$) of their five modules. Attendance at the
6
7 group-sessions were 70% (session 1), 77% (session 2) and 63% (session 3)
8
9 respectively. Two thirds of the participants attended two or more group sessions and
10
11 only 10% attended none.

12
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14 None of the adolescents meeting inclusion criteria at baseline assessment declined
15
16 participation, which indicates good acceptability of the offered treatment.

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

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28 Insert Figure 2 here
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32 **Clinician support**

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34 The average time a clinician spent giving feedback and guidance to participants
35
36 (including time spent on the adolescent *and* parent) was 19.5 minutes per week for the
37
38 Internet-modules. Group sessions required two hours of therapist time per participant
39
40 in total during the 12 weeks, which corresponds to 10 minutes per week and
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42 participant. In total thus, each family got 29.5 minutes of therapist time, per week.
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48 **Changes in clinical outcomes from pre- to post-treatment**

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50 Means, standard deviations and effect sizes for pre to post changes, are presented in
51
52 Table 3. Intention-to-treat analyses of the primary outcome measure (CGI-S) showed a
53
54 significant decrease of SAD severity from pre- to post-treatment, $t(26.05) = 5.62, p < .001$,
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56 with a large effect size, $d = 1.17$ (95%CI 0.61,1.72). For all secondary outcome measures,
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3 analyses revealed significant improvements with moderate to large effect sizes, with the
4
5 exception of quality of life (KIDSCREEN-C/P) where a small effect was observed. At post-
6
7 treatment, 47% of the participants ($n = 14$) no longer met diagnostic criteria for SAD,
8
9 according to DSM-5 criteria and a CGI-rating <4 (level of severity and functional
10
11 impairment below diagnostic threshold) and 30% ($n = 9$) scored ≤ 18 on SPAI-C (cut-off
12
13 for clinical level of social anxiety). On the clinician rated CGI-I 8% ($n=2$) were “very
14
15 much improved”, 23% ($n = 6$) “much improved”, 42% ($n = 11$) “minimally improved”,
16
17 23% ($n = 6$) “not changed” and 4% ($n = 1$) “minimally worse”.
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23 **Changes in clinical outcomes from post-treatment to 6-month follow-up**

24
25 Table 3 gives an overview of means, standard deviations and effect sizes from post-
26
27 treatment to the 6-month follow-up. The improvements seen at post-treatment were
28
29 generally maintained and further augmented at the 6-month follow-up with small effect
30
31 sizes, except for self-focus (SPWSS) that deteriorated slightly. The primary outcome
32
33 measure (CGI-S) showed a significant decrease of SAD severity from post-treatment to
34
35 6-month follow up, $t(25.45) = 2.60, p < .05$, with a small effect size, $d = 0.22$ (95%CI -0.01,
36
37 0.45). At follow-up, 57% ($n = 17$) no longer met diagnostic criteria for SAD and 37% ($n =$
38
39 11) scored ≤ 18 on SPAI-C.
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44 Comparison of pre-treatment and 6-month follow-up levels of social anxiety showed
45
46 overall improvements with large effect-sizes, CGI-S: $t(27.23) = 6.24, p < .001, d = 1.36$
47
48 (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
49
50 SPAI-P: $t(26.08) = 5.57, p < .001, d = 1.14$ (95%CI 0.57, 1.72). Clinician-rated CGI-I
51
52 indicated that, of those who participated in the 6-month follow-up assessment, 19% ($n =$
53
54 5) were “very much improved”, 31% ($n = 8$) “much improved”, 38% ($n = 10$) “minimally
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3 improved", 4% ($n = 1$) "not changed" and 8% ($n = 2$) "minimally worse", compared to
4
5 baseline.

6 7 **Post-hoc analyses**

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9
10 The proportion of parents reporting that they had stayed home from work during the
11
12 last month due to their adolescent's health problems was 27% before treatment and
13
14 13% at 6-month follow-up. Of the adolescents, 50% had stayed home from school during
15
16 the last month due to health problems before treatment and 33% at 6-month follow-up.

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18
19 At 6-month follow-up, six participants reported that they had received additional
20
21 treatment for social anxiety; two participants (7%) got CBT and four participants (13%)
22
23 had initiated or increased SSRI medication. Half of all participants ($n=15$) reported that
24
25 they had used strategies from the treatment since post-treatment assessment, referring
26
27 to exposure, coping strategies (such as breathing exercises and focus shift) and cognitive
28
29 techniques as the most common ones.
30
31

32 33 **Adverse events**

34
35 Seven adolescents (23%) reported having experienced some negative event during the
36
37 course of treatment. These events included increased stress due to the limited time to
38
39 work with treatment modules ($n = 4$; 13%), increased social anxiety ($n=1$; 3%),
40
41 increased panic anxiety ($n=1$; 3%) and increased depression and negative thoughts
42
43 ($n=1$; 3%). Those who reported increased stress and anxiety associated these symptoms
44
45 with the first weeks of treatment and typically described a decrease as treatment
46
47 continued. Two adolescents reported that the negative event (increased negative
48
49 thoughts in one case and increased panic anxiety in the other case) still had some impact
50
51 on their wellbeing at the end of treatment.
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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

1
2
3 has been proposed that socially anxious children and adolescents have a tendency to
4
5 avoid practicing skills on their own that they have learned online, such as conducting in-
6
7 vivo exposure³³. It could therefore be hypothesized that the group-sessions in this study
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9 enhanced the participants' inclination to practice skills at home as a consequence of
10
11 being offered intensive therapist guidance and direct feedback during group-exposure.
12
13

14 Forty seven per cent of participants no longer met diagnostic criteria for SAD after
15
16 treatment, a proportion that further increased to 57% at 6-month follow-up. This is in
17
18 line with levels reported in studies evaluating face-to-face CBT for youth with SAD^{14-16 18}
19
20 ⁵⁷ and higher than strictly Internet-delivered CBT for youth with SAD³³. A recent trial of
21
22 ICBT for youth with SAD reported a relatively limited impact on the clinical diagnosis of
23
24 SAD (in the two active treatment conditions 12.8 and 14.6% at post-treatment and
25
26 29.8% and 35.4 % at 6-month follow-up, no longer met diagnostic criteria for SAD)³³
27
28 and the authors suggest that stand-alone ICBT might not be enough for youth with
29
30 SAD³³. It is tempting to attribute the better outcomes in our trial to the addition of
31
32 group-exposure sessions to the ICBT protocol, though this hypothesis remains to be
33
34 formally evaluated. Discrepancies between our and previous results may also be
35
36 attributable to differences in study samples, study design or other methodological
37
38 aspects.
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43
44 Therapists in this study spent less than 20 minutes per family and week, on the
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46 Internet-delivered treatment, which is comparable to previous ICBT trials for youth^{24 25}.
47
48 Although the group sessions added another 10 minutes per family and week in the
49
50 present trial, group-exposure supplemented ICBT should still be considered a time-
51
52 efficient intervention compared with face-to-face CBT where the therapist time per
53
54 family and week usually ranges from 45-60 minutes.
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3 Around a fifth of the participants reported a negative event during the course of the
4
5 treatment. Some of the events were expected, such as increased social anxiety when
6
7 exposure is initiated. Reports of increased stress were also associated with the first
8
9 weeks of the treatment and can be interpreted as an initial difficulty combining
10
11 treatment with other demands such as schoolwork. Two participants reported having
12
13 experienced some negative events that affected their wellbeing beyond the treatment
14
15 termination but these participants still benefited from treatment.
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17

18
19 Overall, the treatment seems feasible and possibly efficacious for adolescents with
20
21 SAD and their parents, but to be considered for implementation in regular care, an
22
23 intervention must also be feasible from an organizational point of view. A possible
24
25 drawback with the addition of group-exposure to ICBT is that it limits the flexibility of
26
27 the intervention. For instance, several patients must be recruited and able to commence
28
29 treatment at the same time. A possible alternative to group-exposure sessions is to add
30
31 other forms of direct communication between patients and ICBT-therapists, e.g. video
32
33 conferencing or equivalent, something that future studies should investigate further.
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39 **Limitations**

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41 Although this feasibility trial has several strengths, some important limitations need to
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43 be considered when interpreting the results. Causal inferences of observed changes are
44
45 not possible due to lack of a control condition. Thus, improvement could be an effect of
46
47 non-specific factors such as the therapist attention or of the passage of time. However,
48
49 SAD has been shown to commonly follow a chronic course when left untreated² and it is
50
51 not likely that spontaneous remission would explain a significant part of the
52
53 improvements in the study. Additionally, results were maintained and slightly improved
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55 at follow-up, indicating that treatment gains were stable over time, even after the
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3 attention from a therapist had ceased. A small proportion of the participants did seek
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5 additional care between post-treatment and 6-month follow-up, which could have
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7 affected the results. However, these participants all continued to report high levels of
8
9 social anxiety at follow-up, implying that additional care had limited impact on the long-
10
11 term outcome. Another limitation concerns assessment at post-treatment and follow-up.
12
13 Although attempts to reduce bias were made by having these assessments conducted by
14
15 clinicians not involved in the treatment, assessors were not blind to the fact that the
16
17 participant had received treatment.
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19

20 21 22 23 **Conclusions**

24
25 This is the first study of therapist- and parent-guided ICBT supplemented with group-
26
27 exposure for adolescents with SAD. The intervention was highly acceptable to the
28
29 families and significantly reduced social anxiety symptoms up to 6-month follow-up.
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31 Participants were generally satisfied with the treatment and the completion-rate of
32
33 Internet-modules and attendance at group sessions were high, indicating that the
34
35 treatment is feasible and acceptable to the SAD youth population. Furthermore, per-
36
37 patient therapist time was limited, even considering the time spent on group-sessions;
38
39 thus, ICBT supplemented with group-exposure might be cost-effective when compared
40
41 to traditional face-to-face CBT. Further controlled trials are needed.
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48 **Acknowledgements** The authors would like to thank Ulrika Thulin for invaluable help with writing the
49
50 treatment modules, and Cornelia Hanqvist and Jon Juselius for assisting with providing the treatment.
51

52 **Contributors** The study was designed by MN, SV, DMC, ES and JH. MN was the project manager in
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54 collaboration with JH. MN wrote the treatment modules and provided the treatment in collaboration
55
56 with JH and SV. All statistical analyses were conducted by JH and MN. MN drafted the manuscript in
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3 collaboration with JH. The manuscript was reviewed and revised by SV, ES, DMC, BL and LGÖ. All
4
5 authors have read and approved the final manuscript.

6
7 **Funding** This work was supported by the Stockholm County Council (PPG project 20150032; HSNV
8
9 140 99; HSN 1011-1176) and the Swedish Research Council and Swedish Research Council for
10
11 Health, Working Life and Welfare (Forte 2014-4052)

12 **Competing interests** None.

13
14 **Data sharing statement** No additional data are available.

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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.		

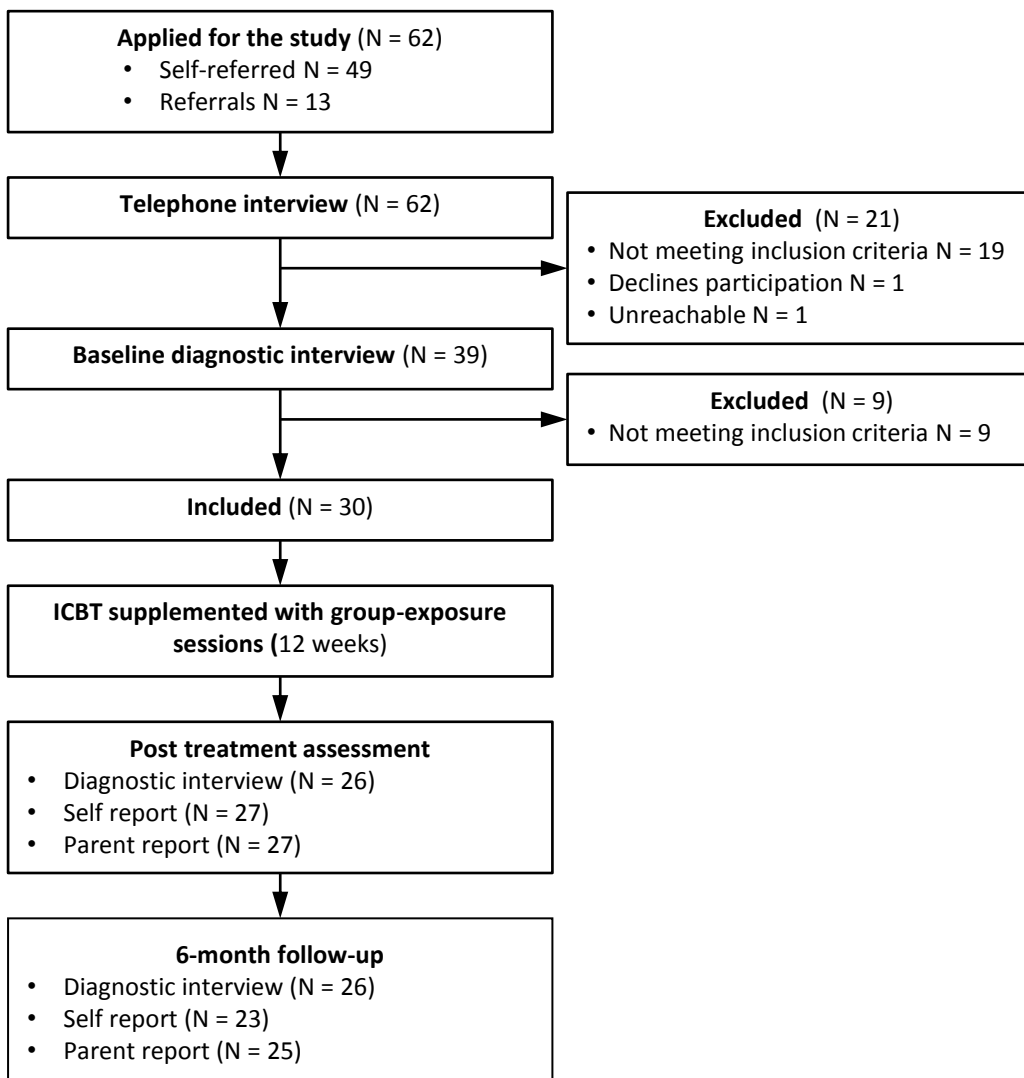
Table 3 Means, standard deviations, pre- to post and post to 6-month follow-up comparisons, and effect sizes of all outcome measures

Measure	Pre		Post		Pre to post comparison		6-month follow-up		Post to follow-up comparison	
	M	SD	M	SD	p	d (95% CI)	M	SD	p	d (95%CI)
<i>Clinician-rated</i>										
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)
<i>Self- and parent rated social anxiety</i>										
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)
<i>Other self- and parent rated measures</i>										
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

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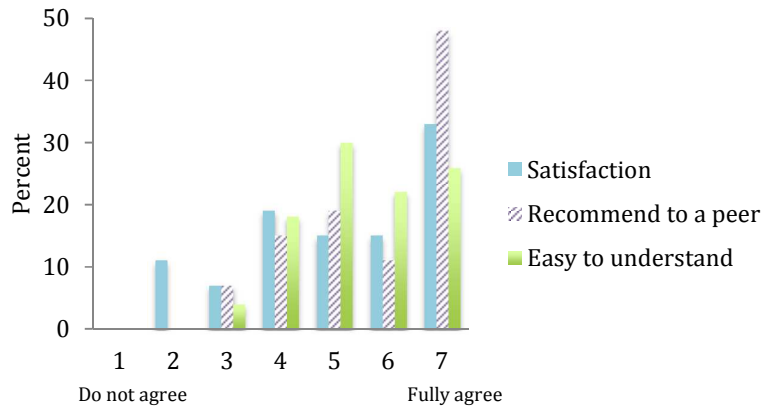


Figure 2. Adolescents' evaluation of BIP SOFT

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BMJ Open

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

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

SCHOLARONE™
Manuscripts

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

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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 ($d = 1.17, 0.85, \text{ and } 0.79$, respectively), as well as in general self- and parent-rated anxiety and depression ($d = 0.76 \text{ and } 0.51$), 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.

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3 **Conclusion:** Therapist- and parent guided Internet-delivered CBT, supplemented
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5 with a limited number of group-exposure sessions is a feasible and promising
6
7 intervention for adolescents with SAD.
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10 **Trial registration number:** Clinicaltrials.gov registration ID NCT02576171
11

12 13 14 Strengths and limitations of this study

- 15
16 ▪ This is the first study to investigate the feasibility and efficacy of a
17 combined Internet-CBT and group-exposure treatment for youth with
18 social anxiety disorder.
- 19
20 ▪ Participants were followed up six months after the end of treatment.
- 21
22 ▪ The study was uncontrolled which limits any causal inference about
23 observed changes.
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32 INTRODUCTION

33
34 Social anxiety disorder (SAD) is characterized by an intense fear of being scrutinized and
35 negatively evaluated in social or performance situations¹. The socially anxious
36
37 individual is typically afraid of making mistakes, being embarrassed in front of others
38
39 and of showing signs of anxiety, such as blushing or trembling, and may therefore avoid
40
41 social and performance situations or endure them under intense distress. The disorder
42
43 has a median age of onset of 9.2 years ² and is one of the most common mental disorders
44
45 among adolescents. SAD is more common in adolescent girls than in adolescent boys
46
47 with a female to male odds ratio of 1.58 (95%CI: 1.18-2.12)². The 12-month prevalence
48
49 is 3.4% ³ and 8.6% of the adolescent population fulfill diagnostic criteria at some point
50
51 between the age of 13 and 18². If the disorder is left untreated it tends to follow a
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53 chronic course² and can lead to severe secondary consequences such as depression⁴ and
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3 suicidality⁵, substance and alcohol dependence⁶, academic underperformance and
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5 increased social isolation⁷. Consequently, SAD causes substantial impairment as well as
6
7 burden on patients' families and long-term societal costs^{8 9}.

8
9
10 Cognitive behavioural therapy (CBT) for SAD is effective for adults¹⁰ as well as for
11
12 children and adolescents^{11 12} and is the first-line treatment according to international
13
14 clinical guidelines (e.g., the National Institute for Health and Care Excellence; NICE)¹³. In
15
16 face-to-face treatment, generic CBT has shown poorer outcomes for youth with SAD
17
18 compared to other anxiety disorders¹⁴, but when treatments have been tailored to
19
20 include SAD-specific components, such as social skills training, the reported effects have
21
22 been larger^{15 16}.

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25 Despite the high level of impairment caused by the disorder, only a small proportion
26
27 of adolescents with social anxiety seek help for their problems^{17 18} and even fewer
28
29 receive effective treatment¹⁹. Barriers to receiving evidence-based psychological
30
31 treatment include limited availability of trained therapists, and practical issues such as
32
33 long travel distances to clinics, and the requirement to take time off school or work to
34
35 visit a clinic.
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39 Internet-delivered CBT (ICBT) has been suggested as a possible solution to some of
40
41 these barriers. It can provide the same treatment components as traditional CBT and
42
43 allow patients to work from home (or wherever suitable), guided by an online-therapist,
44
45 e.g. through e-mail or similar online communication. Treatment becomes more
46
47 accessible as the therapist and patient can communicate asynchronously and it may
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49 increase treatment capacity, as therapist time per patient tends to be lower compared
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51 with face-to-face CBT²⁰⁻²². For adults with SAD, ICBT is an evidence-based treatment²³
52
53 with at least one trial showing that ICBT is non-inferior to face-to-face CBT²⁴. For youth,
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55 ICBT is effective for mixed anxiety disorders when compared to a waitlist control²⁵⁻²⁸,
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3 with similar effects as face-to-face CBT ²⁹, suggesting that ICBT could be a suitable
4
5 treatment for adolescents with SAD. However, a recent study showed that only 12.8%
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7 and 14.6% (in the SAD specific and generic ICBT conditions, respectively) of participants
8
9 were free from their SAD diagnosis at post-treatment assessment, indicating that using
10
11 the Internet, as the only modality to deliver CBT might not be sufficient³⁰.
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14 The objective of the current trial is to evaluate the feasibility and efficacy of ICBT
15
16 supplemented with clinic-based group-exposure sessions, for adolescents with SAD, a
17
18 treatment that could potentially draw on advantages from both formats, where ICBT is a
19
20 cost-effective and accessible format and group-sessions may ensure that key treatment
21
22 components, such as exposure to social situations and social skills training, are
23
24 conveyed properly. Main research questions are: Is the treatment (BIP SOFT) feasible
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26 and acceptable with regard to adolescents' and parents' willingness to work with the
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28 Internet-modules, adolescents' attendance rates at group sessions and treatment
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30 satisfaction? Does the treatment reduce social anxiety symptoms and increase
31
32 adolescents' level of functioning and quality of life?
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39 **METHOD**

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41 The study was conducted at a research unit within the Child and Adolescent Mental
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43 Health Services in Stockholm, Sweden, and was approved by the Regional Ethical Review
44
45 Board in Stockholm, Sweden (2015/1383-31/2). Participants were recruited and
46
47 treated between October 2015 and May 2016.
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49

50 **Participants**

51
52 Participants were 30 adolescents, 13-17 years old, with a principal diagnosis of SAD, and
53
54 their parents. Table 1 gives detailed information on demographic and clinical
55
56 characteristics of the sample. Inclusion criteria were: a) age 13-17 years, b) principal
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3 DSM-5 diagnosis of SAD, c) ability to read and write Swedish, d) access to a computer
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5 with Internet access and e) at least one parent being able to participate in the treatment.
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7 Exclusion criteria were: f) initiation or dose modification of psychotropic drug within
8
9 the past six weeks, g) ≥ 5 sessions of CBT (including exposure) within the last six
10
11 months, h) any ongoing psychological treatment for SAD, i) diagnosed with an autism
12
13 spectrum disorder, current psychosis, eating disorder, severe depression, suicidal
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15 behaviour or other current severe psychiatric condition j) current substance- or alcohol
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17 abuse. Adolescents excluded due to other severe psychiatric conditions, such as severe
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19 depression or suicidality, were referred to more suitable treatments.
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23 Participants were mainly recruited through advertisement in a local paper. The
24
25 advertisement included a website address (www.bup.se/bip) where interested families
26
27 could get study information and sign up. Clinicians working in the child- and adolescent
28
29 health services could also refer patients to the trial.
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32 To achieve sufficient power and to be able to detect a within-group effect size of $d =$
33
34 0.60 from pre to post with a power of 0.85 and $\alpha = 0.05$, allowing for a 10% drop out, we
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36 included 30 participants in the study.
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45 **Measures**

46 *Primary outcome measures*

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48 The Clinical Global Impression – Severity (CGI-S)³¹ is a clinician rating of symptom
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50 severity, ranging from 1 (“normal, not mentally ill”) to 7 (“extremely ill”). The CGI-S
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52 was administered at baseline by the treating therapist. At post-treatment and the 6-
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54 month follow-up, another clinician than the one being responsible for the treatment
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3 administered the CGIS-S.
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8 *Secondary outcome measures*

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10 Mini International Neuropsychiatric Interview for Children and Adolescents (M.I.N.I.
11 KID)³², was used to determine presence of SAD, as well as comorbid conditions. In
12 addition, the SAD section of the Anxiety Disorders Interview Schedule for DSM-IV-Child
13 Version (ADIS-C)³³ was used to further confirm SAD-diagnosis and to assess the
14 intensity of SAD symptoms. An independent rater (a clinical psychologist, not part of the
15 research group, blind to whether the adolescent had been included in the study or not)
16 watched recordings of the baseline interviews and reassessed 20% of them (both
17 included and excluded adolescents), generating an excellent inter-rater reliability at pre-
18 treatment for SAD-diagnosis ($\kappa = 1.0$) and a fair inter-rater reliability for comorbidity (κ
19 = 0.46, $p < .05$).
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32 Clinical global impression – Improvement (CGI-I)³¹ is a clinician rating of the
33 participant's change in symptom severity relative to baseline, ranging from 1 ("very
34 much improved") to 7 ("very much worse"). The Children's Global Assessment Scale
35 (CGAS)³⁴ is a clinician rating of global functioning (scale 0-100), with higher rating
36 indicating higher level of functioning. The M.I.N.I. KID and CGAS were administered at
37 baseline, post-treatment and at the 6-month follow-up, whereas the CGI-I was
38 administered post-treatment and at the 6-month follow-up.
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48 Social Phobia and Anxiety Inventory - Child and Parent Version (SPAI-C/P)³⁵ is a 26-
49 item self-report measure evaluating aspects of SAD on a 3-point scale, where a score of
50 ≥ 18 is considered the clinical level of social anxiety. The Social Phobia Weekly Summary
51 Scale (SPWSS) is a five-item self-report scale^{36,37} measuring dimensions of SAD (social
52 anxiety, avoidance, self-focused attention, anticipatory processing and post-event
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3 processing). The SPAI-C/P and the SPWSS were administered at baseline, every third
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5 week during treatment, post-treatment as well as at the 6-month follow-up.
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7 The Revised Children Anxiety And Depression Scale – Child and Parent Version
8 (RCADS-C/P)³⁸ is a 47-item self-report measure evaluating anxiety disorders (including
9 one subscale for SAD) and depression on a 4-point scale, ranging from *never* to *always*.
10
11 In the current trial one item regarding suicidality, with three options (“I do not think
12 about killing myself”, “I think about killing myself, but would never do it” or “I want to
13 kill myself”), was added at the end of the RCADS-C/P. The Education, Work and Social
14 Adjustment Scale – Child and Parent Version (EWSAS-C/P)^{39 40} is a 5-item self-report
15 scale measuring functional impairment on a 9-point scale (higher rating indicating more
16 impairment). The RCADS-C/P and the EWSAS-C/P were administered at baseline, after
17 six weeks of treatment, post-treatment as well as at the 6-month follow-up.
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30 The Health related quality of life questionnaire for children, adolescents and their
31 parents (KIDSCREEN-10)⁴¹ is a self-report measure assessing health related quality of
32 life. The parent-rated measure Trimbos/iMTA questionnaire for Costs associated with
33 Psychiatric Illness – Child version (TiC-P)⁴² covers e.g. production loss among parents
34 due to health problems in the child. The KIDSCREEN-10 and the TiC-P were
35 administered at baseline, post-treatment and at the 6-month follow-up.
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46 *Feasibility measures, adverse events and therapist time*

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48 The Technology Acceptance Scale – child and parent version (TAS-C/P) is a self-report
49 measure adapted from Venkatesh et al.⁴³, which measures the usefulness, acceptability
50 and satisfaction of the website through which the Internet-modules of the treatment
51 were delivered. The TAS-C/P was administered after three weeks of treatment and post-
52 treatment.
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3 At post-treatment, adolescents and parents were asked to report any negative
4 experiences or adverse events over the course of treatment as well as to what extent the
5 negative event had affected the adolescent's wellbeing.
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10 Amount of therapist time per participant was logged automatically through the
11 Internet-treatment platform.
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14 15 16 **Procedure**

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18 Figure 1 gives an overview of inclusion procedures and assessment points. Families who
19 applied to the study were contacted by telephone and a short screening interview was
20 conducted. Eligible families were invited to diagnostic assessment at the clinic. After
21 thorough information about the study, adolescents gave verbal assent to participate and
22 written informed consent was obtained from parents. The screening interview M.I.N.I.
23 KID (with the supplement of the SAD section of the ADIS-C) was then conducted. The
24 therapist who conducted the baseline assessment was responsible for the treatment of
25 the participant.
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37 Adolescents with a principal diagnosis of SAD were included and adolescents and
38 parents completed baseline self-report measures online through the treatment platform.
39 In each family, one of the parents was assigned the main responsibility to respond to the
40 parent-report measures at each assessment point throughout the study. Adolescents and
41 parents had separate user accounts and a two-factor authentication (an individual
42 password and a single-use code sent to the user's cellular phone) gave access to the
43 online platform.
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53 Self- and parent rated measures administered during the treatment (SPAI C/P,
54 SPWSS, RCADS C/P and EWSAS C/P) were completed online.
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3 At post-treatment and at the 6-month follow-up all participating adolescents and
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5 parents were invited back to the clinic for a diagnostic assessment. To reduce the risk of
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7 biased assessment, a clinician that had not been responsible for the participant's
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9 treatment conducted the post-treatment and follow-up assessments. All self-assessment
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11 scales were administered online post-treatment and at follow-up. Families who could
12
13 not come to the clinic for post-treatment assessment (n = 1) and 6-month follow-up (n =
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15 3) were assessed over the telephone.
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25 **Intervention**

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27 The intervention was 12 weeks of ICBT supplemented with group-exposure, comprising
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29 nine Internet-delivered modules completed individually from home, and three group-
30
31 exposure sessions at the clinic (Table 2). The online treatment platform used in this
32
33 study was developed for delivery of ICBT and has been tested in a number of previous
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35 studies for different psychiatric disorders in youth^{22 28 44-46}. The current treatment (BIP
36
37 SOFT) was based on the cognitive-behavioural model by Rapee and Heimberg⁴⁷ and to
38
39 some extent on the cognitive model by Clark and Wells⁴⁸. The treatment manual was
40
41 developed by the authors and contains CBT components commonly used for SAD in
42
43 youth^{15 49 50}, such as exposure, coping strategies and social skills training. The group
44
45 sessions were mostly based on the Albano and DiBartolo group-CBT manual for
46
47 adolescent SAD⁵⁰. Therapists in the study were three clinical psychologists and two
48
49 master students at their final year of training in clinical psychology.
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54 The Internet-modules included educative texts, animations, audio clips and exercises.

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56 The parental part of the intervention consisted of five Internet-modules with parent-
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3 specific topics such as “parental traps” (e.g., compensating for the adolescent in social
4 situations by for instance speaking for him/her) and doing functional analyses of such
5 parental accommodation (Table 2). Parents were encouraged to be actively involved in
6 their adolescent’s treatment and discuss with the adolescent how they should support
7 him or her throughout the treatment, e.g. during exposure exercises. Parents were also
8 encouraged to bring up parent-specific topics with their therapist, for example how to
9 support the adolescent before or during exposures. Parents could send messages to the
10 therapist throughout the 12 weeks of treatment. Adolescents and parents were
11 instructed to log in and complete one module each week. The modules were assigned in
12 a predetermined order and therefore, all modules but the first were initially locked.
13 Once the participant completed a module, the therapist made the next one available.
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28 The therapists had asynchronous contact online with adolescents and parents every
29 week, commenting on their progress on work sheets and through a built in message
30 function. Therapists were instructed to log in and provide feedback to their families
31 three times per week. If necessary, therapists had telephone contact with families, e.g., if
32 they hadn’t logged in during the last week or if mid-treatment self-reports exceeded a
33 cut-off for depression (>11 on RCADS-C depression subscale) or suicidality.
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41 The group-exposure sessions (at week 4, 6 and 10) ensured that key components of
42 the treatment were demonstrated in a correct way and that participants could practice
43 e.g. exposure under observation of a therapist. To ensure large enough group sizes,
44 cohorts of six participants started the treatment at the same time. The group sessions
45 were two hours long and led by two of the clinical psychologists.
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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 $\kappa < 0.40$, fair when κ is 0.40-0.59, good when κ is 0.60-0.74 and excellent when $\kappa > 0.74$ 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 subject⁵³. 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 $d = (M_1 - M_2 / SD_{\text{pooled}})$. 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-

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3 tests comparing participants with missing versus complete data points on baseline
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5 characteristics revealed no statistically significant differences.
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7 Adolescents completed on average 5.7 ($sd = 2.1$) of the nine Internet-modules and
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9 parents completed on average 4.4 ($sd = 1.0$) of their five modules. The frequency of
10
11 completed modules by the adolescents was distributed as follows: 20% ($n = 6$)
12
13 completed 2-3 modules, 43% ($n = 13$) completed 4-6 modules and 37% ($n = 11$)
14
15 completed 7-9 modules. None completed fewer than two modules.
16
17

18 Attendance at the group-sessions were 70% (session 1), 77% (session 2) and 63%
19
20 (session 3) respectively. Two thirds of the participants attended two or more group
21
22 sessions and only 10% attended none.
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25 None of the adolescents meeting inclusion criteria at baseline assessment declined
26
27 participation, which indicates good acceptability of the offered treatment.
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30 Figure 2 illustrates that a majority of the adolescents were satisfied with the
31
32 treatment, would recommend the treatment to a friend and found the program easy to
33
34 understand. Furthermore, most of the participating adolescents found the treatment's
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36 online platform easy to use, with a mean rating of 5.6 (range 4-7) on the 7-point TAS
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38 scale item (where 7 indicates full agreement with the statement "The program was easy
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40 to use").
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46 Insert Figure 2 here
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50 **Clinician support**

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52 The average time a clinician spent giving feedback and guidance to participants
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54 (including time spent on the adolescent *and* parent) was 19.5 minutes per week for the
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56 Internet-modules. Group sessions required two hours of therapist time per participant
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3 in total during the 12 weeks, which corresponds to 10 minutes per week and
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5 participant. In total thus, each family got 29.5 minutes of therapist time, per week.
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8 9 10 **Changes in clinical outcomes from pre- to post-treatment**

11 Means, standard deviations and effect sizes for pre to post changes, are presented in
12 Table 3. Intention-to-treat analyses of the primary outcome measure (CGI-S) showed a
13 significant decrease of SAD severity from pre- to post-treatment, $t(26.05) = 5.62, p < .001$,
14 with a large effect size, $d = 1.17$ (95%CI 0.61,1.72). For all secondary outcome measures,
15 analyses revealed significant improvements with moderate to large effect sizes, with the
16 exception of quality of life (KIDSCREEN-C/P) where a small effect was observed. At post-
17 treatment, 47% of the participants ($n = 14$) no longer met diagnostic criteria for SAD,
18 according to DSM-5 criteria and a CGI-rating < 4 (level of severity and functional
19 impairment below diagnostic threshold) and 30% ($n = 9$) scored ≤ 18 on SPAI-C (cut-off
20 for clinical level of social anxiety). On the clinician rated CGI-I 8% ($n = 2$) were “very
21 much improved”, 23% ($n = 6$) “much improved”, 42% ($n = 11$) “minimally improved”,
22 23% ($n = 6$) “not changed” and 4% ($n = 1$) “minimally worse”.
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41 **Changes in clinical outcomes from post-treatment to 6-month follow-up**

42 Table 3 gives an overview of means, standard deviations and effect sizes from post-
43 treatment to the 6-month follow-up. The improvements seen at post-treatment were
44 generally maintained and further augmented at the 6-month follow-up with small effect
45 sizes, except for self-focus (SPWSS) that deteriorated slightly. The primary outcome
46 measure (CGI-S) showed a significant decrease of SAD severity from post-treatment to
47 6-month follow up, $t(25.45) = 2.60, p < .05$, with a small effect size, $d = 0.22$ (95%CI -0.01,
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3 0.45). At follow-up, 57% ($n = 17$) no longer met diagnostic criteria for SAD and 37% ($n =$
4
5 11) scored ≤ 18 on SPAI-C.

6
7 Comparison of pre-treatment and 6-month follow-up levels of social anxiety showed
8
9 overall improvements with large effect-sizes, CGI-S: $t(27.23) = 6.24, p < .001, d = 1.36$
10
11 (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
12
13 SPAI-P: $t(26.08) = 5.57, p < .001, d = 1.14$ (95%CI 0.57, 1.72). Clinician-rated CGI-I
14
15 indicated that, of those who participated in the 6-month follow-up assessment, 19% ($n =$
16
17 5) were “very much improved”, 31% ($n = 8$) “much improved”, 38% ($n = 10$) “minimally
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19 improved”, 4% ($n = 1$) “not changed” and 8% ($n = 2$) “minimally worse”, compared to
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24 baseline.

25 **Post-hoc analyses**

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27 The proportion of parents reporting that they had stayed home from work during the
28
29 last month due to their adolescent’s health problems was 27% before treatment and
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31 13% at 6-month follow-up. Of the adolescents, 50% had stayed home from school during
32
33 the last month due to health problems before treatment and 33% at 6-month follow-up.
34
35 At 6-month follow-up, six participants reported that they had received additional
36
37 treatment for social anxiety; two participants (7%) got CBT and four participants (13%)
38
39 had initiated or increased SSRI medication. All these participants fulfilled diagnostic
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41 criteria for SAD at post treatment assessment and five out of six still fulfilled diagnostic
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43 criteria for SAD at follow-up.
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48 Half of all participants ($n=15$) reported that they had used strategies from the
49
50 treatment since post-treatment assessment, referring to exposure, coping strategies
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52 (such as breathing exercises and focus shift) and cognitive techniques as the most
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54 common ones.
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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.

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3 The adolescents completed on average nearly two thirds of the 9 online-modules
4 which is more than in previous studies on ICBT for youth with SAD where participants
5 completed less than half of the modules on average^{26 30}. It is possible that the face-to-
6 face component (group-based exposure sessions) in the present study influenced the
7 working pace with the Internet-modules as participants were recommended to
8 complete the preceding modules before attending group sessions. Even if completion of
9 previous modules was not a prerequisite for attendance at group sessions, participants
10 tended to complete them before attending the sessions. Participants also had peer and
11 therapist support in the group on aspects of the Internet-delivered modules that they
12 found difficult (e.g., designing an idiosyncratic exposure hierarchy), which might have
13 led to more motivation to work with modules *after* group sessions. It has been proposed
14 that socially anxious children and adolescents have a tendency to avoid practicing skills
15 on their own that they have learned online, such as conducting in-vivo exposure³⁰. It
16 could therefore be hypothesized that the group-sessions in this study enhanced the
17 participants' inclination to practice skills at home as a consequence of being offered
18 intensive therapist guidance and direct feedback during group-based exposure.
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39 Forty seven per cent of participants no longer met diagnostic criteria for SAD after
40 treatment, a proportion that further increased to 57% at 6-month follow-up. This is in
41 line with levels reported in studies evaluating face-to-face CBT for youth with SAD^{15 49}
42 ⁵⁵⁻⁵⁷ and higher than strictly Internet-delivered CBT for youth with SAD³⁰. A recent trial
43 of ICBT for youth with SAD reported a relatively limited impact on the clinical diagnosis
44 of SAD (in the two active treatment conditions 12.8 and 14.6% at post-treatment and
45 29.8% and 35.4 % at 6-month follow-up, no longer met diagnostic criteria for SAD)³⁰
46 and the authors suggest that stand-alone ICBT might not be enough for youth with
47 SAD³⁰. It is tempting to attribute the better outcomes in our trial to the addition of
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3 group-based exposure sessions to the ICBT protocol, though this hypothesis remains to
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5 be formally evaluated. Discrepancies between our and previous results may also be
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7 attributable to differences in study samples, study design or other methodological
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9 aspects.
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11
12 Therapists in this study spent less than 20 minutes per family and week, on the
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14 Internet-delivered treatment, which is comparable to previous ICBT trials for youth^{21 22}.
15
16 Although the group sessions added another 10 minutes per family and week in the
17
18 present trial, group-exposure supplemented ICBT should still be considered a time-
19
20 efficient intervention compared with face-to-face CBT where the therapist time per
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22 family and week usually ranges from 45-60 minutes.
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26 Around a fifth of the participants reported a negative event during the course of the
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28 treatment. Some of the events were expected, such as increased social anxiety when
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30 exposure was initiated. Reports of increased stress were also associated with the first
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32 weeks of the treatment and can be interpreted as an initial difficulty combining
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34 treatment with other demands such as schoolwork. Two participants reported having
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36 experienced some negative events that affected their wellbeing beyond the treatment
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38 termination but these participants still benefited from treatment.
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42 Overall, the treatment seems feasible and possibly efficacious for adolescents with
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44 SAD and their parents, but to be considered for implementation in regular care, an
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46 intervention must also be feasible from an organizational point of view. A possible
47
48 drawback with the addition of group-exposure to ICBT is that it limits the flexibility of
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50 the intervention. For instance, several patients must be recruited and able to commence
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52 treatment at the same time. SAD is a challenging disorder to treat and interventions
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54 aspiring to be effective may need to include direct and frequent therapist guidance. On
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56 the other hand, development of new treatments should not only consider treatment
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3 efficacy, but also accessibility, flexibility and cost effectiveness. A possible alternative to
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5 group-based exposure sessions is to add other forms of direct communication between
6
7 patients and ICBT-therapists, e.g. video conferencing or equivalent, something that
8
9 future studies should investigate further.
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11 12 13 **Limitations**

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15 Although this feasibility trial has several strengths, some important limitations need to
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17 be considered when interpreting the results. Causal inferences of observed changes are
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19 not possible due to lack of a control condition. Thus, improvement could be an effect of
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21 non-specific factors such as the therapist attention or of the passage of time. However,
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23 SAD has been shown to commonly follow a chronic course when left untreated² and it is
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25 not likely that spontaneous remission would explain a significant part of the
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27 improvements in the study. Additionally, results were maintained and slightly improved
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29 at follow-up, indicating that treatment gains were stable over time, even after the
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31 attention from a therapist had ceased. A small proportion of the participants did seek
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33 additional care between post-treatment and 6-month follow-up, which could have
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35 affected the results. However, these participants continued to report high levels of social
36
37 anxiety at follow-up, implying that additional care had limited impact on the long-term
38
39 outcome. Although social anxiety is generally more common among women, the current
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41 sample had an overrepresentation of girls. The effect of gender on the results in this trial
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43 is unclear and may be further analyzed in future trials with larger samples.
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50 Another limitation concerns assessment at post-treatment and follow-up. Although
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52 attempts to reduce bias were made by having these assessments conducted by clinicians
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54 not involved in the treatment, assessors were not blind to the fact that the participant
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56 had received treatment.
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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.

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

Variables		N	%
Age (years)	<i>M (SD)</i>	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)	<i>M (SD)</i>	8.9 (4.29)	
Duration of SAD (years)	<i>M (SD)</i>	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

Measure	Pre		Post		Pre to post comparison		6-month follow-up		Post to follow-up comparison	
	M	SD	M	SD	p	d (95% CI)	M	SD	p	d (95%CI)
<i>Clinician-rated</i>										
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)
<i>Self- and parent rated social anxiety</i>										
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)
<i>Other self- and parent rated measures</i>										
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

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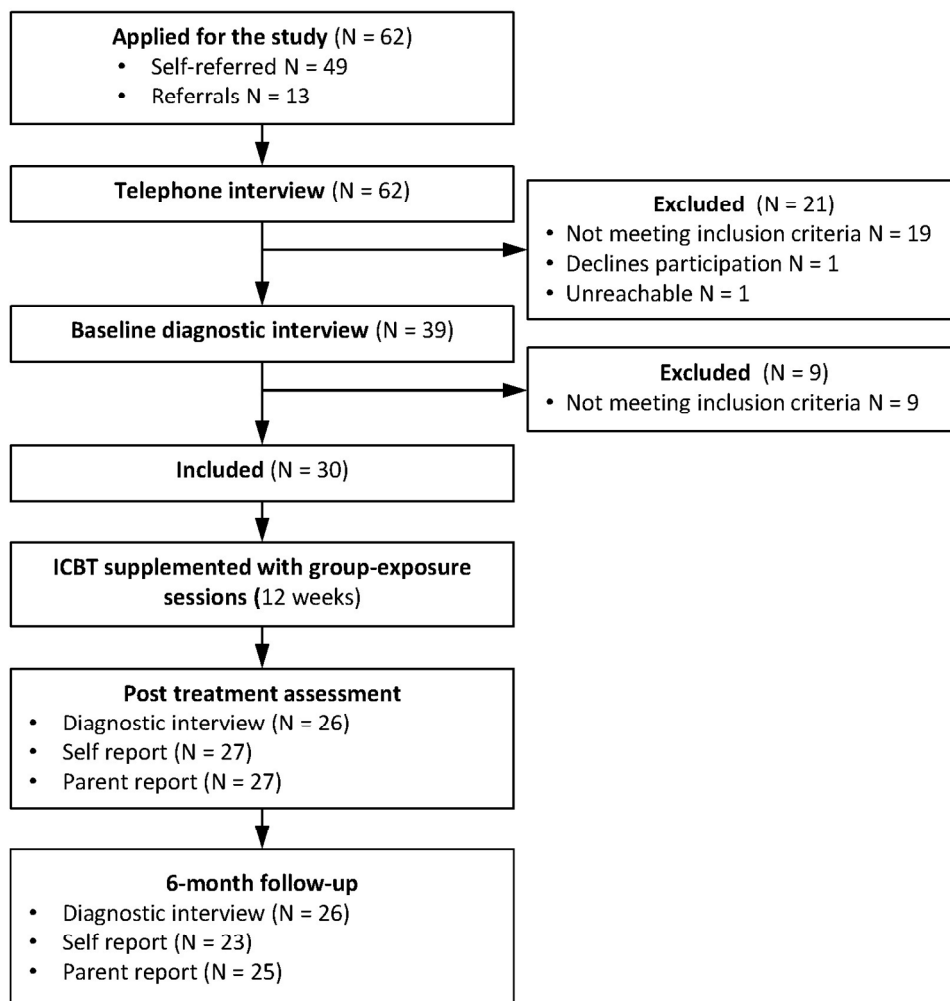


Figure 1. Study flow chart

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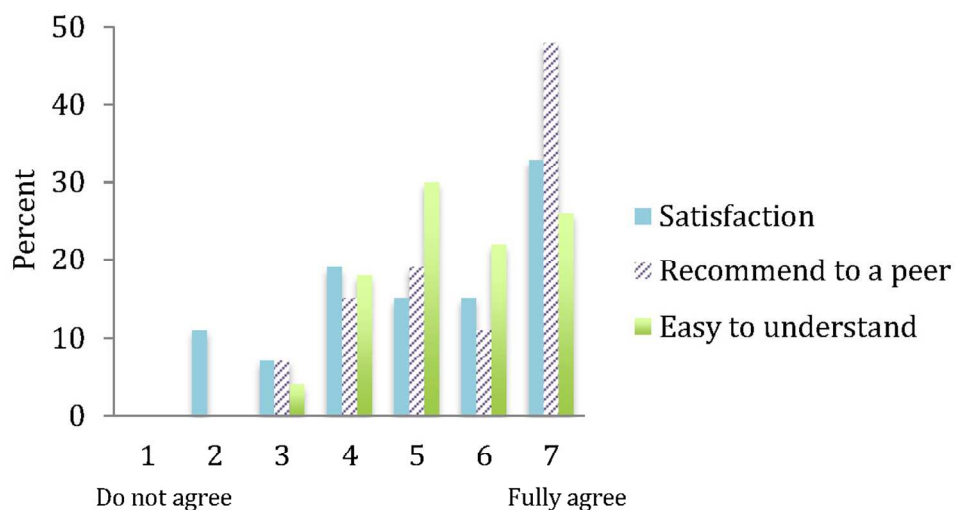


Figure 2. Adolescents' evaluation of BIP SOFT

112x64mm (300 x 300 DPI)

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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:			

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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

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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

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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

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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	

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BMJ Open

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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2017-018345.R2
Article Type:	Research
Date Submitted by the Author:	04-Oct-2017
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Primary Subject Heading:	Mental health
Secondary Subject Heading:	Health services research
Keywords:	Child & adolescent psychiatry < PSYCHIATRY, Anxiety disorders < PSYCHIATRY, MENTAL HEALTH

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Manuscripts

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

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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 ($d = 1.17, 0.85, \text{ and } 0.79$, respectively), as well as in general self- and parent-rated anxiety and depression ($d = 0.76 \text{ and } 0.51$), 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.

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3 **Conclusion:** Therapist- and parent guided Internet-delivered CBT, supplemented
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5 with a limited number of group-exposure sessions is a feasible and promising
6
7 intervention for adolescents with SAD.
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10 **Trial registration number:** Clinicaltrials.gov registration ID NCT02576171
11

12 13 14 Strengths and limitations of this study

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

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34 Social anxiety disorder (SAD) is characterized by an intense fear of being scrutinized and
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36 negatively evaluated in social or performance situations¹. The socially anxious
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38 individual is typically afraid of making mistakes, being embarrassed in front of others
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40 and of showing signs of anxiety, such as blushing or trembling, and may therefore avoid
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42 social and performance situations or endure them under intense distress. The disorder
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44 has a median age of onset of 9.2 years ² and is one of the most common mental disorders
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46 among adolescents. SAD is more common in adolescent girls than in adolescent boys
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48 with a female to male odds ratio of 1.58 (95%CI: 1.18-2.12)². The 12-month prevalence
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50 is 3.4% ³ and 8.6% of the adolescent population fulfill diagnostic criteria at some point
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52 between the age of 13 and 18². If the disorder is left untreated it tends to follow a
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54 chronic course² and can lead to severe secondary consequences such as depression⁴ and
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3 suicidality⁵, substance and alcohol dependence⁶, academic underperformance and
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5 increased social isolation⁷. Consequently, SAD causes substantial impairment as well as
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7 burden on patients' families and long-term societal costs^{8 9}.

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9
10 Cognitive behavioural therapy (CBT) for SAD is effective for adults¹⁰ as well as for
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12 children and adolescents^{11 12} and is the first-line treatment according to international
13
14 clinical guidelines (e.g., the National Institute for Health and Care Excellence; NICE)¹³. In
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16 face-to-face treatment, generic CBT has shown poorer outcomes for youth with SAD
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18 compared to other anxiety disorders¹⁴, but when treatments have been tailored to
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20 include SAD-specific components, such as social skills training, the reported effects have
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22 been larger^{15 16}.

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25 Despite the high level of impairment caused by the disorder, only a small proportion
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27 of adolescents with social anxiety seek help for their problems^{17 18} and even fewer
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29 receive effective treatment¹⁹. Barriers to receiving evidence-based psychological
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31 treatment include limited availability of trained therapists, and practical issues such as
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33 long travel distances to clinics, and the requirement to take time off school or work to
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35 visit a clinic.
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39 Internet-delivered CBT (ICBT) has been suggested as a possible solution to some of
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41 these barriers. It can provide the same treatment components as traditional CBT and
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43 allow patients to work from home (or wherever suitable), guided by an online-therapist,
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45 e.g. through e-mail or similar online communication. Treatment becomes more
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47 accessible as the therapist and patient can communicate asynchronously and it may
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49 increase treatment capacity, as therapist time per patient tends to be lower compared
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51 with face-to-face CBT²⁰⁻²². For adults with SAD, ICBT is an evidence-based treatment²³
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53 with at least one trial showing that ICBT is non-inferior to face-to-face CBT²⁴. For youth,
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55 ICBT is effective for mixed anxiety disorders when compared to a waitlist control²⁵⁻²⁸,
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3 with similar effects as face-to-face CBT ²⁹, suggesting that ICBT could be a suitable
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5 treatment for adolescents with SAD. However, a recent study showed that only 12.8%
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7 and 14.6% (in the SAD specific and generic ICBT conditions, respectively) of participants
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9 were free from their SAD diagnosis at post-treatment assessment, indicating that using
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11 the Internet, as the only modality to deliver CBT might not be sufficient³⁰. Earlier
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13 findings suggest that face-to-face CBT supported by computerized CBT may be more
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15 effective than stand-alone ICBT for adolescents and young adults with anxiety
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17 disorders^{31 32}. Furthermore, it has been suggested that ICBT combined with face-to-face
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19 CBT may be beneficial for adult patients with SAD³³ and depression³⁴. Such a treatment
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21 has, however, never been developed for adolescents with SAD before and the objective
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23 of the current trial is to evaluate the feasibility and efficacy of ICBT supplemented with
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25 clinic-based group-exposure sessions for adolescents with SAD. This treatment could
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27 potentially draw on advantages from both formats, where ICBT is a cost-effective and
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29 accessible format and group-sessions may ensure that key treatment components, such
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31 as exposure to social situations and social skills training, are conveyed properly. Main
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33 research questions are: Is the treatment (BIP SOFT) feasible and acceptable with regard
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35 to adolescents' and parents' willingness to work with the Internet-modules, adolescents'
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37 attendance rates at group sessions and treatment satisfaction? Does the treatment
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39 reduce social anxiety symptoms and increase adolescents' level of functioning and
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41 quality of life?
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50 **METHOD**

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52 The study was conducted at a research unit within the Child and Adolescent Mental
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54 Health Services in Stockholm, Sweden, and was approved by the Regional Ethical Review
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3 Board in Stockholm, Sweden (2015/1383-31/2). Participants were recruited and
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5 treated between October 2015 and May 2016.
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7 8 **Participants**

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10 Participants were 30 adolescents, 13-17 years old, with a principal diagnosis of SAD, and
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12 their parents. Table 1 gives detailed information on demographic and clinical
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14 characteristics of the sample. Inclusion criteria were: a) age 13-17 years, b) principal
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16 DSM-5 diagnosis of SAD, c) ability to read and write Swedish, d) access to a computer
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18 with Internet access and e) at least one parent being able to participate in the treatment.
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20 Exclusion criteria were: f) initiation or dose modification of psychotropic drug within
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22 the past six weeks, g) ≥ 5 sessions of CBT (including exposure) within the last six
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24 months, h) any ongoing psychological treatment for SAD, i) diagnosed with an autism
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26 spectrum disorder, current psychosis, eating disorder, severe depression, suicidal
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28 behaviour or other current severe psychiatric condition j) current substance- or alcohol
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30 abuse. Most participants that were excluded at the initial screening fulfilled an exclusion
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32 criterion, due to having either initiated SSRI medication (or modified the dose) recently,
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34 for having received CBT within the last six months or for being diagnosed with an
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36 autism spectrum disorder. Adolescents excluded due to other severe psychiatric
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38 conditions, such as severe depression or suicidality, were referred to more suitable
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40 treatments.
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46 Participants were mainly recruited through advertisement in a local paper. The
47
48 advertisement included a website address (www.bup.se/bip) where interested families
49
50 could get study information and sign up. Clinicians working in the child- and adolescent
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52 health services could also refer patients to the trial.
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3 To achieve sufficient power and to be able to detect a within-group effect size of $d =$
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5 0.60 from pre to post with a power of 0.85 and $\alpha = 0.05$, allowing for a 10% drop out, we
6
7 included 30 participants in the study.
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16 **Measures**

17 *Primary outcome measures*

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19 The Clinical Global Impression – Severity (CGI-S)³⁵ is a clinician rating of symptom
20
21 severity, ranging from 1 (“normal, not mentally ill”) to 7 (“extremely ill”). The CGI-S
22
23 was administered at baseline by the treating therapist. At post-treatment and the 6-
24
25 month follow-up, another clinician than the one being responsible for the treatment
26
27 administered the CGIS-S.
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33 *Secondary outcome measures*

34
35 Mini International Neuropsychiatric Interview for Children and Adolescents (M.I.N.I.
36
37 KID)³⁶, was used to determine presence of SAD, as well as comorbid conditions. In
38
39 addition, the SAD section of the Anxiety Disorders Interview Schedule for DSM-IV-Child
40
41 Version (ADIS-C)³⁷ was used to further confirm SAD-diagnosis and to assess the
42
43 intensity of SAD symptoms. An independent rater (a clinical psychologist, not part of the
44
45 research group, blind to whether the adolescent had been included in the study or not)
46
47 watched recordings of the baseline interviews and reassessed 20% of them (both
48
49 included and excluded adolescents), generating an excellent inter-rater reliability at pre-
50
51 treatment for SAD-diagnosis ($\kappa = 1.0$) and a fair inter-rater reliability for comorbidity (κ
52
53 = 0.46, $p < .05$).
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3 Clinical global impression – Improvement (CGI-I)³⁵ is a clinician rating of the
4 participant’s change in symptom severity relative to baseline, ranging from 1 (“very
5 much improved”) to 7 (“very much worse”). The Children’s Global Assessment Scale
6 (CGAS)³⁸ is a clinician rating of global functioning (scale 0-100), with higher rating
7 indicating higher level of functioning. The M.I.N.I. KID and CGAS were administered at
8 baseline, post-treatment and at the 6-month follow-up, whereas the CGI-I was
9 administered post-treatment and at the 6-month follow-up.
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19 Social Phobia and Anxiety Inventory - Child and Parent Version (SPAI-C/P)³⁹ is a 26-
20 item self-report measure evaluating aspects of SAD on a 3-point scale, where a score of
21 ≥ 18 is considered the clinical level of social anxiety. The Social Phobia Weekly Summary
22 Scale (SPWSS) is a five-item self-report scale^{40 41} measuring dimensions of SAD (social
23 anxiety, avoidance, self-focused attention, anticipatory processing and post-event
24 processing). The SPAI-C/P and the SPWSS were administered at baseline, every third
25 week during treatment, post-treatment as well as at the 6-month follow-up.
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35 The Revised Children Anxiety And Depression Scale – Child and Parent Version
36 (RCADS-C/P)⁴² is a 47-item self-report measure evaluating anxiety disorders (including
37 one subscale for SAD) and depression on a 4-point scale, ranging from *never* to *always*.
38 In the current trial one item regarding suicidality, with three options (“I do not think
39 about killing myself”, “I think about killing myself, but would never do it” or “I want to
40 kill myself”), was added at the end of the RCADS-C/P. The Education, Work and Social
41 Adjustment Scale – Child and Parent Version (EWSAS-C/P)^{43 44} is a 5-item self-report
42 scale measuring functional impairment on a 9-point scale (higher rating indicating more
43 impairment). The RCADS-C/P and the EWSAS-C/P were administered at baseline, after
44 six weeks of treatment, post-treatment as well as at the 6-month follow-up.
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3 The Health related quality of life questionnaire for children, adolescents and their
4 parents (KIDSCREEN-10)⁴⁵ is a self-report measure assessing health related quality of
5 life. The parent-rated measure Trimbos/iMTA questionnaire for Costs associated with
6 Psychiatric Illness – Child version (TiC-P)⁴⁶ covers e.g. production loss among parents
7 due to health problems in the child. The KIDSCREEN-10 and the TiC-P were
8 administered at baseline, post-treatment and at the 6-month follow-up.
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19 *Feasibility measures, adverse events and therapist time*

20 The Technology Acceptance Scale – child and parent version (TAS-C/P) is a self-report
21 measure adapted from Venkatesh et al. ⁴⁷, which measures the usefulness, acceptability
22 and satisfaction of the website through which the Internet-modules of the treatment
23 were delivered. The TAS-C/P was administered after three weeks of treatment and post-
24 treatment.
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32 At post-treatment, adolescents and parents were asked to report any negative
33 experiences or adverse events over the course of treatment as well as to what extent the
34 negative event had affected the adolescent's wellbeing.
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39 Amount of therapist time per participant was logged automatically through the
40 Internet-treatment platform.
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46 **Procedure**

47 Figure 1 gives an overview of inclusion procedures and assessment points. Families who
48 applied to the study were contacted by telephone and a short screening interview was
49 conducted. Eligible families were invited to diagnostic assessment at the clinic. After
50 thorough information about the study, adolescents gave verbal assent to participate and
51 written informed consent was obtained from parents. The screening interview M.I.N.I.
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3 KID (with the supplement of the SAD section of the ADIS-C) was then conducted. The
4
5 therapist who conducted the baseline assessment was responsible for the treatment of
6
7 the participant.
8

9
10 Adolescents with a principal diagnosis of SAD were included and adolescents and
11
12 parents completed baseline self-report measures online through the treatment platform.
13
14 In each family, one of the parents was assigned the main responsibility to respond to the
15
16 parent-report measures at each assessment point throughout the study. Adolescents and
17
18 parents had separate user accounts and a two-factor authentication (an individual
19
20 password and a single-use code sent to the user's cellular phone) gave access to the
21
22 online platform.
23

24
25 Self- and parent rated measures administered during the treatment (SPAI C/P,
26
27 SPWSS, RCADS C/P and EWSAS C/P) were completed online.
28

29
30 At post-treatment and at the 6-month follow-up all participating adolescents and
31
32 parents were invited back to the clinic for a diagnostic assessment. To reduce the risk of
33
34 biased assessment, a clinician that had not been responsible for the participant's
35
36 treatment conducted the post-treatment and follow-up assessments. All self-assessment
37
38 scales were administered online post-treatment and at follow-up. Families who could
39
40 not come to the clinic for post-treatment assessment (n = 1) and 6-month follow-up (n =
41
42 3) were assessed over the telephone.
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52 **Intervention**

53
54 The intervention was 12 weeks of ICBT supplemented with group-exposure, comprising
55
56 nine Internet-delivered modules completed individually from home, and three group-
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2
3 exposure sessions at the clinic (Table 2). The online treatment platform used in this
4
5 study was developed for delivery of ICBT and has been tested in a number of previous
6
7 studies for different psychiatric disorders in youth^{22 28 48-50}. The current treatment (BIP
8
9 SOFT) was based on the cognitive-behavioural model by Rapee and Heimberg⁵¹ and to
10
11 some extent on the cognitive model by Clark and Wells⁵². The treatment manual was
12
13 developed by the authors and contains CBT components commonly used for SAD in
14
15 youth^{15 53 54}, such as exposure, coping strategies and social skills training. The group
16
17 sessions were mostly based on the Albano and DiBartolo group-CBT manual for
18
19 adolescent SAD⁵⁴. Therapists in the study were three clinical psychologists and two
20
21 master students at their final year of training in clinical psychology.
22
23

24
25 The Internet-modules included educative texts, animations, audio clips and exercises.
26
27 The parental part of the intervention consisted of five Internet-modules with parent-
28
29 specific topics such as “parental traps” (e.g., compensating for the adolescent in social
30
31 situations by for instance speaking for him/her) and doing functional analyses of such
32
33 parental accommodation (Table 2). Parents were encouraged to be actively involved in
34
35 their adolescent’s treatment and discuss with the adolescent how they should support
36
37 him or her throughout the treatment, e.g. during exposure exercises. Parents were also
38
39 encouraged to bring up parent-specific topics with their therapist, for example how to
40
41 support the adolescent before or during exposures. Parents could send messages to the
42
43 therapist throughout the 12 weeks of treatment with the purpose to keep parents active
44
45 as co-therapists. Therapists were instructed to only give support on actual treatment
46
47 content and to only answer messages about the adolescents (or about parents’
48
49 relationship with the adolescents) and not regarding parents’ own difficulties.
50
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53 Adolescents and parents were instructed to log in and complete one module each week.
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55 The modules were assigned in a predetermined order and therefore, all modules but the
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3 first were initially locked. Once the participant completed a module, the therapist made
4
5 the next one available.
6

7
8 The therapists had asynchronous contact online with adolescents and parents every
9
10 week, commenting on their progress on work sheets and through a built in message
11
12 function. Therapists were instructed to log in and provide feedback to their families
13
14 three times per week. If necessary, therapists had telephone contact with families, e.g., if
15
16 they hadn't logged in during the last week or if mid-treatment self-reports exceeded a
17
18 cut-off for depression (>11 on RCADS-C depression subscale) or suicidality.
19

20
21 The group-exposure sessions (at week 4, 6 and 10) ensured that key components of
22
23 the treatment were demonstrated in a correct way and that participants could practice
24
25 e.g. exposure under observation of a therapist. To ensure large enough group sizes,
26
27 cohorts of six participants started the treatment at the same time. The group sessions
28
29 were two hours long and led by two of the clinical psychologists.
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34 Insert Table 2 here
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38 39 **Statistical analysis**

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41 All analyses were conducted in SPSS Version 23.
42

43
44 Cohen's kappa coefficient (κ)⁵⁵ was used to calculate inter-rater reliability for SAD-
45
46 diagnosis and comorbidity at pre-treatment assessment. The level of reliability is
47
48 interpreted as poor when $\kappa < 0.40$, fair when κ is 0.40-0.59, good when κ is 0.60-0.74 and
49
50 excellent when $\kappa > 0.74$ ⁵⁶.
51

52
53 Linear mixed models were used to analyse changes from pre- to post-treatment, and
54
55 from post-treatment to 6-month follow-up. Mixed model analyses use all available data
56
57 and account for correlations between measurements within the same subject⁵⁷. Thus,
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3 missing data is handled within the model. All mixed models in this study included a fixed
4
5 effect for time (pre, post and 6-month follow-up) and a random effect for individual
6
7 subjects. Potential missing bias was investigated using *t*-tests that compared the
8
9 baseline characteristics of those who had complete data at post-treatment with those
10
11 who had missing data. For SPAI C/P and SPWSS three mid-treatment (week 3, 6 and 9)
12
13 time points were included in the analyses, and for RCADS C/P and EWSAS C/P one mid-
14
15 treatment (week 6) time point was included in the analyses.
16
17

18
19 Effect sizes are reported as Cohen's $d = (M_1 - M_2 / SD_{\text{pooled}})$. Effect sizes are defined
20
21 according to Cohen's suggested levels, small ($d \geq 0.20$), moderate ($d \geq 0.50$) and large (d
22
23 ≥ 0.80)⁵⁸.
24

25 RESULTS

26 Response rate and feasibility

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28 Mid-treatment measures were completed by 97% of the participating families at week
29
30 three, 83% at week six and 70% at week nine. Post-treatment and 6-month follow-up
31
32 measures were completed by 90% and 83% of the participating families, respectively. T-
33
34 tests comparing participants with missing versus complete data points on baseline
35
36 characteristics revealed no statistically significant differences.
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38

39
40 Adolescents completed on average 5.7 ($sd = 2.1$) of the nine Internet-modules and
41
42 parents completed on average 4.4 ($sd = 1.0$) of their five modules. The frequency of
43
44 completed modules by the adolescents was distributed as follows: 20% ($n = 6$)
45
46 completed 2-3 modules, 43% ($n = 13$) completed 4-6 modules and 37% ($n = 11$)
47
48 completed 7-9 modules. None completed fewer than two modules.
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51
52 Attendance at the group-sessions were 70% (session 1), 77% (session 2) and 63%
53
54 (session 3) respectively. Two thirds of the participants attended two or more group
55
56 sessions and only 10% attended none.
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3 None of the adolescents meeting inclusion criteria at baseline assessment declined
4 participation, which indicates good acceptability of the offered treatment.
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6

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

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

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45 Means, standard deviations and effect sizes for pre to post changes, are presented in
46 Table 3. Intention-to-treat analyses of the primary outcome measure (CGI-S) showed a
47 significant decrease of SAD severity from pre- to post-treatment, $t(26.05) = 5.62, p < .001$,
48 with a large effect size, $d = 1.17$ (95%CI 0.61,1.72). For all secondary outcome measures,
49 analyses revealed significant improvements with moderate to large effect sizes, with the
50 exception of quality of life (KIDSCREEN-C/P) where a small effect was observed. At post-
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3 treatment, 47% of the participants ($n = 14$) no longer met diagnostic criteria for SAD,
4
5 according to DSM-5 criteria and a CGI-rating <4 (level of severity and functional
6
7 impairment below diagnostic threshold) and 30% ($n = 9$) scored ≤ 18 on SPAI-C (cut-off
8
9 for clinical level of social anxiety). On the clinician rated CGI-I 8% ($n=2$) were “very
10
11 much improved”, 23% ($n = 6$) “much improved”, 42% ($n = 11$) “minimally improved”,
12
13 23% ($n = 6$) “not changed” and 4% ($n = 1$) “minimally worse”.
14
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19 **Changes in clinical outcomes from post-treatment to 6-month follow-up**

20
21 Table 3 gives an overview of means, standard deviations and effect sizes from post-
22
23 treatment to the 6-month follow-up. The improvements seen at post-treatment were
24
25 generally maintained and further augmented at the 6-month follow-up with small effect
26
27 sizes, except for self-focus (SPWSS) that deteriorated slightly. The primary outcome
28
29 measure (CGI-S) showed a significant decrease of SAD severity from post-treatment to
30
31 6-month follow up, $t(25.45) = 2.60, p < .05$, with a small effect size, $d = 0.22$ (95%CI -0.01,
32
33 0.45). At follow-up, 57% ($n = 17$) no longer met diagnostic criteria for SAD and 37% ($n =$
34
35 11) scored ≤ 18 on SPAI-C.
36
37

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39 Comparison of pre-treatment and 6-month follow-up levels of social anxiety showed
40
41 overall improvements with large effect-sizes, CGI-S: $t(27.23) = 6.24, p < .001, d = 1.36$
42
43 (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
44
45 SPAI-P: $t(26.08) = 5.57, p < .001, d = 1.14$ (95%CI 0.57, 1.72). Clinician-rated CGI-I
46
47 indicated that, of those who participated in the 6-month follow-up assessment, 19% ($n =$
48
49 5) were “very much improved”, 31% ($n = 8$) “much improved”, 38% ($n = 10$) “minimally
50
51 improved”, 4% ($n = 1$) “not changed” and 8% ($n = 2$) “minimally worse”, compared to
52
53 baseline.
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57 **Post-hoc analyses**

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3 The proportion of parents reporting that they had stayed home from work during the
4
5 last month due to their adolescent's health problems was 27% before treatment and
6
7 13% at 6-month follow-up. Of the adolescents, 50% had stayed home from school during
8
9 the last month due to health problems before treatment and 33% at 6-month follow-up.
10
11 At 6-month follow-up, six participants reported that they had received additional
12
13 treatment for social anxiety; two participants (7%) got CBT and four participants (13%)
14
15 had initiated or increased SSRI medication. All these participants fulfilled diagnostic
16
17 criteria for SAD at post treatment assessment and five out of six still fulfilled diagnostic
18
19 criteria for SAD at follow-up.
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21

22
23 Half of all participants ($n=15$) reported that they had used strategies from the
24
25 treatment since post-treatment assessment, referring to exposure, coping strategies
26
27 (such as breathing exercises and focus shift) and cognitive techniques as the most
28
29 common ones.
30
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32 33 **Adverse events**

34
35 Seven adolescents (23%) reported having experienced some negative event during the
36
37 course of treatment. These events included increased stress due to the limited time to
38
39 work with treatment modules ($n=4$; 13%), increased social anxiety ($n=1$; 3%),
40
41 increased panic anxiety ($n=1$; 3%) and increased depression and negative thoughts
42
43 ($n=1$; 3%). Those who reported increased stress and anxiety associated these symptoms
44
45 with the first weeks of treatment and typically described a decrease as treatment
46
47 continued. Two adolescents reported that the negative event (increased negative
48
49 thoughts in one case and increased panic anxiety in the other case) still had some impact
50
51 on their wellbeing at the end of treatment.
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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

1
2
3 that socially anxious children and adolescents have a tendency to avoid practicing skills
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5 on their own that they have learned online, such as conducting in-vivo exposure³⁰. It
6
7 could therefore be hypothesized that the group-sessions in this study enhanced the
8
9 participants' inclination to practice skills at home as a consequence of being offered
10
11 intensive therapist guidance and direct feedback during group-based exposure. A
12
13 majority of the participants completed a large number of online treatment modules and
14
15 group sessions, which gave them time to conduct a significant amount of exposure
16
17 (introduced in online module 3) and social skills training (introduced in group session 1
18
19 at week four). However, we did not track the number of completed exposure- and social
20
21 skills training exercises in other ways than by proxy, through measuring module
22
23 completion and group attendance.
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27
28 Forty seven per cent of participants no longer met diagnostic criteria for SAD after
29
30 treatment, a proportion that further increased to 57% at 6-month follow-up. This is in
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32 line with levels reported in studies evaluating face-to-face CBT for youth with SAD^{15 53}
33
34⁵⁹⁻⁶¹ and higher than strictly Internet-delivered CBT for youth with SAD³⁰. A recent trial
35
36 of ICBT for youth with SAD reported a relatively limited impact on the clinical diagnosis
37
38 of SAD (in the two active treatment conditions 12.8 and 14.6% at post-treatment and
39
40 29.8% and 35.4 % at 6-month follow-up, no longer met diagnostic criteria for SAD)³⁰
41
42 and the authors suggest that stand-alone ICBT might not be enough for youth with
43
44 SAD³⁰. It is tempting to attribute the better outcomes in our trial to the addition of
45
46 group-based exposure sessions to the ICBT protocol, though this hypothesis remains to
47
48 be formally evaluated. Discrepancies between our and previous results may also be
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50 attributable to differences in study samples, study design or other methodological
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52 aspects.
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3 Therapists in this study spent less than 20 minutes per family and week, on the
4
5 Internet-delivered treatment, which is comparable to previous ICBT trials for youth^{21 22}.
6
7 Although the group sessions added another 10 minutes per family and week in the
8
9 present trial, group-exposure supplemented ICBT should still be considered a time-
10
11 efficient intervention compared with face-to-face CBT where the therapist time per
12
13 family and week usually ranges from 45-60 minutes.
14
15

16
17 Around a fifth of the participants reported a negative event during the course of the
18
19 treatment. Some of the events were expected, such as increased social anxiety when
20
21 exposure was initiated. Reports of increased stress were also associated with the first
22
23 weeks of the treatment and can be interpreted as an initial difficulty combining
24
25 treatment with other demands such as schoolwork. Two participants reported having
26
27 experienced some negative events that affected their wellbeing beyond the treatment
28
29 termination but these participants still benefited from treatment.
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32
33 Overall, the treatment seems feasible and possibly efficacious for adolescents with
34
35 SAD and their parents, but to be considered for implementation in regular care, an
36
37 intervention must also be feasible from an organizational point of view. A possible
38
39 drawback with the addition of group-exposure to ICBT is that it limits the flexibility of
40
41 the intervention. For instance, several patients must be recruited and able to commence
42
43 treatment at the same time. SAD is a challenging disorder to treat and interventions
44
45 aspiring to be effective may need to include direct and frequent therapist guidance. On
46
47 the other hand, development of new treatments should not only consider treatment
48
49 efficacy, but also accessibility, flexibility and cost effectiveness. A possible alternative to
50
51 group-based exposure sessions is to add other forms of direct communication between
52
53 patients and ICBT-therapists, e.g. video conferencing or equivalent, something that
54
55 future studies should investigate further.
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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 untreated² 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

1
2
3 families and significantly reduced social anxiety symptoms up to 6-month follow-up.
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5 Participants were generally satisfied with the treatment and the completion-rate of
6
7 Internet-modules and attendance at group sessions were high, indicating that the
8
9 treatment is feasible and acceptable to the SAD youth population. Furthermore, per-
10
11 patient therapist time was limited, even considering the time spent on group-sessions;
12
13 thus, ICBT supplemented with group-based exposure sessions might be cost-effective
14
15 when compared to traditional face-to-face CBT. Further controlled trials are needed.
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20

21 **Acknowledgements** The authors would like to thank Ulrika Thulin for invaluable help with writing the
22
23 treatment modules, and Cornelia Hanqvist and Jon Juselius for assisting with providing the treatment.

24 **Contributors** The study was designed by MN, SV, DMC, ES and JH. MN was the project manager in
25
26 collaboration with JH. MN wrote the treatment modules and provided the treatment in collaboration
27
28 with JH and SV. All statistical analyses were conducted by JH and MN. MN drafted the manuscript in
29
30 collaboration with JH. The manuscript was reviewed and revised by SV, ES, DMC, BL and LGÖ. All
31
32 authors have read and approved the final manuscript.
33

34 **Funding** This work was supported by the Stockholm County Council (PPG project 20150032; HSNV
35
36 140 99; HSN 1011-1176) and the Swedish Research Council and Swedish Research Council for
37
38 Health, Working Life and Welfare (Forte 2014-4052)

39 **Competing interests** None.

40
41 **Data sharing statement** No additional data are available.
42

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

Variables		N	%
Age (years)	<i>M (SD)</i>	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)	<i>M (SD)</i>	8.9 (4.29)	
Duration of SAD (years)	<i>M (SD)</i>	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

Measure	Pre		Post		Pre to post comparison		6-month follow-up		Post to follow-up comparison	
	M	SD	M	SD	p	d (95% CI)	M	SD	p	d (95%CI)
<i>Clinician-rated</i>										
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)
<i>Self- and parent rated social anxiety</i>										
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)
<i>Other self- and parent rated measures</i>										
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

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For peer review only

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7 Figure 2. Adolescents' evaluation of BIP SOFT
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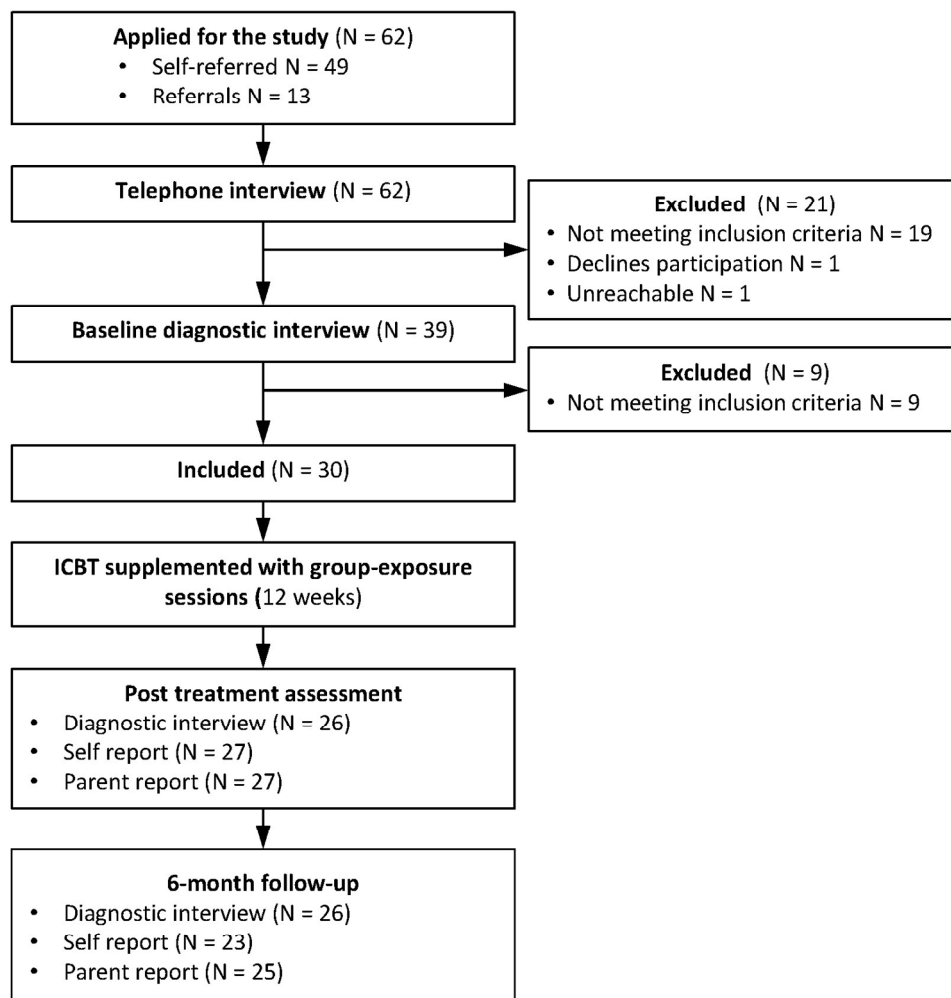


Figure 1. Study flow chart

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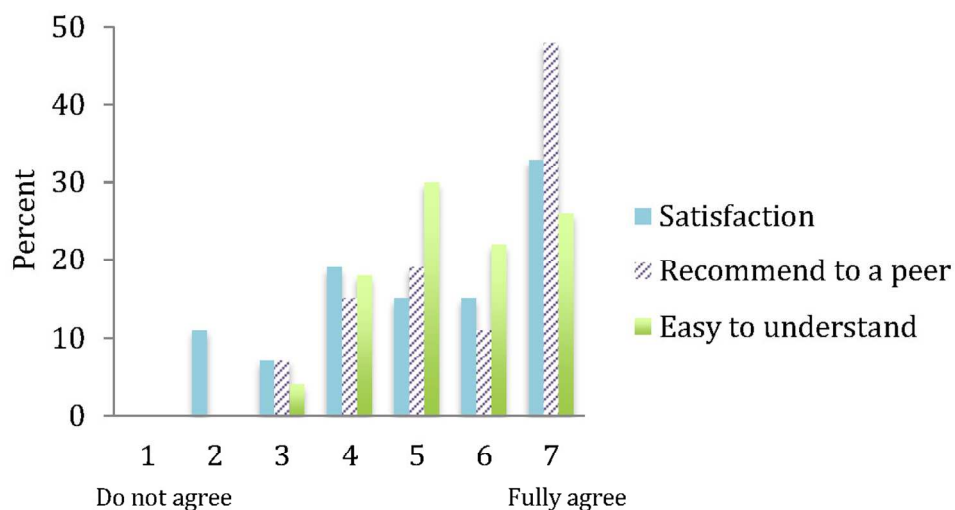


Figure 2. Adolescents' evaluation of BIP SOFT

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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:			

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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:			

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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

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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

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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	

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