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Complete List of Authors:	Grudin, Rebecca; Karolinska Institutet, Department of Clinical Neuroscience Ahlen, Johan; Karolinska Institutet, Department of Global Public Health; Region Stockholm, The Centre for Epidemiology and Community Medicine Mataix-Cols, David; Karolinska Institute, Centre for Psychiatry Research, Department of Clinical Neuroscience & Stockholm Health Care Services, Region Stockholm, CAP Research Centre Lenhard, Fabian; Karolinska Institute, Centre for Psychiatry Research, Department of Clinical Neuroscience & Stockholm Health Care Services, Region Stockholm, CAP Research Centre Henje, Eva; Umeå Universitet, Department of Clinical Science, Child- and Adolescent Psychiatry Månsson, Cecilia; Region Stockholm, CAMHS Trauma clinic, Child- and Adolescent Mental Health Services Sahlin, Hanna; Karolinska Institutet, Centre for Psychiatry Research, Department of Clinical Neuroscience, Stockholm Health Care Services, Region Stockholm, The Centre for Psychotherapy, Education and Research Beckman, Maria; Karolinska Institute, Centre for Psychiatry Research, Department of Clinical Neuroscience, Stockholm Health Care Services, Region Stockholm, The Centre for Psychotherapy, Education and Research Serlachius , Eva ; Karolinska Institutet, Department of Clinical Neuroscience; Lund University, Department of Clinical Sciences, Faculty of Medicine Vigerland, Sarah; Karolinska Institute, Centre for Psychiatry Research, Department of Clinical Neuroscience & Stockholm Health Care Services, Region Stockholm, CAP Research Centre
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Therapist-guided and self-guided Internet-delivered behavioural activation for adolescents with depression: a randomised feasibility trial

Rebecca Grudin[a*], Johan Ahlen[b, c], David Mataix-Cols[a], Fabian Lenhard[a], Eva Henje[d], Cecilia Månsson[e], Hanna Sahlin[f], Maria Beckman[f], Eva Serlachius[g, h], Sarah Vigerland[a]

[a]Centre for Psychiatry Research, Department of Clinical Neuroscience, Karolinska Institutet, & Stockholm Health Care Services, Region Stockholm, CAP Research Centre, Gävlegatan 22, SE-113 30 Stockholm, Sweden

[b]The Centre for Epidemiology and Community Medicine, Box 45436, SE-104 31 Stockholm, Region Stockholm, Sweden

[c]Department of Global Public Health, Karolinska Institutet, SE-171 77 Stockholm, Sweden

[d]Department of Clinical Science, Child- and Adolescent Psychiatry, Umeå University, SE-901 85 Umeå, Sweden

[e]Child- and Adolescent Mental Health Services, Region Stockholm, CAMHS Trauma clinic, Tideliusgatan 22, SE-118 69 Stockhholm, Sweden

[f]Centre for Psychiatry Research, Department of Clinical Neuroscience, Karolinska Institutet, & Stockholm Health Care Services, Region Stockholm, The Centre for Psychotherapy, Education & Research, Liljeholmstorget 7, SE-117 63 Stockholm, Sweden

[g]Department of Clinical Neuroscience, Karolinska Institutet, SE-171 77 Stockholm, Sweden

[h]Department of Clinical Sciences, Faculty of Medicine, Lund University, Baravägen 1, SE-222 40 Lund, Sweden

*Correspondence to Rebecca Grudin: rebecca.grudin@ki.se

Abstract

Objective Access to effective treatments for adolescents with depression needs to improve. Few studies have evaluated behavioural activation (BA) for adolescent depression, and none have evaluated remotely-delivered BA. This study explored the feasibility and acceptability of therapist-guided and self-guided Internet-delivered BA (I-BA) in preparation for a randomized controlled trial (RCT).

Design A pilot, single-masked randomised controlled trial.

Setting A specialist outpatient clinic in Sweden.

Participants Thirty-two adolescents with mild to moderate major depressive disorder, aged 13-17.

Interventions Ten weeks of therapist-guided I-BA or self-guided I-BA or treatment as usual (TAU).

Outcomes Feasibility measures included participant retention, acceptability, safety and satisfaction. The primary measure of clinical efficacy was the masked assessor–rated Children's Depression Rating Scale, Revised (CDRS-R) score at the 3-month follow-up.

Results Participant retention was acceptable, with two drop-outs. Most participants in TAU had been offered interventions by the primary endpoint. The average number of completed chapters (total 8) for adolescents was 7.5 in therapist-guided I-BA, and 5.4 in self-guided I-BA. No serious adverse events were recorded. Satisfaction was acceptable in both I-BA groups. Both I-BA groups, but not TAU, showed statistically significant changes on the primary outcome measure with large within-group effect sizes (Cohen's d = 2.43 and 2.23 respectively).

Conclusions Both therapist-guided and self-guided I-BA are acceptable and potentially efficacious treatments for adolescents with depression. It is feasible to conduct a large-scale RCTs to establish the efficacy and cost-effectiveness of I-BA vs TAU.

Trial registration number Clinicaltrials.gov, NCT04117789.

Article summary: Strengths and limitations of this study

- Strengths include the randomised controlled design, the use of an active control group and the careful assessment of the contents of TAU.
- Another strength was that assessors were masked to treatment allocation at the primary endpoint.
- TAU was a heterogeneous condition and masked assessors correctly guessed group allocation more often than chance.

Keywords

Depression; Adolescents; Feasibility trial; Behavioral activation; Self-guided; Internet interventions

Introduction

Depression is one of the leading causes of disability worldwide[1]. Adolescence is a risk period for developing depression, associated with a sharp increase in prevalence[2]. Adolescent depression is associated with a range of adverse outcomes, including impaired academic, social and work functioning[3 4], poor mental and physical health in adulthood[5 6] and increased risk of suicide[7]. Early detection and treatment of adolescent depression markedly decreases the likelihood of future clinical depression and other mental health issuess[8].

Cognitive Behaviour Therapy (CBT) is considered a well-established intervention for adolescents with depression[9], and is also currently recommended in clinical practice and national guidelines[10 11]. Behavioural activation (BA) is a common type of CBT for depression. The main goal of BA is to increase engagement in values-based activities and to decrease the avoidant behaviours that often maintain depressive symptoms[12-15]. BA is considered an evidence-based treatment for adults with depression[16] and three open trials indicate that BA is a feasible intervention for adolescents with depression[12 13 15]. A small RCT comparing BA to evidence-based interventions (CBT and IPT) showed promising results[14], but BA for depressed adolescents is yet to be evaluated in an adequately powered RCT.

Despite its high prevalence, only a minority of young people with depression receive evidence-based treatments[17-19]. Internet-delivered CBT (ICBT) was developed to improve access to treatment, and has several potential advantages over traditional in-person treatments, e.g. bridging geographical distances between therapists and patients, requiring less therapist time[20], and a lower risk of therapist drift[20].

Studies in adults have shown that ICBT is effective and probably cost-effective for several psychiatric disorders, including depression[20]. In children and adolescents, there is growing support for the efficacy of ICBT for several psychiatric disorders[21], but it is still unclear whether ICBT is an efficacious intervention for adolescent depression. To date, two RCTs (both N = 70) on ICBT with additional therapist-chat communication have shown significant reductions in depressive symptoms for adolescents with mild to moderate depression compared to attention control[22 23]. Two other studies, one small and one unpublished, both including adolescents with subthreshold, rather than diagnosed, depression, show mixed results[24 25].

Internet-based interventions can be therapist-guided or self-guided (i.e. with or without therapist support). The importance of therapist support is unclear in children and adolescents, and results are inconsistent[26 27]. If ICBT could be entirely unguided, without sacrificing efficacy and safety, it would be much easier to disseminate.

Adequately powered trials are needed to explore whether ICBT with and without therapist-support for adolescent depression is safe, effective and cost-effective. However, there are important feasibility questions that should be addressed before conducting a large trial. Therefore, we designed a randomised feasibility trial of therapist-guided and self-guided Internet-delivered BA (I-BA), compared to treatment as usual (TAU). The primary objective of the current study was to evaluate the feasibility of the study design. Secondary objectives were to explore the acceptability of the I-BA interventions and to provide preliminary clinical efficacy data to assist in the power calculations for a future fully powered trial. This will also be the first trial to explore online delivered BA for adolescents.

Methods

Study design

This was a single-masked randomised controlled feasibility trial of therapist-guided I-BA, self-guided I-BA and TAU for adolescents with mild to moderate major depressive disorder (MDD). Participants were randomly assigned at a 1:1:1 ratio. The study was conducted at the the Child and Adolescent Psychiatry Research Center in in Stockholm, Sweden. The planned recruitment period was six months. Masked rater assessments were conducted at posttreatment (week 11), and 3-month follow-up (primary end point) visits. No changes in the methods were made after the registration and subsequent start of the trial.

Participants

Inclusion criteria were: adolescents aged 13–17; a diagnosis of mild or moderate MDD according to the *DSM-5*[28]; eventual use of psychotropic medications (antidepressants, central stimulants and neuroleptics) had been stable for at least 6 weeks prior to inclusion; at least one parent/caregiver able to partake in treatment; both adolescent and parent fluent in Swedish; access to a internet-connected computer.

Exclusion criteria were: acute psychiatric problems (i.e. high risk of suicide or alcohol and substance abuse); social problems requiring other actions at first hand (i.e. abuse in the family, high and prolonged absence from school); previous CBT for MDD within the last 12 months (defined as ≥ 3 sessions of CBT/BA, other than psychoeducation); current use of benzodiazepines; ongoing psychological treatment for any psychiatric disorder.

Sample size

This feasibility trial was not powered to detect statistically significant differences between groups. However, we aimed to include a sufficient number of participants to explore within group changes from baseline to the primary endpoint. In two recent RCTs[14 29] large within group effects were found on depressive symptoms ($d > 1.2$; $d = 1.4$). Based on previous literature, and taking a potentially high attrition rate into account, we aimed to recruit a total of 45 participants to be able to detect a within group effect of d=1.2 (alpha value of 0.05 and 90% power).

Recruitment and procedures

The study was advertised at the CAMHS and primary health care clinics, in newspapers, and social media. Referrals from health care professionals and self-referrals from families all over Sweden were accepted.

Applicants were first contacted for an initial telephone screening, and then invited to a face-to-face visit for a thorough assessment of study eligibility. Video assessments were offered after the outbreak of the COVID-19 pandemic and to families that could not travel to the clinic. Verbal and written information was provided to the adolescents and their parents, and all provided written consent. During the face-to-face assessment, a trained psychologist a) verified the MDD diagnosis, according to the DSM-5 criteria, b) assessed current level of depression symptom severity using the CDRS-R, and c) assessed psychiatric comorbidity. After the assessment, included participants and parents completed the baseline measures and were then randomised . Within a week after completion of the baseline measures, patients allocated to the I-BA treatments started treatment, and participants allocated to TAU received a referral to their local CAMHS or paediatric primary care unit. **Figure 1** shows the CONSORT flowchart.

To ensure patient-safety, participants in all treatment arms answered brief, weekly measures of depressive symptoms during the intervention, allowing suicidal ideation to be monitored and, if needed, assessed. If further psychiatric assessments or any preventive actions were needed, the study team referred the patient to emergency psychiatric services.

Follow-up assessments were conducted at post-treatment and three month follow-up by masked assessors.

Interventions

The I-BA treatment protocol was inspired by previously published literature on BA[14 15]. The I-BA treatments were delivered through a secure online platform and consisted of eight chapters with age-appropriate texts, animations, films and various exercises delivered over ten weeks. The first four chapters introduced the most essential components of BA (i.e. scheduling of values-based activities and targeting avoidance behaviours). Psychoeducation and sleep hygiene were added to the BA protocol. An overview of the treatment content is presented in **Table 1** and example screenshots from the intervention are presented in supplementary **Figure S1**.

In the therapist-guided I-BA arm, participants had regular asynchronous contact with a clinical psychologist via the platform. The therapist provided feedback, answered questions, and prompted the participant to complete the next chapter if required. The content of the self-guided I-BA programme was identical to the therapist-guided version, except for the therapist support. Both conditions of I-BA included a parallel eight-chapters parental course (see **Table 1** for an overview of the content), which was accessed through separate login accounts.

The control condition was treatment as usual (TAU). Participants randomised to TAU were referred to their local CAMHS or paediatric primary care services and were free to receive any treatment, either psychosocial, pharmacological or the combination of both.

Table 1. An overview of the treatment content of I-BA.

Chapter	Adolescent	Parent
1	Introduction to I-BA. Psychoeducation on depression. Rationale for BA. *Homework*: activity monitoring.	Introduction to I-BA. Psychoeducation on depression. Rationale for BA. Learn about common parental traps. *Homework*: notice one's parental behaviours when the adolescent shows depressive behaviours. Discuss with the adolescent how to collaborate in treatment.
2	Values assessment. Set treatment goals. *Homework*: activity scheduling.	Facilitate and encourage values-based activation; communication skills I: validate your child's feelings. *Homework:* practise validating others' and your child's emotions, encourage values-based activation.
3	Continued values-based activation. Psychoeducation on sleep. *Homework*: activity scheduling and sleep hygiene.	Spending positive time with your adolescent. *Homework*: suggest positive time with your adolescent.
4	Continued values-based activation. Overcome barriers to activation through identifying and overcoming avoidance. *Homework*: activity scheduling, sleep hygiene and practise overcoming avoidance.	Communication skills II: How to avoid and manage conflicts. *Homework*: practise conflict management.
5	Continued values-based activation. Overcome barriers to activation through shifting focus to the present situation. *Homework*: activity scheduling, sleep hygiene and practise shifting focus.	Take care of yourself as a parent supporting a child with depression. *Homework*: take care of yourself.
6	Continued values-based activation. Problem solving. *Homework*: activity scheduling, sleep hygiene and practise problem-solving.	Collaborative problem-solving. *Homework*: practise collaborative problem-solving
7	Putting it all together. *Homework*: activity scheduling.	Putting it all together. *Homework*: choose two tasks from previously introduced skills.
8	Treatment summary. Relapse prevention. Evaluation of the treatment.	Course summary. Relapse prevention. Evaluation of treatment.
Abbreviations: I-BA = Internet-delivered Behavioural Therapy, BA = Behavioural Activation.		

Patient involvement

Three patient representatives, who had previously suffered from depression, were involved in the development of I-BA, providing feedback on language and content, ensuring that the content was inclusive (e.g. LGBTQ), understandable and useful.

Measures

Baseline assessment

The Mini-International Neuropsychiatric Interview for Children (MINI-KID)[30] was administered to confirm the primary diagnosis of MDD and to screen for psychiatric comorbidities. Suicide risk assessment was based on all available information collected at the inclusion assessment visit (e.g. suicide ideation and behaviour, past and present suicidal behaviour). To assess recurrent non-suicidal self-injury, the 7-item Deliberate Self Harm Inventory for youths[31] was used. Demographic data was collected at the initial assessment and from parents through a questionnaire administered online.

Study design feasibility

We evaluated study take-up by calculating the average number of included participants per week. Participant retention is presented in **Figure 1**. The specific contents of TAU were collected from each participant's official medical records and by interviewing the families after the three-month follow-up assessment.

Acceptability of I-BA

The average number of completed chapters for adolescents and their parents were documented. Adolescents who completed less than half (< 4) of the I-BA-chapters were defined as having discontinued treatment. Treatment credibility was measured with four qualitative questions scored on a 5-point Likert scale at week 3 (total range 4 to 20, with higher values representing higher credibility). Treatment satisfaction was assessed with the Client Satisfaction Questionnaire (CSQ) at post-treatment (adolescent and parent version; total range 8–32, with higher values indicating higher satisfaction)[32]. All adverse events communicated by participants (e.g. via SMS, phone calls, at follow-up visits) were documented by the trial coordinator (RG). Adverse events were also assessed with the Negative Effects Questionnaire, 20 Items (NEQ-20), administered at post-treatment and at three-month follow-up (adolescent and parent version; total range 0–80, with higher values representing more reported adverse events)[33]. Therapist time in the treatment platform was

logged automatically, and time spent on phone calls was logged manually by the therapist. These indicators were combined to a measure of therapist time per family and chapter.

Clinical outcomes

The Children's Depression Rating Scale, Revised (CDRS-R, primary measure of clinical efficacy), is a semi-structured clinical interview used to assess depressive symptom severity in children (total range 17 to 113, with higher values representing more depressive symptoms)[34]. All interviews with CDRS-R were audio-recorded.

Other clinician-rated measures included the Children's Global Assessment Scale (CGAS)[35], Clinical Global Impression Scale – Severity and Improvement (CGI-S and CGI-I)[36]. Treatment response was defined as a CGI-I rating of 1 or 2 at the three-month follow-up.

Adolescent- and parent-rated questionnaires were administered online at pre- and post-treatment and at three-month follow-up. Depressive symptoms were assessed with the SMFQ, adolescent and parent version; total range is 0-26, with higher values representing more symptoms)[37 38]. Impaired functioning due to depression was measured with the Work and Social Adjustment Scale (WSAS, adolescent and parent version; total range 0 to 40, with higher values indicating greater impairment)[39]. Anxiety symptoms were assessed by the anxiety subscales in the Revised Children's Anxiety and Depression Scale – Short version (RCADS-S, adolescent and parent version; total range 0 to 45, with higher values indicating worse outcome)[40]. KIDSCREEN-10 Index (adolescent and parent version; total range from 10-50, with higher values indicating better quality of life) was used to measure general health-related quality of life[41]. Difficulties with sleep were measured by the Insomnia Severity Index (ISI, adolescent version; total range 0 to 28, with higher values indicating a worse outcome)[42] and irritability by Affective Reactivity Index (ARI, adolescent version; total range 0 to 12, with higher values indicating worse outcome)[43]. Both ISI and ARI were administered to adolescents only. No changes were made to outcomes after the trial commenced.

Randomisation and allocation concealment

Block randomisation with five random sets of blocks of three and six, respectively, were created by an independent clinician using an online service (www.random.org). Once a participant was included, the independent clinician opened a sealed opaque envelope revealing treatment allocation.

Post- and three-month follow-up assessments were conducted by four clinical psychologists masked to treatment allocation. In the event of unmasking, a new assessor re-rated the recording. Masking integrity was measured at each assessment point by asking masked assessors to guess each participant's group allocation and indicating the reasons for their guesses (i.e. totally random guess, due to impression of improvement)[44].

Analytical methods

Data on trial feasibility (i.e. participant retention, uptake, and content of TAU) and data on acceptability (i.e. adherence, credibility, satisfaction, and adverse events) were analysed using descriptive statistics.

We used linear mixed regression models to estimate within group effects for all continuous outcome measures. All models included a fixed effect of time and a random intercept for the participant effect. We followed an intent to treat analysis and used available data from all included participants. Thus, missing data is handled within the model. Time was treated as a continuous variable from 0–2 (baseline, post-treatment and three-month follow-up) as there were three months between each time point. Alpha levels (two-tailed) were set to $p < 0.05$. Within-group effect sizes (Cohen's d) were calculated using the accumulated beta-coefficients (pre to three-month follow-up) from the regression models as the nominator and the pooled SD at pre as the denominator [45]. Additionally, the proportion of treatment responders at three-month follow-up was calculated with intent to treat analysis according to pre-specified criteria. Analyses were performed with SPSS version 27 and Excel version 16.

Results

Study design feasibility

Study take-up

A total of 154 families were screened by telephone and 32 participants were included between 14 October 2019 and 24 April 2020. Approximately a fourth had been recommended by a health care provider to self-refer to the study. The recruitment rate was slow before we started advertising in local media (0.5 included per week), and then higher after advertising (2.3 included per week).

Participant retention and study flow

A total of 32 adolescents from all over Sweden were recruited and randomised to therapist-guided I-BA (n = 11), self-guided I-BA (n = 10) or TAU (n = 11). **Table 2** shows the demographic and clinical characteristics of the sample at baseline. **Figure 1** shows the study flow. Two participants dropped out of the study. Both had been allocated to TAU. At post-treatment, there were no missing data on the primary outcome measure CDRS-R in therapist-guided I-BA, one in self-guided and two in TAU. At three-month follow-up, there were missing data for one participant in therapist-guided, three in self-guided and two in TAU. The last 3-month follow-up assessement occurred on the 15th of October 2020.

Figure 1 approximately here.

Table 2. Baseline demographic and clinical characteristics of the total sample and for each group.

	Total (n = 32)	Therapist-guided I-BA (n = 11)	Self-guided I-BA (n = 10)	TAU (n = 11)
Age, mean (SD), min-max	15.4 (1.6), 13–17	14.6 (1.2), 13–17	15.1 (1.8), 13-17	16.5 (1.3), 14–17
Gender, n (%)				
Female	19 (59%)	6 (55%)	7 (70%)	6 (55%)
Male	13 (41%)	5 (45%)	3 (30%)	5 (45%)
Main contact person, mothers, n (%)	30 (94%)	9 (82%)	10 (100%)	11 (100%)
Education of contact person				
Elementary school	1 (3%)	0 (0%)	0 (0%)	1 (3%)
High school	3 (9%)	1 (9%)	1 (10%)	1 (9%)
Higher education < 2 years	5 (16%)	1 (9%)	4 (40%)	0 (0%)
Higher education > 2 years	21 (66%)	7 (64%)	5 (50%)	9 (82%)
Post graduate degree	2 (6%)	2 (18%)	0 (0%)	0 (0%)
Comorbidity[1], n (%)				
None	6 (19%)	1 (9%)	2 (20%)	3(27%)
One diagnosis	12 (38%)	5 (45%)	3 (30%)	4 (36%)
Two or more diagnoses	14 (44%)	5 (45%)	5 (45%)	4 (36%)
Anxiety disorder/s[1]	23 (72%)	7 (64%)	8 (80%)	8 (73%)
ADHD/ASD	5 (16%)	3 (27%)	0 (0%)	2 (18%)
Current use of antidepressants, n (%)	2 (6%)	1 (9%)	0 (0%)	1 (3%)
Risk for suicide[2]				
No suicidal ideation	3 (9%)	1 (9%)	0 (0%)	2 (18%)
Low risk	16 (50%)	6 (55%)	4 (40%)	6 (55%)
Moderate risk	13 (41%)	4 (36%)	6 (60%)	3 (27%)
High risk	0 (0%)	0 (0%)	0 (0%)	0 (0%)

[1]Including all anxiety disorders in MINI-KID. [2]According to the definitions of suicidality used in MINI-KID.
Abbreviations: ADHD, Attention-deficit/hyperactivity disorder; ASD, Autism spectrum disorder.

Treatment content in TAU

Five of the referrals were sent to primary care and six to CAMHS. Two participants in TAU never attended their first visits at the clinic to which they were referred. Five out of 11 participants allocated to TAU had started an intervention by post-assessment. This number had increased to nine at the three-month follow-up. According to interviews with families and medical records at the three-month follow-up, patients in TAU received pharmacological, psychological, supportive, or a combination of either of these interventions as well as psychiatric or neuropsychiatric assessement during the study. Details on TAU content are presented in supplementary **Table S1a-b.**

Acceptability of I-BA

Treatment adherence

The average number of completed chapters at post-treatment was 7.5 (SD 1.0) for adolescents, and 7.4 (SD 1.3) for parents in therapist-guided I-BA, and 5.4 (SD 2.5) for adolescents and 5.9 (SD 2.8) for parents in self-guided I-BA. Eight adolescents (73%) and eight parents (73%) in therapist-guided I-BA, and three adolescents (30%) and four parents (40%) in self-guided I-BA had completed all 8 chapters by the end of treatment. No participant in therapist-guided I-BA, and three in self-guided I-BA, discontinued treatment.

Credibility and satisfaction

Average treatment credibility was 14.3 (SD 2.7) for therapist-guided I-BA (n = 11), 14.1 (SD 3.9) for self-guided I-BA (n = 9) and 11.1 (SD 3.4) for TAU (n = 8). Average treatment satisfaction at post-treatment was 24.7 (SD 5.33) for therapist-guided I-BA (n = 11), 21.3 (SD 6.8) for self-guided I-BA (n = 9) and 17.7 (SD 6.3) for TAU (n = 10).

Adverse events and negative effects

From baseline to three-month follow-up 17 adverse events were documented for therapist-guided and self-guided I-BA, respectively, and 25 for TAU. None of the adverse events were assessed as serious. The most commonly reported negative effect on NEQ in the I-BA-groups, reported by a total of five participants from both groups, was not trusting the treatment and not feeling that the treatment produced any results. In TAU, the most commonly reported negative effects on NEQ were feeling that the treatment did not produce any results, feeling that the treatment was not motivating and not always understanding the treatment.

Therapist time (therapist-guided I-BA)

The average therapist time per family and chapter was 23 minutes (SD = 6 minutes). This includes both messages in the platform and occasional telephone calls relating to the treatment. Average telephone time per participant was 3.6 min (SD = 7.1), and median 0.0 min (IQR: 6.0 min) throughout the treatment.

Clinical outcomes

Primary outcome measure

A series of linear mixed models showed a significant decrease in masked assessor-rated depressive symptoms (CDRS-R) over time for therapist-guided I-BA (B = −11.3, P < 0.001, 95% CI −14.9 to −7.7), and self-guided I-BA (B = −10.38, P < 0.001, 95% CI −13.93 to −6.82), but not for TAU (B = −4.40, P = 0.077, 95% CI −9.33 to 0.52, P > 0.05) (**Table 3** and **Figure 2**). Within group Cohen's d was 2.43 (CI 1.66 to 3.20) for therapist-guided I-BA, 2.23 (CI 1.47 to 3.00) for self-guided I-BA, and 0.95 (CI -0.11 to 2.01) for TAU.

Table 3. Means (SD) for the three assessment points, presented separately for the three groups.

Measure	**Therapist-guided I-BA (n = 11)**	**Self-guided I-BA (n = 10)**	**TAU (n = 11)**
Clinician-rated	Mean (SD)[1]	Mean (SD)	Mean (SD)
CDRS-R			
Pretreatment	52.2 (9.4)	55.1 (10.2)	53.2 (9.0)
Posttreatment	34.8 (10.1)	39.0 (12.0)	44.9 (10.0)
Three-month follow-up[2]	29.1 (10.1)	31.6 (11.0)	44.6 (13.6)
Child- and parent-rated			
SMFQ-A			
Pretreatment	13.6 (5.4)	13.9 (6.5)	16.8 (6.2)
Posttreatment	6.2 (5.6)	4.9 (5.5)	12.9 (7.8)
Three-month follow-up	4.6 (4.5)	8.3 (6.0)	9.6 (5.8)
SMFQ-P			
Pretreatment	11.6 (5.8)	12.5 (5.9)	15.2 (4.1)
Posttreatment	7.6 (5.0)	5.5 (4.7)	11.2 (7.2)
Three-month follow-up	5.7 (4.3)	5.0 (3.6)	9.3 (5.0)
WSAS-A			
Pretreatment	17.9 (8.7)	13.8 (7.0)	16.1 (5.5)
Posttreatment	12.0 (6.6)	9.7 (11.2)	15.8 (10.6)
Three-month follow-up	7.0 (5.4)	5.6 (7.9)	12.9 (10.0)

Abbreviations: TAU = Treatment as usual; CDRS-R = Children's Depression Rating Scale, Revised; SMFQ-A/P = Short version of Mood and Feeling Questionnaire, adolescent and parent version; WSAS-A = Work and Social Adjustment Scale – adolescent Version

[1]Observed means.

[2]Primary endpoint.

Figure 2 approximately here.

Secondary outcome measures

Descriptive statistics on secondary outcome measures are reported in **Table 3** and supplementary **Table S2**. A series of linear mixed models showed significant decreases in self-rated depressive symptoms (SMFQ-A) for all three groups: therapist-guided I-BA (B =−4.4, P < 0.001, 95% CI −6.2 to −2.6), self-guided I-BA (B = −3.39, P < 0.05, 95% CI −6.48 to −0.30), and TAU (B =−4.04, P = 0.001, 95% CI −6.22 to −1.86). Within group effect sizes (Cohen's d) were 1.45 for therapist-guided I-BA, 1.12 for self-guided I-BA and 1.34 for TAU.

Significant decreases were shown for self-rated impaired functioning (WSAS-A) for therapist-guided I-BA (B = −5.24, P < 0.001, 95% CI −7.65 to −2.82), and self-guided I-BA (B = −3.58, P < 0.01, 95% CI −6.08 to −1.10), but not for TAU (B = −1.81, P = 0.163, 95% CI −4.43 to 0.80). Within group Cohen's d was 1.47 for therapist-guided I-BA, 1.00 for self-guided I-BA, and 0.51 for TAU.

Significant decreases were shown for parent-rated depressive symptoms (SMFQ-P) for therapist-guided I-BA (B =−2.83, P < 0.01, 95% CI −4.31 to −1.34), self-guided I-BA (B = −3.75, P < 0.01, 95% CI −5.65 to −1.85), and for TAU (B = −3.29, P < 0.01, 95% CI −5.17 to −1.42). Within group Cohen's *d* was 1.05 for therapist-guided I-BA, 1.40 for self-guided I-BA, and 1.22 for TAU. Means and within-group effects for CGAS, CGI-S, RCADS-S-A/P, KIDSCREEN-10-A/P, ISI, ARI and WSAS-P are presented in supplementary **Table S3.**

Treatment response (CGI-I)

At the primary endpoint, seven participants (64%) in therapist-guided BA, six participants (60%) in self-guided BA, and four in TAU (36%) were classified as treatment responders according to the CGI-I.

Masking integrity

Masking was unintentionally broken at two follow-up assessments (one in therapist-guided at post and one in TAU at three-month follow-up). At posttreatment, the assessors' guesses were correct in 48.2 % of the occasions, and at three-month follow-up the corresponding proportion was 61.5 %.

Discussion

This feasibility trial, where adolescents with mild to moderate depression were randomized to therapist-guided I-BA, self-guided I-BA or TAU, evaluated the feasibility of the study design, the acceptability of the treatment arms and provided preliminary clinical efficacy data. The pace of recruitment was initially slow but improved substantially when we placed advertisements in local media. It was possible to successfully refer all participants randomised to TAU to their local primary care or child adolescent mental health services, and all but one

patient received treatment in these services, though the start of treatment was often delayed. As expected, TAU was a heterogeneous condition; participants received pharmacological, psychological or combination of both interventions. Implications for a future large scale RCT include the need of a combination of recruitment sources, nationwide participant inclusion and that TAU is a reasonable and ethically acceptable control condition.

Overall, both I-BA groups were rated as more credible and more satisfactory than TAU. However, most families had probably hoped for one of the I-BA groups, which could have affected the lower ratings in the TAU group. Adherence was lower in the self-guided I-BA group but clinical outcomes were overall similar. Whether self-guided I-BA is a viable treatment alternative will be answered in a larger RCT. The advantages of self-guided interventions are obvious in terms of small costs and scalability.

Previous research has indicated that ICBT is efficacious for adolescent depression[22 23]. To the best of our knowledge, this is the first trial on online-delivered BA for this age group. Our results suggest that delivering BA online, with or without therapist-support, could also be a feasible and potentially effective way of treating depression in adolescents. We found large within-group effects on clinician-rated depressive symptoms for both I-BA groups. These results are consistent with previous trials, where face-to-face BA has been found to be potentially effective for adolescent depression[13-15]. In a small RCT, similar results were found for face-to-face BA and evidence-based practice for depression[46], while in the current trial we found lower effect sizes and response rates in the TAU group. The encouraging results of this feasibility study should be considered preliminary and the relative efficacy of therapist-guided and self-guided I-BA will need to be established in a definitive RCT.

This trial has several strengths, including a randomised controlled design, the use of masked assessors, high treatment adherence in the I-BA-groups, the use of an active control group and the careful recording of adverse events. Further, the contents of TAU were carefully assessed and reported. This study also has some limitations. First, while TAU ensures patient safety and allows for comparison to current clinical practice, it is a heterogeneous condition[47]. The nature and quality of TAU will impact the effect size of the I-BA[48]. Thus, a detailed description of TAU is important, for interpretation of the results, as well as for enabling replication. In this study we collected information about the content of TAU through medical records and interviewing parents. Both methods are subject to uncertainty, but showed good

agreement with each other. Second, generalisability of the results to other settings and locations might be limited. Usual care for adolescents with depression might differ between regions within Sweden and between different countries and healthcare systems. Third, although clinic referrals were accepted in this trial, all included patients were self-referred, and thus may be less complex than a clinically referred sample and more motivated to ICBT. However, about a fourth of participants self-referred to the study upon recommendation by a health care provider, and all included patients were diagnosed with major depressive disorder. Fourth, despite our best efforts, masked assessors correctly guessed group allocation more often than chance. Additional measures to improve masking, such as employing external masked assessors who are fully unaware of study aims and hypotheses[49] would have been preferable.

Conclusions

In conclusion, it should be feasible to conduct a fully powered RCT comparing therapist-guided and self-guided I-BA with TAU, in order to evaluate their relative efficacy and cost-effectiveness in adolescents with mild to moderate depression.

Author statements

Contributors

Authors JA, DMC, FL, EH, ES, and SV designed the study. RG wrote the protocol, was the project manager, and produced the treatment content, with input from JA, ES and SV. RG, JA and SV provided the I-BA treatments. Authors RG undertook the statistical analyses, with input from JA. Author RG also wrote the first draft of the manuscript, in collaboration with SV. All authors contributed to and have approved the final manuscript.

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Competing interests

The authors declare no financial or personal interests that could have influenced the work reported in this paper. Prof Mataix-Cols reports personal fees from UpToDate, Inc, outside the submitted work

Patient consent for publication

Not required.

Ethics approval

The study protocol was approved by the Regional Ethical Review Board in Stockholm, Sweden (reference number 2019/03235).

Data sharing statement

The data are pseudonymised according to national (Swedish) and European Union legislation, and cannot be anonymised and published in an open repository. Participants in the trial have not consented for their data to be shared with other international researchers for research purposes.

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Figure 1

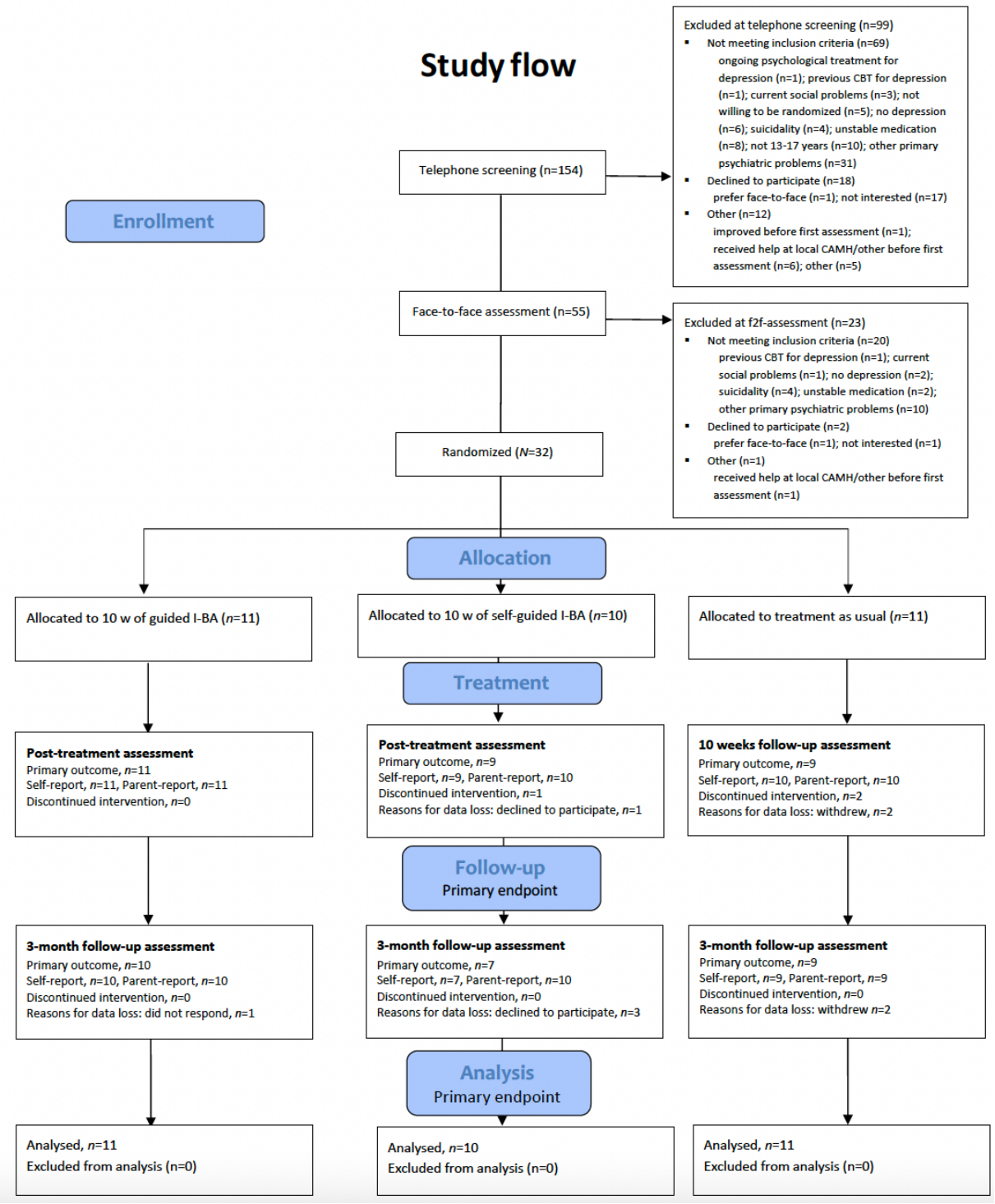


Figure 1 Consolidated Standards of Reporting Trials flow diagram.

Abbreviations: I-BA = Internet-delivered behavioural activation; CDRS-R = Children's Depression Rating Scale, revised; SMFQ = Short Mood and Feelings Questionnaire.

Figure 2

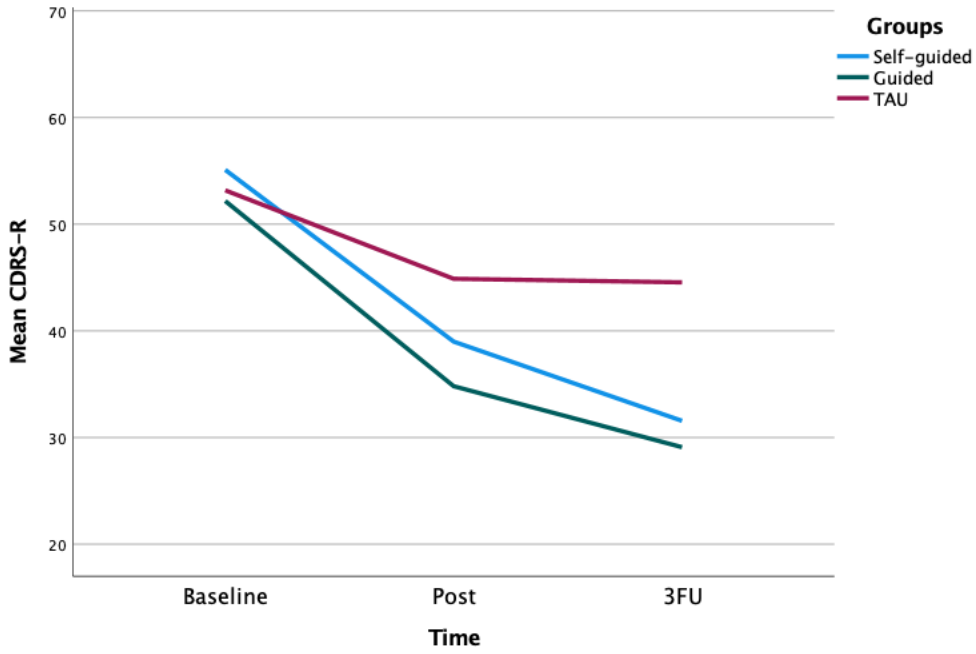
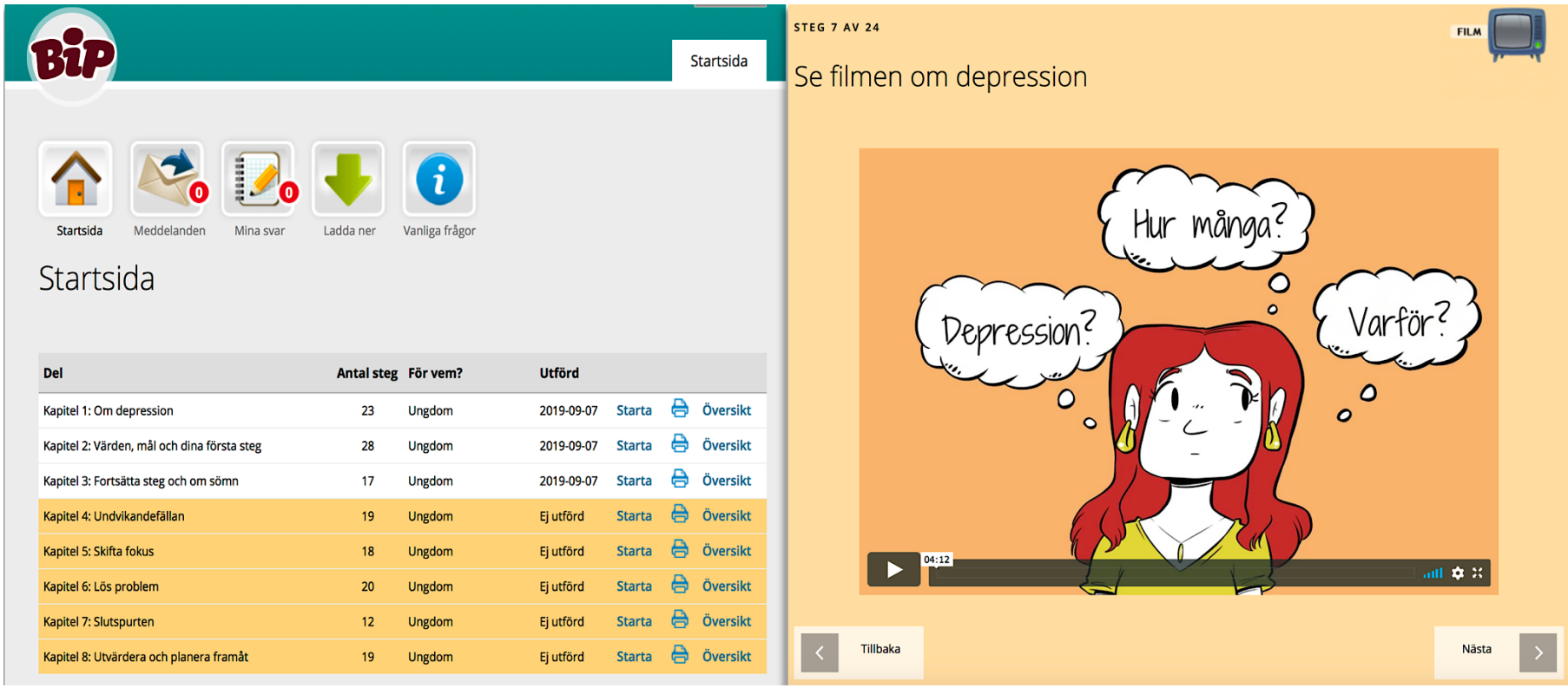


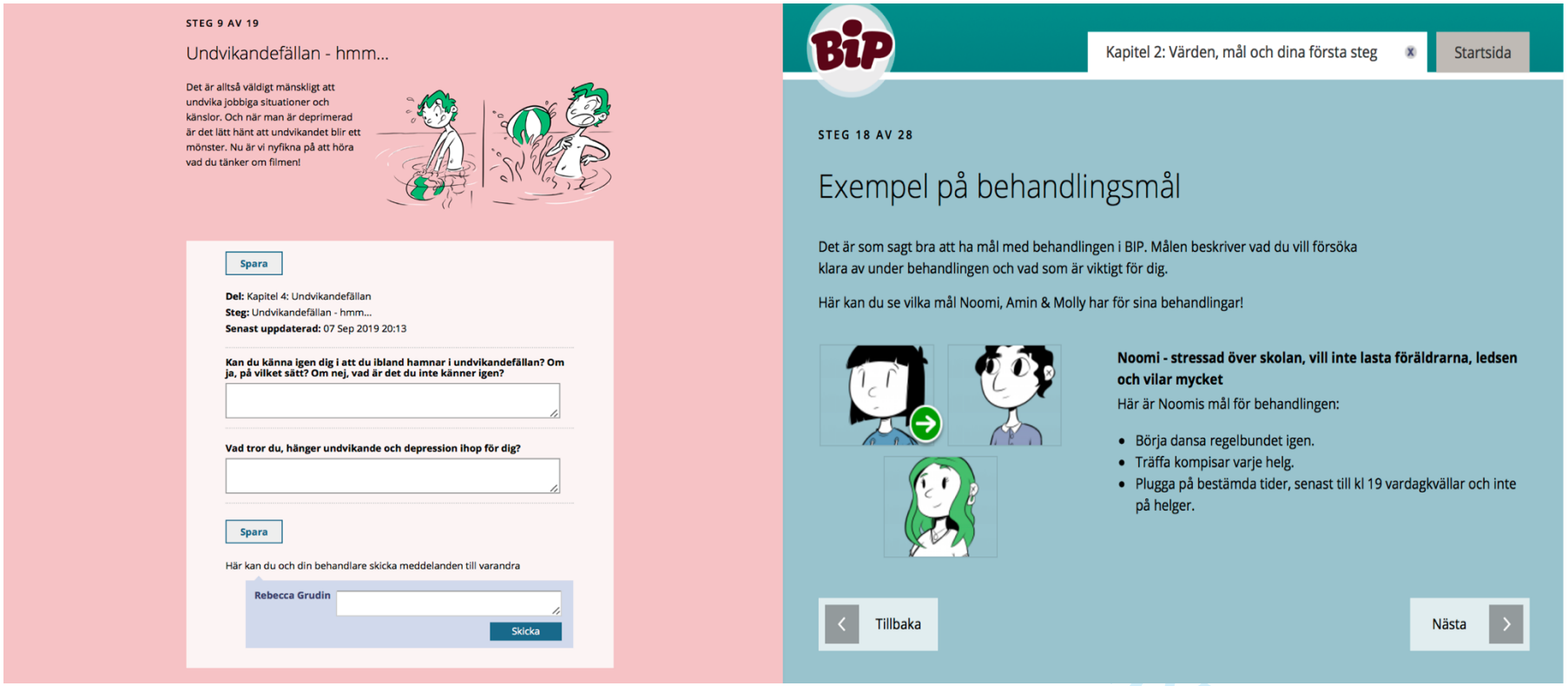
Figure 2. Graphical representation of the CDRS-R Total score across the three assessment points. Primary endpoint is the three-month follow-up. Error bars indicate 95% CIs. 3FU, three-month follow-up. CDRS-R, Children's Depression Rating Scale – Revised.

Figure S1. Screenshots of I-BA treatment

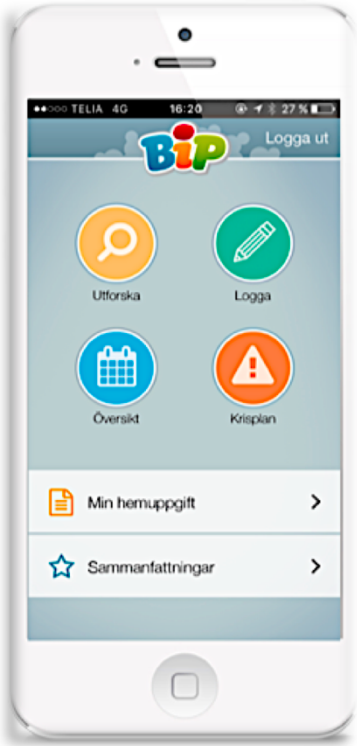
1. To the left: Overview and start page, with list of chapters (BIP Depression). To the right: A psychoeducative video about depression.



2. To the left: An exercise about the avoidance trap. To the right: The three fictional characters sharing their treatment goals.



3. To the left: The app that adolescents use for doing home assignments between chapters. To the right: Written information to the caregivers about how to validate your adolescent's emotions.



4. Encrypted messaging function which is included in guided I-BA. The psychologist responds within 1-2 days on weekdays to messages from the participant.

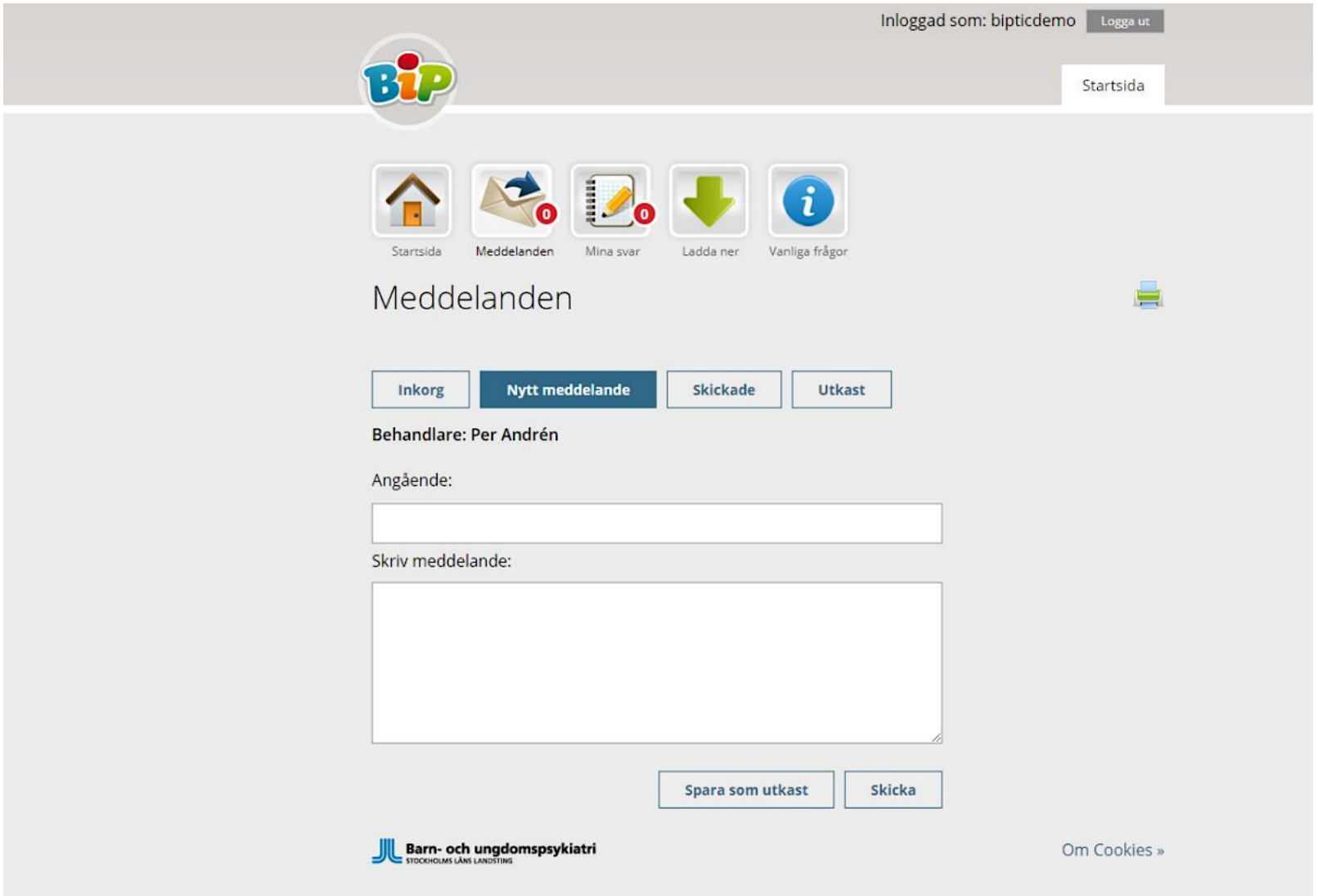


Table S1a. TAU content, including details on treatment type, intensity and provider according to interviews with parents

ID	Medications / Indication	No. of visits, incl initial psychiatric assessment	Psychological or psychosocial treatment	No. of sessions	Other intervention (no. visits)	Comments
1	Antidepressant (SSRI, 25 mg Sertraline)	–	CBT	5 sessions of CBT	–	
2	Antidepressant (SSRI, Fluoxetine, 20 mg)	–	Supportive therapy	1–2 sessions of supportive therapy	–	
3	–	2 visits (psychiatric assessment only)	–	–	–	No intervention was offered after the psychiatric assessment due to improvement.
4	Melatonine	–	CBT	10 sessions of CBT	–	
5	Melatonine + Vitamin D	–	CBT	7 sessions CBT	–	
6	–	–	Supportive therapy	10 sessions of supportive therapy	–	
7	Promethazine (Lergigan) + Melatonine	–	–	–	Neuropsychiatric assessment	
8	–	–	CBT	7 sessions	–	

9	Antidepressant + sleep medication + antihistamine (unknown types and dosage)	See comment	–	–	–	Initially this participant was referred to the CAMHS and received 1 visit (classified as psychiatric assessment), and later self-referred to primary care and received the specified medications.

Table S1b. TAU content, including details on treatment type, intensity and provider according to medical records

ID	Medications	No. of visits, incl initial psychiatric assessment	Psychological or psychosocial treatment	No. of sessions	Other intervention (no. visits)	Target for the intervention/s	Comments
1	Antidepressant (SSRI, Sertraline, 25 mg x 1)	3 visits	CBT	5 sessions of CBT	–	Social anxiety	
2	Antidepressant (SSRI, Fluoxetine 20 mg x 1)	3 visits	PDT/Supportive Therapy	5 sessions of PDT	–	Depression and unspecified anxiety	Medical records imply that it was mainly Supportive therapy, but classified as PDT according to treatment plan.
3	–	1 visit (psychiatric assessment only)	–	–	–	Depression	
4	Hydroxyzine (Atarax, 25 mg x 0,5-1) + Melatonine (Melatonine, 2 mg x 1-3)	–	CBT/Supportive therapy	8 sessions of CBT	–	Depression	No visits or telephone calls registered with a psychiatrist. The therapist seems to have consulted the doctor who initiated medical treatment without patient visist.
5	Melatonine (Melatonine, 4 mg) Vitamin D (Benferol, 800ie)	1 visit	CBT	11 sessions	–	Depression	
6	–	–	Supportive therapy	10 sessions	–	Depression	

7	Promethazine (Lergigan, 25 mg as required) + Melatonine (Melatonine, 3 mg x 3)	1 visit and 1 telephone call	–	–	Neuropsychiatric assessment, 5 visits plus 3 telephone calls	Melatonine for sleep problems, and Lergigan for unspecified anxiety; Suspected neuropsychiatric symptoms	
8	–	–	CBT	8 visits	–	Depression	
9	–	1 visit (psychiatric assessment only)	–	–	–	Depression	Psychiatric assessment included brief psychoeducation, then a referral was sent to primary care since the patient turned 18 years

Table S2. Means (SD) for all measures at the three assessment points for the three groups in the study.

Group / Measure	Guided I-BA (n=11)	Self-guided I-BA (n=10)	TAU (n=11)
Clinician-rated			
CGAS			
Baseline	56.6 (4.2)	54.7 (6.4)	52.9 (6.4)
Post	66.1 (13.3)	60.6 (11.5)	59.6 (7.8)
3-month FU	70.6 (15.4)	63.6 (12.5)	64.3 (10.1)
CGI-S			
Baseline	3.5 (0.8)	4.1 (1.1)	3.7 (0.7)
Post	2.2 (1.3)	3.0 (1.4)	3.3 (1.2)
3-month FU	2.0 (1.5)	2.3 (1.4)	3.0 (1.8)
Child-rated			
RCADS-S-A			
Baseline	12.5 (4.3)	14.4 (8.8)	12.7 (6.2)
Post	7.9 (5.2)	7.4 (4.6)	15.5 (10.3)
3-month FU	8.3 (5.3)	10.1 (5.7)	12.3 (9.0)
KIDSCREEN-10-A			
Baseline	31.3 (5.3)	30.7 (4.2)	28.4 (4.2)
Post	34.4 (5.3)	36.0 (6.2)	30.4 (5.2)
3-month FU	38.0 (5.1)	38.3 (6.0)	33.7 (4.9)
ISI			
Baseline	12.4 (6.3)	12.3 (6.2)	15.5 (3.5)
Post	6.1 (4.3)	7.6 (5.7)	14.3 (7.9)
3-month FU	4.3 (3.6)	7.0 (4.4)	10.2 (5.5)
ARI			
Baseline	3.8 (1.8)	6.6 (4.1)	6.6 (4.1)
Post	3.4 (2.7)	3.9 (4.0)	5.5 (4.2)
3-month FU	2.3 (1.6)	2.7 (4.4)	4.0 (3.4)

Parent-rated			
WSAS-P			
Baseline	18.5 (8.4)	16.1 (11.0)	19.2 (7.9)
Post	13.2 (7.0)	11.7 (9.6)	21.9 (7.9)
3-month follow-up§	11.6 (9.7)	13.1 (11.1)	13.2 (8.9)
RCADS-S-P			
Baseline	10.6 (6.6)	10.3 (4.9)	10.4 (7.0)
Post	9.2 (6.4)	8.8 (4.1)	10.0 (5.3)
3-month FU	7.7 (6.1)	6.5 (4.5)	7.9 (5.7)
KIDSCREEN-10-P			
Baseline	29.6 (4.2)	30.3 (5.6)	28.0 (5.4)
Post	31.5 (3.3)	34.8 (4.4)	31.2 (4.7)
3-month FU	34.2 (3.4)	33.0 (8.3)	31.6 (5.0)

I-BA = Internet-delivered behavioural activation; TAU = treatment as usual; CGAS = Children's Global Assessment Scale**;** CGI-S = Clinical Global Impression – Severity; RCADS-S (A/P) = Revised Children's Anxiety and Depression Scale, short version, anxiety subscales, adolescent and parent version; KIDSCREEN-10 (A/P) = a measure for general health-related quality of life, adolescent and parent version; ISI = Insomnia Severity Index; ARI = Affective Reactivity Index; WSAS (P) = Work and Social Adjustment Scale, parent version
^Observed means.
†Coefficients at post-treatment and at the 3-month follow-up compared with baseline.
§Primary endpoint.

Table S3. Fixed effects and effect sizes for all measures at follow-up compared to baseline, presented separately for the three groups and types of rater.

Group / Measure	Guided I-BA (n=11)		Self-guided I-BA (n=10)		TAU (n=11)	
	Unstandardized coefficient B (95 % CI)	**Effect size (Cohen's *d*, 95 % CI)**	**Unstandardized coefficient B (95 % CI)**	**Effect size (Cohen's *d*, 95 % CI)**	**Unstandardized coefficient B (95 % CI)**	**Effect size (Cohen's *d*, 95 % CI)**
Clinician-rated						
CGI-S	-0.69 (-1.12 to -0.26)**	1.57 (0.59 to 2.55)	-0.85 (-1.24 to -0.46)***	1.94 (1.05 to 2.83)	-0.37 (-0.86 to 0.12)	0.85 (-0.26 to 1.96)
CGAS	6.86 (2.46 to 11.25)**	2.36 (0.85 to 3.87)	4.35 (1.21 to 7.50)**	1.50 (0.42 to 2.58)	5.76 (3.12 to 8.41)***	1.98 (1.07 to 2.89)
Child-rated						
RCADS-S	-2.12 (-0.92 to -3.32)***	0.66 (0.29 to 1.03)	-2.48 (–4.85 to -0.10)*	0.77 (0.03 to 1.50)	-0.29 (-2.75 to 2.16)	0.09 (-0.67 to 0.85)
ARI	-0.63 (-1.40 to 0.14)	0.35 (-0.07 to 0.77)	-2.01 (– 3.37 to -0.65)**	1.10 (0.36 to 1.85)	-1.40 (-2.40 to -0.40)**	0.77 (0.22 to 1.31)
ISI	-4.14 (-5.69 to -2.60)***	1.51 (0.94 to 2.07)	-2.64 (-4.36 to -0.92)**	0.96 (0.33 to 1.59)	-2.69 (-4.91 to -0.47)*	0.98 (0.17 to 1.79)
KIDSCREEN-10	3.03 (1.80 to 4.27)***	1.31 (0.77 to 1.84)	3.46 (1.93 to 4.99)***	1.49 (0.83 to 2.15)	2.71 (0.65 to 4.76)*	1.17 (0.28 to 2.05)
Parent-rated						
WSAS	-3.23 (-5.09 to -1.37)**	0.72 (0.31 to 1.14)	-1.50 (-3.27 to 0.27)	0.34 (-0.06 to 0.73)	-2.63 (-5.31 to 0.04)	0.59 (-0.01 to 1.19)
RCADS-S	-1.59 (-2.94 to -0.24)*	0.53 (0.08 to 0.97)	-2.20 (-3.58 to -0.82)**	0.73 (0.27 to 1.18)	-1.39 (-3.17 to 0.39)	0.46 (-0.13 to 1.05)
KIDSCREEN-10	2.16 (1.14 to 3.17)***	0.86 (0.46 to 1.27)	2.25 (0.74 to 3.76)**	0.90 (0.30 to 1.51)	1.82 (0.01 to 3.62)*	0.73 (0.00 to 1.45)

I-BA = Internet-delivered behavioural activation; TAU = treatment as usual; CGAS = Children's Global Assessment Scale**;** CGI-S = Clinical Global Impression – Severity; RCADS-S (A/P) = Revised Children's Anxiety and Depression Scale, short version, anxiety subscales, adolescent and parent version; KIDSCREEN-10 (A/P) = a measure for general health-related quality of life, adolescent and parent version; ISI = Insomnia Severity Index; ARI = Affective Reactivity Index; WSAS (P) = Work and Social Adjustment Scale, parent version

⁎p < 0.05, ⁎⁎p < 0.01, ⁎⁎⁎p < 0.001.

‡All Cohen's d effect sizes are calculated from the regression model. The 3-month follow-up effect sizes compare to baseline. Effect sizes of 0.2, 0.5 and 0.8 are considered small, moderate and large, respectively.

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	4-5
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	5
Participants	4a	Eligibility criteria for participants	5-6
	4b	Settings and locations where the data were collected	5
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7-8
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9-10
	6b	Any changes to trial outcomes after the trial commenced, with reasons	10
Sample size	7a	How sample size was determined	6
	7b	When applicable, explanation of any interim analyses and stopping guidelines	Study protocol, p 28
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	10-11
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	10-11
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	10-11
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	10

Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	11
	11b	If relevant, description of the similarity of interventions	7
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Not used
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 primary outcome	Figures, Figure 1, p 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figures, Figure 1, p 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	11
	14b	Why the trial ended or was stopped	5
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	13
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Figures, Figure 1, p 1
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)	15-17
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not applicable
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Not applicable
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	14
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	18-19
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	19
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	18-19
Other information			
Registration	23	Registration number and name of trial registry	2
Protocol	24	Where the full trial protocol can be accessed, if available	Not available
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	19

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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Therapist-guided and self-guided Internet-delivered behavioural activation for adolescents with depression: a randomised feasibility trial

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Therapist-guided and self-guided Internet-delivered behavioural activation for adolescents with depression: a randomised feasibility trial

Rebecca Grudin[a*], Johan Ahlen[b, c], David Mataix-Cols[a], Fabian Lenhard[a], Eva Henje[d], Cecilia Månsson[e], Hanna Sahlin[f], Maria Beckman[f], Eva Serlachius[g, h], Sarah Vigerland[a]

[a]Centre for Psychiatry Research, Department of Clinical Neuroscience, Karolinska Institutet, & Stockholm Health Care Services, Region Stockholm, CAP Research Centre, Gävlegatan 22, SE-113 30 Stockholm, Sweden

[b]The Centre for Epidemiology and Community Medicine, Box 45436, SE-104 31 Stockholm, Region Stockholm, Sweden

[c]Department of Global Public Health, Karolinska Institutet, SE-171 77 Stockholm, Sweden

[d]Department of Clinical Science, Child and Adolescent Psychiatry, Umeå University, SE-901 85 Umeå, Sweden

[e]Child and Adolescent Mental Health Services, Region Stockholm, CAMHS Trauma Clinic, Tideliusgatan 22, SE-118 69 Stockholm, Sweden

[f]Centre for Psychiatry Research, Department of Clinical Neuroscience, Karolinska Institutet, & Stockholm Health Care Services, Region Stockholm, The Centre for Psychotherapy, Education & Research, Liljeholmstorget 7, SE-117 63 Stockholm, Sweden

[g]Department of Clinical Neuroscience, Karolinska Institutet, SE-171 77 Stockholm, Sweden

[h]Department of Clinical Sciences, Faculty of Medicine, Lund University, Baravägen 1, SE-222 40 Lund, Sweden

*Correspondence to Rebecca Grudin: rebecca.grudin@ki.se

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Abstract

Objective: Access to effective treatments for adolescents with depression needs to improve. Few studies have evaluated behavioural activation (BA) for adolescent depression, and none remotely-delivered BA. This study explored the feasibility and acceptability of therapist-guided and self-guided Internet-delivered BA (I-BA) in preparation for a future randomised controlled trial (RCT).

Design: A single-masked randomised controlled feasibility trial.

Setting: A specialist outpatient clinic in Sweden.

Participants: Thirty-two adolescents with mild to moderate major depression, aged 13–17.

Interventions: Ten weeks of therapist-guided I-BA or self-guided I-BA, or treatment as usual (TAU). Both versions of I-BA included parental support. TAU included referral to usual care within child and youth psychiatry or primary care.

Outcomes: Feasibility measures included study take-up, participant retention, acceptability, safety, and satisfaction. The primary outcome measure was the masked assessor-rated Children's Depression Rating Scale, Revised. The primary endpoint was the three-month follow-up.

Results: 154 adolescents were screened and 32 were randomised to therapist-guided I-BA (n = 11), self-guided I-BA (n = 10), or TAU (n = 11). Participant retention was acceptable, with two drop-outs in TAU. Most participants in TAU had been offered interventions by the primary endpoint. The mean number of completed chapters (total of 8) for adolescents was 7.5 in therapist-guided I-BA and 5.4 in self-guided I-BA. No serious adverse events were recorded. Satisfaction was acceptable in both I-BA groups. Following an intent-to-treat approach, the linear mixed effects model revealed that both therapist-guided and self-guided I-BA (Cohen's d = 2.43 and 2.23 respectively), but not TAU (Cohen's d = 0.95), showed statistically significant changes on the primary outcome measure with large within-group effect sizes.

Conclusions: Both therapist-guided and self-guided I-BA are acceptable and potentially efficacious treatments for adolescents with depression. It is feasible to conduct a large-scale RCT to establish the efficacy and cost-effectiveness of I-BA vs TAU.

Trial registration number: Clinicaltrials.gov, NCT04117789.

Trial funding: Kavli Trust and Frimurare Barnhuset Trust in Stockholm.

Article summary: Strengths and limitations of this study

- Strengths include a randomised controlled design, use of an active control group, and careful assessment of the contents of TAU.
- An additional strength was that assessors were masked to treatment allocation at the primary endpoint.
- Limitations include the heterogenous condition of TAU and masked assessors correctly guessing group allocation more often than by chance.

Keywords

Depression; Adolescents; Feasibility trial; Behavioural activation; Self-guided; Internet interventions

Introduction

Depression is one of the leading causes of disability worldwide[1]. Adolescence is a risk period for developing depression, associated with a sharp increase in prevalence[2 3]. Comorbidity with other mental disorders is prevalent among adolescents with depression[4], with sleep disorders and anxiety being among the most common[5]. Adolescent depression is associated with a range of adverse outcomes, including impaired academic, social, and work functioning[6 7], poor mental and physical health in adulthood[8 9], and increased risk of suicide[10]. Early detection and treatment of adolescent depression markedly decreases the likelihood of future clinical depression and other mental health issuess[11].

Cognitive Behaviour Therapy (CBT) is a well-established intervention for adolescents with depression[12], and is also currently recommended in clinical practice and national guidelines[13 14]. Behavioural activation (BA) is an important component of CBT for depression, but can also be delivered as a stand-alone therapy[15]. The main goal of BA is to increase engagement in values-based activities and to decrease the avoidant behaviours that often maintain depressive symptoms[16-19]. BA is considered an evidence-based treatment for adults with depression[20 21] and three open trials indicate that BA is also a feasible intervention for adolescents with depression[16 17 19]. A small RCT that compared BA to evidence-based interventions (CBT and Interpersonal psychotherapy) showed promising results[18], but BA for depressed adolescents has yet to be evaluated in an adequately powered RCT. BA, unlike traditional CBT for depression, does not include cognitive restructuring[22], although it seems to be equally effective [23]. Furthermore, dismantling studies have proposed that BA might be a sufficient treatment component on its own[24 25]. In line with this suggestion, a meta-analysis of adolescent depression treatments found that psychological interventions with a cognitive component were no more effective than those without cognitive work[26]. Because BA is brief and readily understood, it might suit adolescents particularly well. Another potential benefit is that, given its focus on reducing avoidance behaviours[27], BA may also be effective for reducing anxiety, which is important because anxiety is often co-morbid with depression in this age group[5].

Despite the high prevalence of depression among young people, only a minority receive evidence-based treatments[28-30]. Internet-delivered CBT (ICBT) was developed to improve access to treatment, and has several potential advantages over traditional in-person treatments,

(bridging geographical distances, requiring less therapist time, lower risk of therapist drift, etc.[31]). Studies in adults have shown that ICBT is effective and probably cost-effective for several psychiatric disorders, including depression[31]. In children and adolescents, there is growing support for the efficacy of ICBT for several psychiatric disorders[32], but it is still unclear whether ICBT is an efficacious intervention for adolescent depression. To date, three trials on ICBT with clinically depressed adolescents have been published. Two of them (both N = 70), included therapist-chat communication and showed significant reductions in depressive symptoms for adolescents compared to attention control[33 34]. The third, an open trial (N = 15) investigating the feasibility of a transdiagnostic Internet-delivered intervention based on rational emotive behaviour therapy for adolescents diagnosed with anxiety and depressive disorders, found a reduction in self-reported anxiety and depressive symptoms[35]. A number of ICBT studies have also been conducted in subclinical samples with promising results[36-39].

Internet-based interventions can be either therapist-guided or self-guided, i.e. delivered with or without remote therapist support. According to a recent meta-analysis of ICBT for adults, therapist-guided ICBT was associated with greater improvement than self-guided treatment[40]. However, self-guided ICBT was as effective as guided ICBT among adults with mild or sub-threshold depression. The importance of therapist support is unclear in children and adolescents, and results are inconsistent[41] [42]. If ICBT could be entirely unguided, without sacrificing efficacy and safety, it could drastically increase availability to treatment.

Adequately powered trials are needed to explore whether ICBT with and without therapist-support is safe, effective, and cost-effective for adolescent depression. However, important questions regarding feasibility of study design, acceptability of interventions, and preliminary efficacy should be addressed before conducting large trials. Therefore, we designed a randomised feasibility trial of therapist-guided and self-guided Internet-delivered BA (I-BA), to compare to treatment as usual (TAU). The primary objective of the study was to evaluate the feasibility of the study design, e.g., study take-up, participant retention, and feasibility of using TAU as a control group. Secondary objectives were to explore the acceptability of the I-BA interventions, e.g., treatment adherence, credibility, satisfaction, and adverse events, and to provide preliminary clinical efficacy data to assist with power calculations for a fully

powered trial. This will also be the first trial to explore online delivered BA for depressed adolescents and their parents.

Methods

Study design

This study was a single-masked, parallel three-arm randomised controlled feasibility trial of therapist-guided I-BA, self-guided I-BA, and TAU for adolescents with mild to moderate major depressive disorder (MDD). Group allocation was masked for outcome assessors, but not for participants or therapists. Participants were randomly assigned at a 1:1:1 ratio. The study was conducted at a clinical research unit within Child and Adolescent Mental Health Services (CAMHS) in Stockholm, Sweden. The planned recruitment period was six months. Masked rater assessments were conducted at post-treatment (week 11) and three-month follow-up (primary end point) visits. There were two reasons for setting the three-month-follow up as the primary end point: first, this increased the likelihood that participants assigned to TAU would have received treatment; second, previous ICBT trials have shown a continued improvement from post-treatment to three-month follow-up[43 44]. No changes in the methods were made after the registration and subsequent start of the trial.

Participants

Inclusion criteria were: age 13–17; a diagnosis of mild or moderate MDD according to the *DSM-5*[45]; use of psychotropic medications (i.e., antidepressants, central stimulants, and antipsychotics) that had been stable for at least six weeks prior to inclusion; at least one caregiver able to partake in the treatment; both adolescent and caregiver fluent in Swedish; access to the internet via a smartphone and a computer.

Exclusion criteria were: acute psychiatric problems (e.g., high risk of suicide or alcohol and substance abuse); social problems requiring other immediate actions (e.g., abuse in the family, high and prolonged absence from school); previous CBT for MDD within the last 12 months (defined as ≥ 3 sessions of CBT/BA, other than psychoeducation); current use of benzodiazepines; ongoing psychological treatment for any psychiatric disorder.

Sample size

This feasibility trial was not powered to detect statistically significant differences between groups. However, we aimed to include a sufficient number of participants to explore within-group changes from baseline to the primary end point. In two recent RCTs[18 46], large within-group effects were found on depressive symptoms ($d > 1.2$; $d = 1.4$). Based on previous results, we aimed to recruit a total of 45 participants to be able to detect a within-group effect of d=1.2 (alpha value of 0.05 and 90% power), taking a potentially high attrition of 25% into account. Power calculation was performed using Statulator[47].

Recruitment and procedures

Participants were recruited at CAMHS and primary health care clinics through information distributed orally and electronically to managers and clinicians, and via flyers distributed in waiting rooms. About three months after the study began, we also advertised in newspapers and social media. Referrals from healthcare professionals and self-referrals from families all over Sweden were also accepted.

Applicants were first contacted for an initial telephone screening and then invited to a face-to-face visit for a thorough assessment of study eligibility. Video assessments were offered to families that could not travel to the clinic and to everyone after the start of the COVID-19 pandemic. Verbal and written information was provided to the adolescents and their parents, who all gave written consent. During the face-to-face assessment, a trained psychologist: a) verified the MDD diagnosis, according to the DSM-5 criteria; b) assessed current level of depression symptom severity using the CDRS-R; and c) assessed psychiatric comorbidity. After the assessment, included participants and parents completed the baseline measures and were then randomised. Within a week after completion of the baseline measures, patients allocated to the I-BA treatments started treatment, and participants allocated to TAU received a referral to their local CAMHS or paediatric primary care unit. **Figure 1** shows the CONSORT flowchart.

To ensure patient safety, participants in all treatments were given brief, weekly questions about depressive symptoms during the intervention, which allowed suicidal ideation to be monitored and, if needed, assessed. If further psychiatric assessments or any preventive actions were needed, the study team referred the patient to emergency psychiatric services.

Follow-up assessments were conducted at post-treatment and after three months by assessors masked to treatment allocation. Self- and parent-reported measures were completed online at all assessment points.

Interventions

The specific I-BA treatment protocol was developed and adapted to an online format for this study, and although it has not been otherwise evaluated in its current form, it was inspired by previous BA protocols[18 48]. BA commonly provides treatment rationale and psychoeducation, activity monitoring, activity scheduling, contingency management, values and goal assessments, and skills training in problem solving and communication skills, relaxation techniques, and relapse prevention. BA also targets verbal and avoidance behaviours[49]. While various BA protocols include and emphasize different components, activity monitoring and scheduling are always present[50]. In our protocol, we included all of the aforementioned BA components apart from relaxation. Verbal behaviours were targeted through shifting focus. Sleep hygiene was added to the BA protocol because sleep problems are a common comorbidity of depression[5] that are often addressed in face-to-face BA[51].

The two I-BA treatments were delivered through a secure online platform, each consisting of eight chapters with age-appropriate texts, animations, films, and various exercises delivered over ten weeks. Each chapter took approximately 30 to 60 minutes to complete. The first four chapters introduced the most essential components of BA (i.e., scheduling of values-based activities and targeting avoidance behaviours). An overview of the treatment content is presented in **Table 1,** and sample screenshots from the intervention are presented in supplementary **Figure S1**.

Between each chapter, both adolescents and parents were assigned homework (see **Table 1** for details). To assist the adolescents with these assignments, a mobile application was developed to provide summaries of each chapter, instructions for homework assignments, and an activity diary to help with planning and evaluation of scheduled activities. The application included automatic prompts to login in case of inactivity and an easily-accessible individualized emergency plan.

In the therapist-guided I-BA arm, the participants had weekly asynchronous contact with a clinical psychologist via written messages within the platform. The psychologists logged in at least every other day during workdays to provide feedback, answer questions, and, if needed, prompt the participants to complete the next chapter. The therapists were recommended to spend around 20 to 30 minutes per family per week. Occasional phone calls were added when deemed necessary. The content of the self-guided I-BA programme was identical to the therapist-guided version, except that the participants did not have access to any therapist support.

Both conditions of I-BA in this study included a parallel eight-chapter course for parents (see **Table 1** for details) which was accessed through separate login accounts. Involving parents is a common BA adaptation for young people, and parents are taught how to encourage the young person to complete scheduled activities[50]. This parental course was based on CBT-strategies commonly used in parent training programs[52] such as praise and other forms of positive parental attention aiming at strengthening the relationship between caregivers and their children. The control condition was treatment as usual (TAU). Participants randomised to TAU were referred to their local CAMHS or paediatric primary care services and were free to receive any treatment, whether psychosocial, pharmacological, or a combination of both.

Table 1. An overview of the treatment content of I-BA.

Chapter	Adolescent	Parent
1	Introduction to I-BA. Psychoeducation about depression. Rationale for BA. *Homework*: activity monitoring.	Introduction to I-BA. Psychoeducation about depression. Rationale for BA. Learning about common parental traps. *Homework*: noticing one's parental behaviours when the adolescent shows depressive behaviours. Discussing with the adolescent how to collaborate in treatment.
2	Values assessment. Set treatment goals. *Homework*: activity scheduling.	Facilitating and encouraging values-based activation. Communication skills part I: validating your child's feelings. *Homework:* practising validating others' and your child's emotions, encouraging values-based activation.
3	Continued values-based activation. Psychoeducation about sleep. *Homework*: activity scheduling and sleep hygiene.	Spending positive time with your adolescent. *Homework*: suggesting positive time with your adolescent.
4	Continued values-based activation. Overcoming barriers to activation through identifying and overcoming avoidance. *Homework*: activity scheduling, sleep hygiene and practising overcoming avoidance.	Communication skills part II: avoiding and managing conflicts. *Homework*: practising conflict management.
5	Continued values-based activation. Overcome barriers to activation through shifting focus to the present situation. *Homework*: activity scheduling, sleep hygiene, and practising shifting focus.	Taking care of yourself as a parent supporting a child with depression. *Homework*: taking care of yourself.
6	Continued values-based activation. Problem solving. *Homework*: activity scheduling, sleep hygiene, and practising problem-solving.	Collaborative problem-solving. *Homework*: practising collaborative problem-solving.
7	Putting it all together. *Homework*: activity scheduling.	Putting it all together. *Homework*: choosing two tasks from previously introduced skills.
8	Treatment summary. Relapse prevention. Evaluation of treatment.	Course summary. Relapse prevention. Evaluation of treatment.
Abbreviations: I-BA = Internet-delivered Behavioural Activation, BA = Behavioural Activation.		

Patient involvement

Three patient representatives who had previously suffered from depression were involved in the development of I-BA, providing feedback on language and content, ensuring that the content was inclusive (e.g. of LGBTQ concerns), understandable and useful.

Measures

Baseline assessment

The Mini-International Neuropsychiatric Interview for Children (MINI-KID)[53] was administered to confirm the primary diagnosis of MDD and to screen for psychiatric comorbidities. Suicide risk assessment was based on all available information, including the sections about suicidality in MINI-KID and CDRS-R collected at the inclusion assessment visit. To assess recurrent non-suicidal self-injury, the seven-item Deliberate Self-Harm Inventory for youths[54] was used. Demographic data of adolescents (e.g., age, gender, current and previous psychotropic medication, and previous psychological treatment) were collected at the initial assessment, and data about the parents were collected through an online questionnaire.

Study design feasibility

We evaluated study take-up by calculating the average number of included participants per week. Participant retention is presented in **Figure 1**. The specific contents of TAU in terms of type and indication for medication, number of visits, type of psychological or psychosocial treatment and number of sessions, and number of sessions of other potential interventions were collected from each participant's official medical records and by interviewing the families after the three-month follow-up assessment.

Acceptability of I-BA

The average number of completed chapters for adolescents and their parents were documented. Adolescents who completed less than half (< 4) of the I-BA-chapters were defined as having discontinued treatment.

To measure treatment credibility, four questions were administered to all adolescents and their parents at week three: 1) How much did they believe the treatment suited adolescents with depression? 2) How much did they believe the treatment would help them? 3) If and to what extent would they recommend this treatment to a friend with depression? and 4) How

much improvement did they expect from the treatment? The total range of this scale was 4 to 20, with higher values representing higher credibility.

Treatment satisfaction was assessed with the Client Satisfaction Questionnaire (CSQ) at post-treatment (adolescent and parent version; total range 8–32, with higher values indicating higher satisfaction)[55]. All adverse events, i.e. untoward medical occurrences after exposure to the intervention (but not necessarily caused by the intervention) were communicated by participants (e.g. via SMS, phone calls, at follow-up visits) and documented by the trial coordinator (RG) until three-month follow-up. Adverse events were also assessed with the Negative Effects Questionnaire with 20 items (NEQ-20) administered at post-treatment and at three-month follow-up (adolescent and parent version; total range 0–80, with higher values representing more reported adverse events)[56]. NEQ has been developed to investigate negative effects of psychological treatments, such as experiencing unpleasant feelings during treatment and not believing that things can improve. Because we did not systematically ask about adverse events, the administration of NEQ at predefined time points increased the likelihood of identifying adverse events. Furthermore, NEQ includes treatment-related questions like lacking confidence in one's treatment or having unpleasant memories resurface (these factors are often not reported spontaneously).

Therapist time was logged automatically in the treatment platform. The platform registered how many minutes the therapist spends on each participant (including reading their responses and providing feedback). The entire time a therapist had a certain participant "open" was included, e.g., navigating between worksheets, answering messages, etc. If therapists were interrupted while working, they could edit the amount of time registered to a more accurate sum. Time spent on phone calls with adolescents and their parents was logged manually by the therapist. These two indicators, i.e., therapist time in the platform and time spent on phone calls, were combined as a measure of therapist time per family and chapter.

Working alliance was assessed with the Working Alliance Inventory-6 items (WAI-6) at three weeks and post-treatment (adolescent and parent versions)[57] .

Clinical outcomes

The Children's Depression Rating Scale, Revised (CDRS-R, primary measure of clinical efficacy) is a semi-structured clinical interview used to assess depressive symptom severity in children (total range 17–113 with higher values representing more depressive symptoms)[58]. All interviews with CDRS-R were audio-recorded.

Other clinician-rated measures included the Children's Global Assessment Scale (CGAS)[59] and Clinical Global Impression Scale – Severity and Improvement (CGI-S and CGI-I)[60]. CGI-I was only conducted at post-treatment and the three-month follow-up. Treatment response was defined as a CGI-I rating of 1 or 2 at the three-month follow-up. Percentages that still fulfilled MDD diagnosis at three-month follow-up will be presented.

Depressive symptoms were assessed with the Short Mood and Feelings Questionnaire (SMFQ, adolescent and parent versions, total range 0–26 with higher values representing more symptoms)[61 62]. Impaired functioning due to depression was measured with the Work and Social Adjustment Scale (WSAS, adolescent and parent versions, total range 0–40 with higher values indicating greater impairment)[63]. Anxiety symptoms were assessed by the anxiety subscales in the Revised Children's Anxiety and Depression Scale – Short version (RCADS-S, adolescent and parent versions; total range 0–45 with higher values indicating worse outcome)[64]. KIDSCREEN-10 Index (adolescent and parent versions, total range 10–50 with higher values indicating better quality of life) was used to measure general health-related quality of life[65]. Difficulties with sleep were measured by the Insomnia Severity Index (ISI, adolescent version, total range 0–28 with higher values indicating a worse outcome)[66] and irritability by Affective Reactivity Index (ARI, adolescent version, total range 0–12with higher values indicating worse outcome)[67].

Behavioral Activation of Depression Scale Short Form (BADS-SF) is a self-report measure developed to measure the proposed mediators of BA, i.e., activation and avoidances[68]. Total range of the scales is 0–54 with higher values indicating high activation and low avoidance. Need for further treatment was assessed at three-month follow-up with a non-validated single-item questionnaire (adolescent and parent versions). ISI, ARI, and BADS were administered to adolescents only.

WAI, BADS-SF and Need for further treatment were included in this study to test for feasibility only and will be presented in the supplementary material. No changes were made to outcomes after the trial commenced. More information on measures is available in Data supplement 1.

Randomisation and allocation concealment

Block randomisation, with five random sets of blocks of three and six respectively, were created by an independent clinician using an online service (http://www.random.org). Once a participant was included, the independent clinician opened a sealed opaque envelope revealing a numbered paper with treatment allocation.

Post-treatment and three-month follow-up assessments were conducted by four clinical psychologists masked to treatment allocation. In the event of unmasking, a new assessor re-rated the recording. Masking integrity was measured at each assessment point by asking masked assessors to guess each participant's group allocation and indicate the reasons for their conjecture (e.g., totally random guess, impression of improvement, etc.)[69].

Analytical methods

Data on trial feasibility (e.g., study take-up, participant retention, and content of TAU) and data on acceptability (e.g., adherence, credibility, satisfaction, and adverse events) were analysed using descriptive statistics.

We used linear mixed regression models to estimate within-group effects for all continuous clinical outcome measures. All models included a fixed effect of time and a random intercept for participant effect. In contrast to standard modeling of repeated data, where listwise deletion is used for all cases with missing data at any time point[70], the linear mixed model estimates effects using all available observations at all time-points. The linear mixed model has been shown to yield reliable estimates in various types of missing data patterns[71]. Time was treated as a continuous variable from 0–2 (pre-treatment, post-treatment, and three-month follow-up) because there were three months between each time point. Alpha levels (two-tailed) were set to $p < 0.05$. Within-group effect sizes (Cohen's *d*) were calculated using the accumulated beta-coefficients (pre-treatment to three-month follow-up) from the regression models as the nominator and the pooled SD at pre-treatment as the denominator [72].

Additionally, the proportion of treatment responders at three-month follow-up was calculated with intent to treat analysis according to pre-specified criteria. Analyses were performed with SPSS version 27 and Excel version 16.

Results

Study design feasibility

Study take-up

Between 14 October 2019 and 24 April 2020, a total of 154 families were screened by telephone and 32 participants were included. Approximately a fourth had been recommended by a health care provider to self-refer to the study. The recruitment rate was slow before we started advertising in local media (0.5 included per week), but higher after advertising (2.3 included per week). Although we had not reached the goal of including 45 participants after the planned six-month recruitment period, we decided to end recruitment because we had fewer drop-outs than expected and thus enough participants to answer our feasibility questions.

Participant retention and study flow

A total of 32 adolescents from all over Sweden were recruited and randomised to therapist-guided I-BA (n = 11), self-guided I-BA (n = 10) or TAU (n = 11). **Table 2** shows the demographic and clinical characteristics of the sample at baseline. **Figure 1** shows the study flow. Two participants dropped out of the study. Both drop-outs were dissatisfied that they had been allocated to TAU and did not want to attend their appointments within regular healthcare or continue as study participants. At post-treatment, there were no missing data on the primary outcome measure CDRS-R in therapist-guided I-BA, one in self-guided, and two in TAU. At three-month follow-up, there were missing data for one participant in therapist-guided, three in self-guided, and two in TAU. The final three-month follow-up assessment occurred on 15 October 2020.

Figure 1 approximately here.

Table 2. Baseline demographic and clinical characteristics of the total sample and for each group.

	Total (n = 32)	Therapist-guided I-BA (n = 11)	Self-guided I-BA (n = 10)	TAU (n = 11)
Age, mean (SD), min-max	15.4 (1.6), 13–17	14.6 (1.2), 13–17	15.1 (1.8), 13-17	16.5 (1.3), 14–17
Gender, n (%)				
Female	19 (59%)	6 (55%)	7 (70%)	6 (55%)
Male	13 (41%)	5 (45%)	3 (30%)	5 (45%)
Main contact person, mothers, n (%)	30 (94%)	9 (82%)	10 (100%)	11 (100%)
Education of contact person				
Elementary school	1 (3%)	0 (0%)	0 (0%)	1 (3%)
High school	3 (9%)	1 (9%)	1 (10%)	1 (9%)
Higher education < 2 years	5 (16%)	1 (9%)	4 (40%)	0 (0%)
Higher education > 2 years	21 (66%)	7 (64%)	5 (50%)	9 (82%)
Post-graduate degree	2 (6%)	2 (18%)	0 (0%)	0 (0%)
Comorbidity[1], n (%)				
None	6 (19%)	1 (9%)	2 (20%)	3(27%)
One diagnosis	12 (38%)	5 (45%)	3 (30%)	4 (36%)
Two or more diagnoses	14 (44%)	5 (45%)	5 (45%)	4 (36%)
Anxiety disorder/s[1]	23 (72%)	7 (64%)	8 (80%)	8 (73%)
ADHD/ASD	5 (16%)	3 (27%)	0 (0%)	2 (18%)
Current use of antidepressants, n (%)	2 (6%)	1 (9%)	0 (0%)	1 (3%)
Risk for suicide[2]				
No suicidal ideation	3 (9%)	1 (9%)	0 (0%)	2 (18%)
Low risk	16 (50%)	6 (55%)	4 (40%)	6 (55%)
Moderate risk	13 (41%)	4 (36%)	6 (60%)	3 (27%)
High risk	0 (0%)	0 (0%)	0 (0%)	0 (0%)

[1]Including all anxiety disorders in MINI-KID. [2]According to the definitions of suicidality used in MINI-KID. Abbreviations: ADHD, attention-deficit/hyperactivity disorder; ASD, autism spectrum disorder.

Treatment content in TAU

Five of the referrals were sent to primary care and six to CAMHS. Two participants in TAU never attended the first visits at the clinic to which they were referred. Five out of 11 participants allocated to TAU had started an intervention by post-assessment. This number had increased to nine at the three-month follow-up. According to interviews with families and medical records at the three-month follow-up, patients in TAU received pharmacological (n = 1), psychological (n = 1), supportive (n = 1), or a combination of these interventions (n = 4) as well as psychiatric (n = 1) or neuropsychiatric assessment and medications (n = 1) during the study. Details on TAU content are presented in supplementary **Table S1a-b.**

Acceptability of I-BA

Treatment adherence

The average number of completed chapters at post-treatment was 7.5 (SD 1.0) for adolescents and 7.4 (SD 1.3) for parents in therapist-guided I-BA, and 5.4 (SD 2.5) for adolescents and 5.9 (SD 2.8) for parents in self-guided I-BA. Eight adolescents (73%) and eight parents (73%) in therapist-guided I-BA, and three adolescents (30%) and four parents (40%) in self-guided I-BA had completed all eight chapters by the end of treatment. Zero participants in therapist-guided I-BA, and three in self-guided I-BA, discontinued treatment.

Credibility and satisfaction

Average treatment credibility was 14.3 (SD 2.7) for therapist-guided I-BA (n = 11), 14.1 (SD 3.9) for self-guided I-BA (n = 9), and 11.1 (SD 3.4) for TAU (n = 8). Average treatment satisfaction at post-treatment was 24.7 (SD 5.33) for therapist-guided I-BA (n = 11), 21.3 (SD 6.8) for self-guided I-BA (n = 9), and 17.7 (SD 6.3) for TAU (n = 10).

Adverse events and negative effects

From baseline to three-month follow-up, 17 adverse events were documented each in therapist-guided and self-guided I-BA and 25 in TAU. None of the adverse events were assessed as serious. The most commonly reported negative effect on NEQ in the I-BA-groups, reported by a total of five participants from both groups, was not trusting the treatment and not feeling that the treatment produced any results. In TAU, the most commonly reported negative effects on NEQ were feeling that the treatment did not produce any results, feeling that the treatment was not motivating, and not always understanding the treatment.

Therapist time (therapist-guided I-BA)

The average therapist time per family and chapter was 23 minutes (SD = 6 minutes). This measure includes both messages in the platform and occasional telephone calls relating to the treatment. Mean average telephone time per participant was 3.6 min (SD = 7.1) and median was 0.0 min (IQR: 6.0 min) throughout the treatment.

Clinical outcomes

Primary outcome measure

A series of linear mixed models showed a significant decrease in masked assessor-rated depressive symptoms (CDRS-R) over time for therapist-guided I-BA (B = −11.3, P < 0.001, 95% CI −14.9 to −7.7), and self-guided I-BA (B = −10.38, P < 0.001, 95% CI −13.93 to −6.82), but not for TAU (B = −4.40, P = 0.077, 95% CI −9.33 to 0.52, P > 0.05) (**Table 3** and **Figure 2**). Within-group Cohen's *d* was 2.43 (CI 1.66 to 3.20) for therapist-guided I-BA, 2.23 (CI 1.47 to 3.00) for self-guided I-BA, and 0.95 (CI -0.11 to 2.01) for TAU.

Table 3. Means (SD) for the three assessment points presented separately for the three groups.

Measure	**Therapist-guided I-BA (n = 11)**	**Self-guided I-BA (n = 10)**	**TAU (n = 11)**
Clinician-rated	Mean (SD)[1]	Mean (SD)	Mean (SD)
CDRS-R			
Pretreatment	52.2 (9.4)	55.1 (10.2)	53.2 (9.0)
Posttreatment	34.8 (10.1)	39.0 (12.0)	44.9 (10.0)
Three-month follow-up[2]	29.1 (10.1)	31.6 (11.0)	44.6 (13.6)
Child- and parent-rated			
SMFQ-A			
Pretreatment	13.6 (5.4)	13.9 (6.5)	16.8 (6.2)
Posttreatment	6.2 (5.6)	4.9 (5.5)	12.9 (7.8)
Three-month follow-up	4.6 (4.5)	8.3 (6.0)	9.6 (5.8)
SMFQ-P			
Pretreatment	11.6 (5.8)	12.5 (5.9)	15.2 (4.1)
Posttreatment	7.6 (5.0)	5.5 (4.7)	11.2 (7.2)
Three-month follow-up	5.7 (4.3)	5.0 (3.6)	9.3 (5.0)
WSAS-A			
Pretreatment	17.9 (8.7)	13.8 (7.0)	16.1 (5.5)
Posttreatment	12.0 (6.6)	9.7 (11.2)	15.8 (10.6)
Three-month follow-up	7.0 (5.4)	5.6 (7.9)	12.9 (10.0)

Abbreviations: TAU = Treatment as usual; CDRS-R = Children's Depression Rating Scale, Revised; SMFQ-A/P = Short version of Mood and Feeling Questionnaire, adolescent and parent version; WSAS-A = Work and Social Adjustment Scale – adolescent Version
[1]Observed means.
[2]Primary end point.

Figure 2 approximately here.

Secondary outcome measures

Descriptive statistics on secondary outcome measures are reported in **Table 3** and supplementary **Table S2**. A series of linear mixed models showed significant decreases in self-rated depressive symptoms (SMFQ-A) for all three groups: therapist-guided I-BA (B =−4.4, P < 0.001, 95% CI −6.2 to −2.6), self-guided I-BA (B = −3.39, P < 0.05, 95% CI −6.48 to −0.30), and TAU (B =−4.04, P = 0.001, 95% CI −6.22 to −1.86). Within-group effect sizes (Cohen's *d*) were 1.45 for therapist-guided I-BA, 1.12 for self-guided I-BA, and 1.34 for TAU.

Significant decreases were shown for self-rated impaired functioning (WSAS-A) for therapist-guided I-BA (B = −5.24, P < 0.001, 95% CI −7.65 to −2.82) and self-guided I-BA (B = −3.58, P < 0.01, 95% CI −6.08 to −1.10), but not for TAU (B = −1.81, P = 0.163, 95% CI −4.43 to 0.80). Within-group Cohen's *d* was 1.47 for therapist-guided I-BA, 1.00 for self-guided I-BA, and 0.51 for TAU.

Significant decreases were shown for parent-rated depressive symptoms (SMFQ-P) for therapist-guided I-BA (B =−2.83, P < 0.01, 95% CI −4.31 to −1.34), self-guided I-BA (B = −3.75, P < 0.01, 95% CI −5.65 to −1.85), and for TAU (B = −3.29, P < 0.01, 95% CI −5.17 to −1.42). Within-group Cohen's *d* was 1.05 for therapist-guided I-BA, 1.40 for self-guided I-BA, and 1.22 for TAU.

Of the secondary measures, CGAS, ISI, KIDSCREEN-10 (adolescent- and parent-rated) showed significant improvements in all three groups. Remaining secondary measures (CGI-S, RCADS-S-A/P, WSAS-P, ARI) showed significant improvements in some, but not all groups. Means and within-group effects for CGAS, CGI-S, RCADS-S-A/P, KIDSCREEN-10-A/P, ISI, ARI, and WSAS-P are presented in supplementary **Table S3.**

Treatment response (CGI-I)

At the primary end point, seven participants (64%) in therapist-guided I-BA, six participants (60%) in self-guided I-BA, and four in TAU (36%) were classified as treatment responders according to the CGI-I. At the three-month follow-up, 78%, 67%, and 56% no longer fulfilled criteria for MDD in therapist-guided I-BA, self-guided I-BA, and TAU respectively.

Masking integrity

Masking was unintentionally broken at two follow-up assessments (one in therapist-guided at posttreatment and one in TAU at three-month follow-up). At posttreatment, the assessors' guesses were correct 48.2% of the time, and at three-month follow-up, 61.5% of the time.

Discussion

This feasibility trial, where adolescents with mild to moderate depression were randomised to therapist-guided I-BA, self-guided I-BA or TAU, evaluated the feasibility of the study design, the acceptability of the treatments, and provided preliminary clinical efficacy data.

Most participants screened positive for two or more diagnoses according to MINI-KID, indicating that comorbidity was common in this sample. The pace of recruitment was initially slow but improved substantially when we placed advertisements in local media. Drop-out of participants was low and data loss acceptable. It was possible to successfully refer all participants randomised to TAU to their local primary care or CAMHS, and all but one patient received treatment in these services, though the start of treatment was often delayed. As expected, TAU was a heterogeneous condition; participants received pharmacological, psychological, or combination of both interventions. Implications for a future large-scale RCT include the importance of broad recruitment strategies, such as nationwide participant inclusion, and close collaboration with clinical services to ensure that participants randomised to TAU have access to treatment as soon as possible.

Overall, both I-BA groups were rated as more credible and more satisfactory than TAU. However, most families had probably hoped for one of the I-BA groups, which could have been a factor in the lower ratings for the TAU group. Furthermore, both I-BA treatments started immediately after randomisation, while some participants in TAU had to wait to start treatments at their local clinics. This inherent difference between the interventions and potential dissatisfaction with treatment availability in TAU may have influenced clinical outcomes. Adherence was lower in the self-guided I-BA group, but clinical outcomes were similar overall. Whether self-guided I-BA is a viable treatment alternative will be answered in a larger RCT. The advantages of self-guided interventions are obvious in terms of low costs and scalability.

Previous research has indicated that ICBT is efficacious for adolescent depression[33 34]. To the best of our knowledge, this is the first trial on online-delivered BA for this age group. Our results suggest that delivering BA online, with or without therapist-support, could also be a feasible and potentially effective way of treating depression in adolescents. We found large within-group effects on clinician-rated depressive symptoms for both I-BA groups. These

results are consistent with previous trials, where face-to-face BA has been found to be potentially effective for adolescent depression[17-19]. In a small RCT, similar results were found for face-to-face BA and evidence-based practice for depression[73], while in the current trial we found lower effect sizes and response rates in the TAU group. The encouraging results of this feasibility study should nevertheless be considered preliminary, and the relative efficacy of therapist-guided and self-guided I-BA will need to be established in a definitive RCT.

This trial has several strengths, including a randomised controlled design, the use of masked assessors, high treatment adherence in the I-BA-groups, the use of an ecologically valid control group, and the careful recording of adverse events. Furthermore, the contents of TAU were carefully assessed and reported. This study also has some limitations. First, while TAU ensures patient safety and allows for comparison to current clinical practice, it is a heterogeneous condition[74], and the nature and quality of TAU will affect results of the larger RCT[75]. Thus, a detailed description of TAU is important for interpretating the results as well as for enabling replication. In this study, we collected information about the content of TAU through medical records and interviewing parents. Both methods are subject to uncertainty, but showed good agreement with each other. Second, generalisability of the results to other settings and locations might be limited. Usual care for adolescents with depression might differ among the regions in Sweden and among different countries and healthcare systems. Third, although clinic referrals were accepted in this trial, all included patients were self-referred, and thus may be less complex and more motivated for ICBT than a clinically-referred sample. However, about a fourth of participants self-referred to the study upon recommendation by a health care provider, and all included patients were diagnosed with major depressive disorder. Fourth, despite our best efforts, masked assessors correctly guessed group allocation more often than they would have by chance. Additional measures, such as employing external masked assessors who are fully unaware of study aims and hypotheses[76] might be needed to improve masking.

Conclusions

Both therapist-guided and self-guided I-BA are acceptable and potentially efficacious treatments for adolescents with depression, and TAU is a reasonable and ethically-acceptable

control condition. In conclusion, it should be feasible to conduct a fully-powered RCT comparing therapist-guided and self-guided I-BA with TAU, in order to evaluate their relative efficacy and cost-effectiveness in adolescents with mild to moderate depression.

Author statements

Contributors

Authors JA, DMC, FL, EH, ES, and SV designed the study. RG wrote the protocol, was the project manager, and produced the treatment content with input from JA, ES, and SV. RG, JA, and SV provided the I-BA treatments. Author RG undertook the statistical analyses and wrote the first draft of the manuscript in collaboration with JA. All authors (RG, JA, DMC, FL, EH, CM, HS, MB, ES, and SV) contributed to and have approved the final manuscript.

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Competing interests

The authors declare no financial or personal interests that could have influenced the work reported in this paper. Prof. Mataix-Cols reports personal fees from UpToDate, Inc. which was not involved in this work.

Patient consent for publication

Not required.

Ethics approval

The study protocol was approved by the Regional Ethical Review Board in Stockholm, Sweden (reference number 2019/03235).

Study protocol

The study protocol for this feasibility trial is available from the first author upon request.

Data sharing statement

The data are pseudonymised according to national (Swedish) and European Union legislation, and cannot be anonymised and published in an open repository. Participants in the trial have not consented for their data to be shared with other international researchers for research purposes.

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Figure legends

Figure 1

Note. Consolidated Standards of Reporting Trials flow diagram.
Abbreviations: CBT = Cognitive Behavioural Therapy; I-BA = Internet-delivered behavioural activation; CAMHS = Children and Adolescent Mental Healthcare Services

Figure 2

Note. Graphical representation of the CDRS-R Total score across the three assessment points. Primary endpoint is the three-month follow-up.
3FU = three-month follow-up; CDRS-R = Children's Depression Rating Scale – Revised.

Figure S1

Note. All screenshots in this figure are published with permission from the principal investigator Eva Serlachius, responsible for development of the platform, and the illustrator Magnus Marklund.

Figure 1

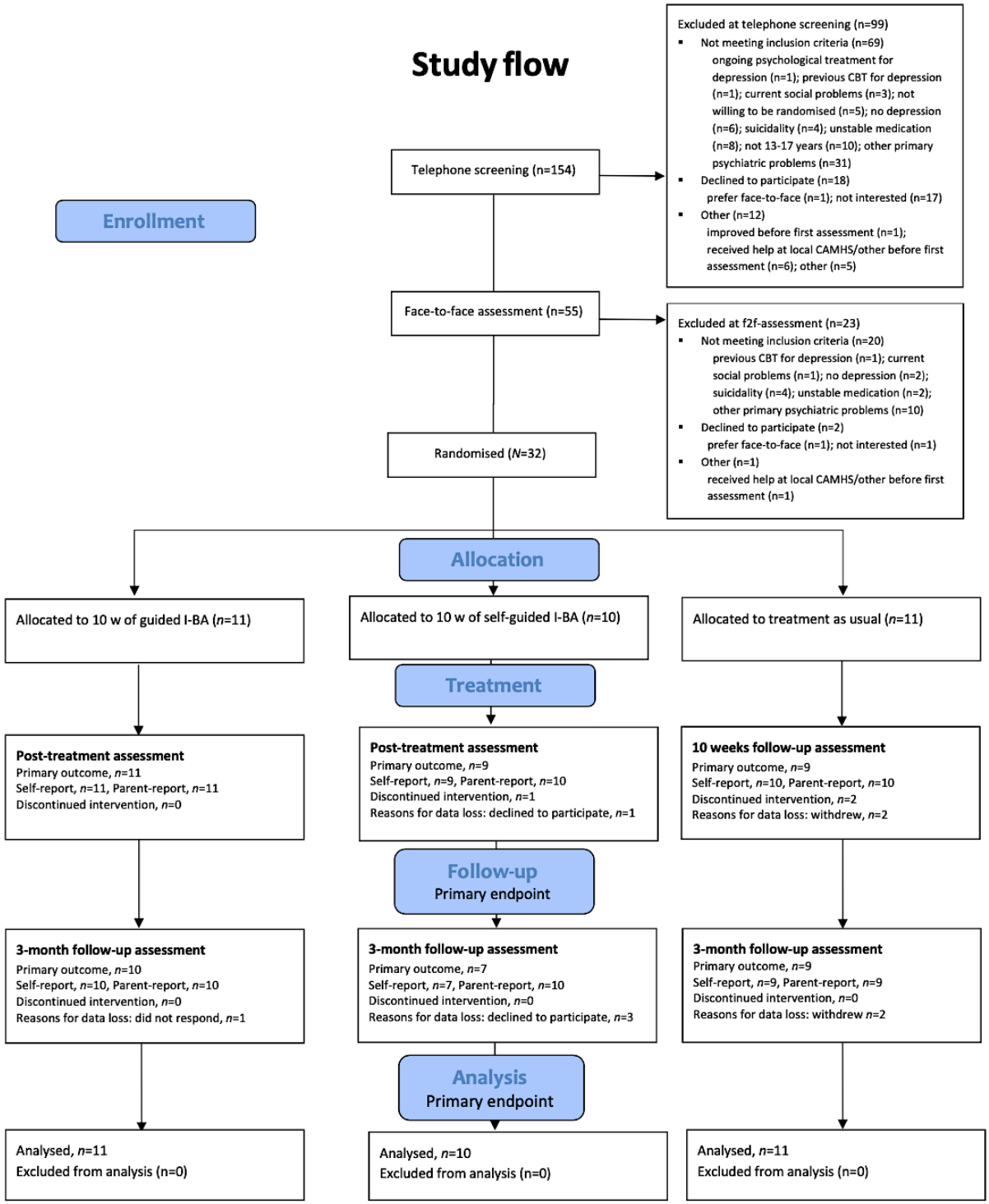
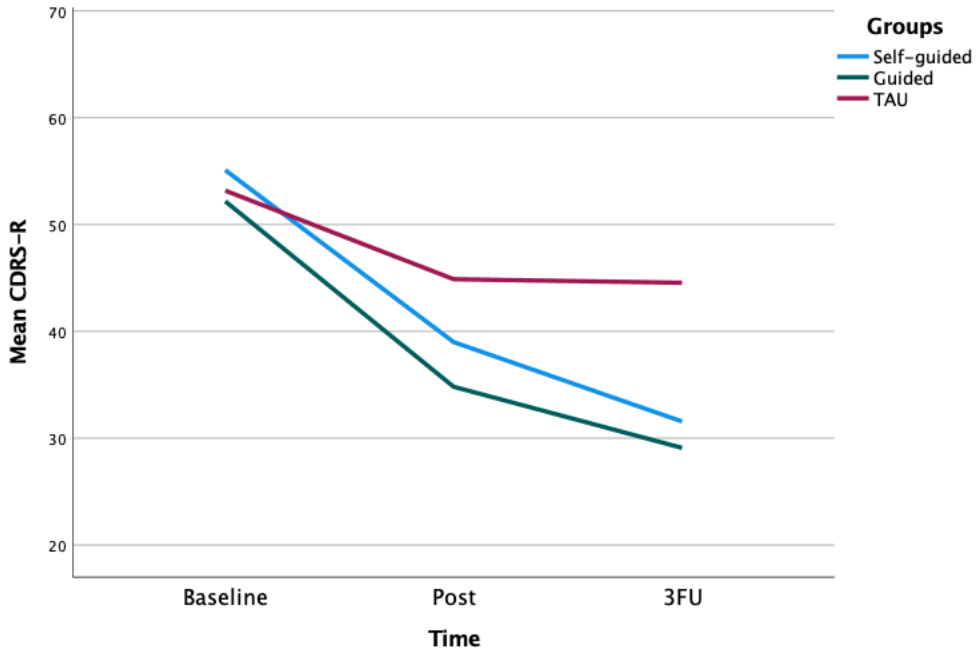

Study flow
Enrollment
Telephone screening (n=154)
Excluded at telephone screening (n=99)
Not meeting inclusion criteria (n=69)
ongoing psychological treatment for depression (n=1); previous CBT for depression (n=1); current social problems (n=3); not willing to be randomised (n=5); no depression (n=6); suicidality (n=4); unstable medication (n=8); not 13-17 years (n=10); other primary psychiatric problems (n=31)
Declined to participate (n=18)
prefer face-to-face (n=1); not interested (n=17)
Other (n=12)
improved before first assessment (n=1); received help at local CAMHS/other before first assessment (n=6); other (n=5)
Face-to-face assessment (n=55)
Excluded at f2f-assessment (n=23)
Not meeting inclusion criteria (n=20)
previous CBT for depression (n=1); current social problems (n=1); no depression (n=2); suicidality (n=4); unstable medication (n=2); other primary psychiatric problems (n=10)
Declined to participate (n=2)
prefer face-to-face (n=1); not interested (n=1)
Other (n=1)
received help at local CAMHS/other before first assessment (n=1)
Randomised (N=32)
Allocation
Allocated to 10 w of guided I-BA (n=11)
Allocated to 10 w of self-guided I-BA (n=10)
Allocated to treatment as usual (n=11)
Treatment
Post-treatment assessment
Primary outcome, n=11
Self-report, n=11, Parent-report, n=11
Discontinued intervention, n=0
Post-treatment assessment
Primary outcome, n=9
Self-report, n=9, Parent-report, n=10
Discontinued intervention, n=1
Reasons for data loss: declined to participate, n=1
10 weeks follow-up assessment
Primary outcome, n=9
Self-report, n=10, Parent-report, n=10
Discontinued intervention, n=2
Reasons for data loss: withdrew, n=2
Follow-up
Primary endpoint
3-month follow-up assessment
Primary outcome, n=10
Self-report, n=10, Parent-report, n=10
Discontinued intervention, n=0
Reasons for data loss: did not respond, n=1
3-month follow-up assessment
Primary outcome, n=7
Self-report, n=7, Parent-report, n=10
Discontinued intervention, n=0
Reasons for data loss: declined to participate, n=3
3-month follow-up assessment
Primary outcome, n=9
Self-report, n=9, Parent-report, n=9
Discontinued intervention, n=0
Reasons for data loss: withdrew n=2
Analysis
Primary endpoint
Analysed, n=11
Excluded from analysis (n=0)
Analysed, n=10
Excluded from analysis (n=0)
Analysed, n=11
Excluded from analysis (n=0)

Figure 2

Changes in CDRS-R score over time for each group



Supplementary material 1: Additional information about the measures used in this study

Swedish translations of all measures were used in the current study. Unless otherwise stated, there are no specific validation studies in Swedish.

Measures of acceptability of I-BA

Treatment credibility – adolescent and parent versions

This measure includes four qualitative questions about treatment credibility, asking how well the treatment suits adolescents with depression, how much they believe this treatment will help them, to what extent they would recommend this treatment to a friend with depression, and how much they expect to improve from the treatment. Each item is scored on a 5-point Likert scale from 1–5, total range 4–20 with higher values indicating higher credibility.

Client Satisfaction Questionnaire (CSQ) – adolescent and parent version

CSQ[1] measures various aspects of satisfaction with treatment, e.g., perception of quality of treatment, if the treatment adequately addressed their needs and overall satisfaction. CSQ has eight self-rated items on a 4-point scale from 1–4, total range 8–32 with higher values indicating greater satisfaction). The scale has high internal consistency and correlates with therapists' estimates of client satisfaction[1].

Negative Effects Questionnaire-20 (NEQ-20) – adolescent and parent version

NEQ-20 is a condensed version of the original 32 item self-report questionnaire[2] for monitoring and reporting treatment related adverse and unwanted events such as not having confidence in one's treatment or that unpleasant memories have resurfaced. The questionnaire uses a 5-point Likert-scale ranging from 0 ("not at all) to 4 ("extremely") and includes an open question at the end about other possible negative or adverse events. Total range is 0–80 with higher values indicating more reported adverse events. In a psychometric evaluation, the Swedish version of NEQ-32 was found to have good internal consistency[2]. In another Swedish study, NEQ-20 did not demonstrate any bias in terms of responders' sociodemographic background and showed comparable validity for a condensed scale of 20 instead of 32 items[3].

Working alliance inventory, 6 items (WAI-6) – *adolescent and parent version*

WAI measures a participant's perceived working alliances with her/his therapist. WAI-6 was developed from the original 36-item WAI[4] and is rated on a 7-point Likert-scale from 1–7, total range 6–42 with higher values indicating stronger working alliances. In self-guided ICBT, the word "therapist" was changed to "programme".

Measures of clinical outcomes

Children's Depression Rating Scale, Revised (CDRS-R)

CDRS-R[5] is the most widely-used rating scale in clinical trials for assessing severity of depression and change in depressive symptoms with children and adolescents[5-7]. CDRS-R is a semi-structured interview-based measure modelled on the adult Hamilton Rating Scale for Depression. Item values range from 1–5 or 1–7, total range 17–113 with higher scores indicating more clinically significant difficulties. A raw score of ≥ 40 is indicative of depression, while a score of ≤ 28 is often used to define remission (minimal or no symptoms)[7]. CDRS-R has shown good internal consistency and good construct validity and is also considered a good measure of symptom change[7].

Children's Global Assessment Scale (CGAS)

CGAS[8] is a single-item scale from 1–100 that integrates psychological, social, and academic functioning in children as a measure of global functioning. The questionnaire is assessor-rated and has established validity and reliability[9].

Clinical Global Impression Scale – Severity (CGI-S)

CGI-S[10] is a single-item clinician rating of symptom severity for a specific disorder. Ratings are made on a seven-point scale range from 1 ("no symptoms") to 7 ("extreme symptoms"). CGI correlates well with established outcomes scales such as Hamilton Rating Scale for Depression and Brief Psychiatric Rating Scale[11].

Clinical Global Impression Scale – Improvement (CGI-I)

CGI-I[10] provides a clinician-rated opinion of global improvement. The measure consists of a single item about the level of improvement compared to state at admission, which is rated on a seven-point scale (1=very much improved, 2=much improved, 3=minimally improved, 4=no change, 5=minimally worse, 6=much worse, 7=very much worse). The questionnaire

has established validity and reliability[11]. Treatment response is commonly defined as a score of 1 (very much improved) or 2 (much improved)[12].

Need for further treatment – adolescent and parent version

This non-validated single-item questionnaire was created by David Mataix-Cols' research team, and it asks whether the participant considers her/himself in need of further treatment for her/his depression. The item is scored on a scale from 0 (no need for further treatment) to 4 (extensive need for further treatment).

Short Mood and Feelings Questionnaire (SMFQ) – *adolescent and parent version*

SMFQ[13] is a 13-item self-reported measure of depressive symptoms. Each item is scored on a 3-point scale (0 = not true, 1 = sometimes, 2 = true), total range 0–26 with higher values indicating more depressive symptoms. The total score is derived by summing together the values for each 13 items. The questionnaire has established validity and reliability[13 14]. According to a Swedish study, SMFQ is, with gender-based cut-offs, efficient as a screening tool in clinical adolescent populations, but not in children[15].

Work and Social Adjustment Scale (WSAS*) – adolescent and parent version*

WSAS is a 5-item child-rated scale of impaired functioning in school, everyday life, friends and social life, recreation, hobbies, family and close relationships and was adapted from the Work and Social Adjustment Scale[16 17]. Each item is scored on a 9-point Likert scale of 0–8, total score 0–40 with higher scores indicating greater impairment. In an evaluation of the Swedish translation of this scale, WSAS showed excellent internal consistency, adequate test-retest reliability and good convergent and divergent validity. WSAS is highly sensitive to change after treatment[17].

Revised Children's Anxiety and Depression Scale – Short Version (RCADS-S) – *adolescent and parent version*

RCADS-S[18] is a shortened version of the Spence Child Anxiety Scale, which is an adolescent and parent self-report measure of anxiety- and depression-related psychopathology. Only the anxiety subscales were administered, since depression is measured thoroughly by other measures. After eliminating the depression subscale, RCADS-S-C consists of 15 items, reflecting a single "broad anxiety" dimension. The four-graded scale

ranges from 0 = “Never” to 3 = “Always”, total range 0–45 with higher scores indicating more anxiety symptoms. The 15-item Anxiety Total scale in the shortened version of RCADS has shown significant correspondence with anxiety diagnostic groups based on structured clinical interviews[18].

KIDSCREEN-10 Index – adolescent and parent version

The KIDSCREEN-10 Index[19] was developed from the longer KIDSCREEN-52 and is considered a valid measure for assessing an adolescent’s general health-related quality of life. KIDSCREEN-10 consists of 10 items, each with a 5-level response category (1–5) and an additional question about general health. Total range is 10–50 with higher values indicating better health-related quality of life.

Insomnia Severity Index (ISI)

ISI*[20]* is brief screening measure of insomnia on a seven-item scale, each item scored 0–4, total range 0–28 points with higher values indicating more sleep disturbances. The scale is reliable and sensitive to change[20].

Affective Reactivity Index (ARI)

ARI[21] is measure of irritability that consists of six items on a scale of three (0–2) and one item on impairment due to irritability, total range 0–12 points with higher values indicating more irritability. ARI has been demonstrated to have excellent internal consistency and differentiated cases from controls in a clinic a community sample[21].

Behavioral Activation of Depression Scale – short form (BADS-SF)

BADS-SF is a 9-item self-report measure designed to track changes in proposed mediators of BA (activation and avoidance)[22]. Each item is scored from 0 (not at all) to 6 (completely), total score 0–54 with higher values indicating higher degree of activation and lower degree of avoidance. BADS-SF has two subscales, activation (focused, goal-directed activation and completion of scheduled activities) and avoidance/rumination (avoidance of negative aversive states and engaging in rumination rather than active problem solving). BADS-SF has acceptable internal consistency reliability, construct and predictive validity[22].

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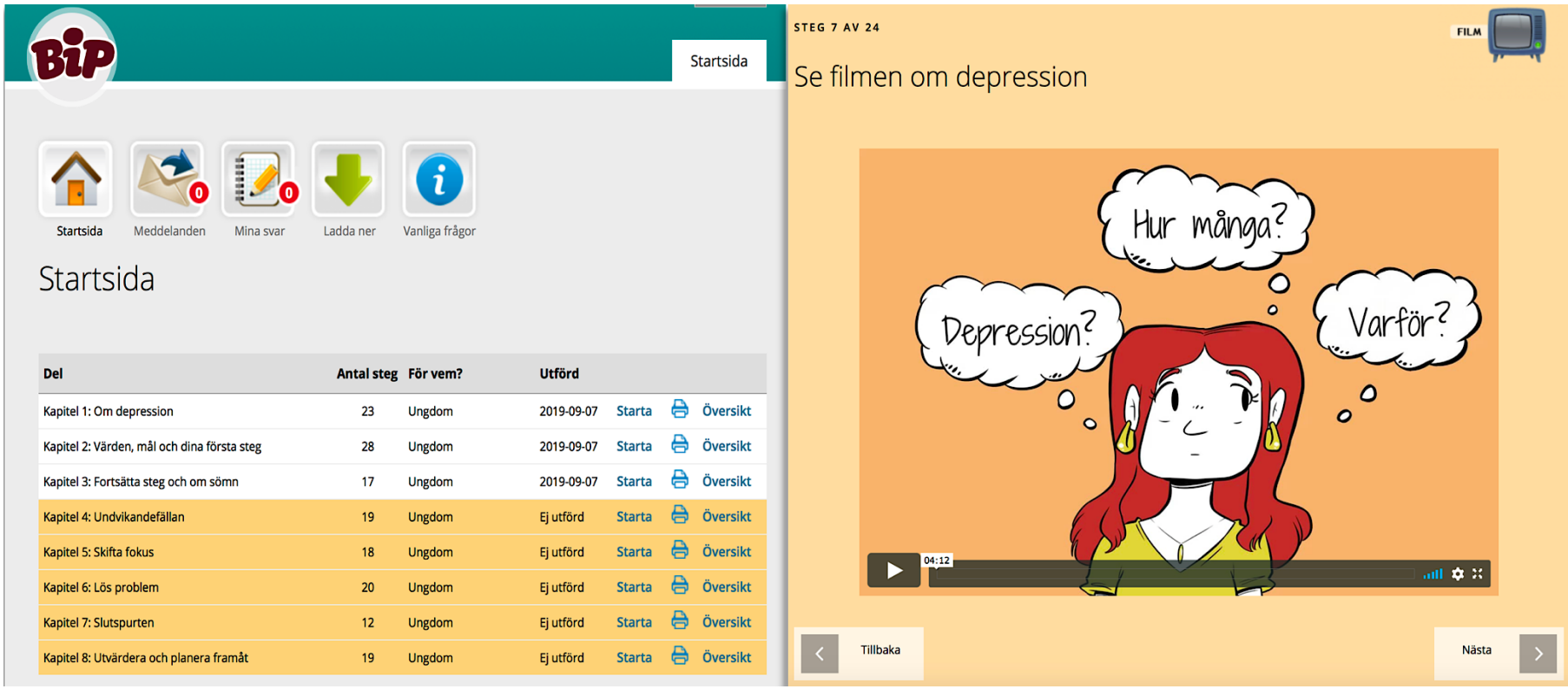
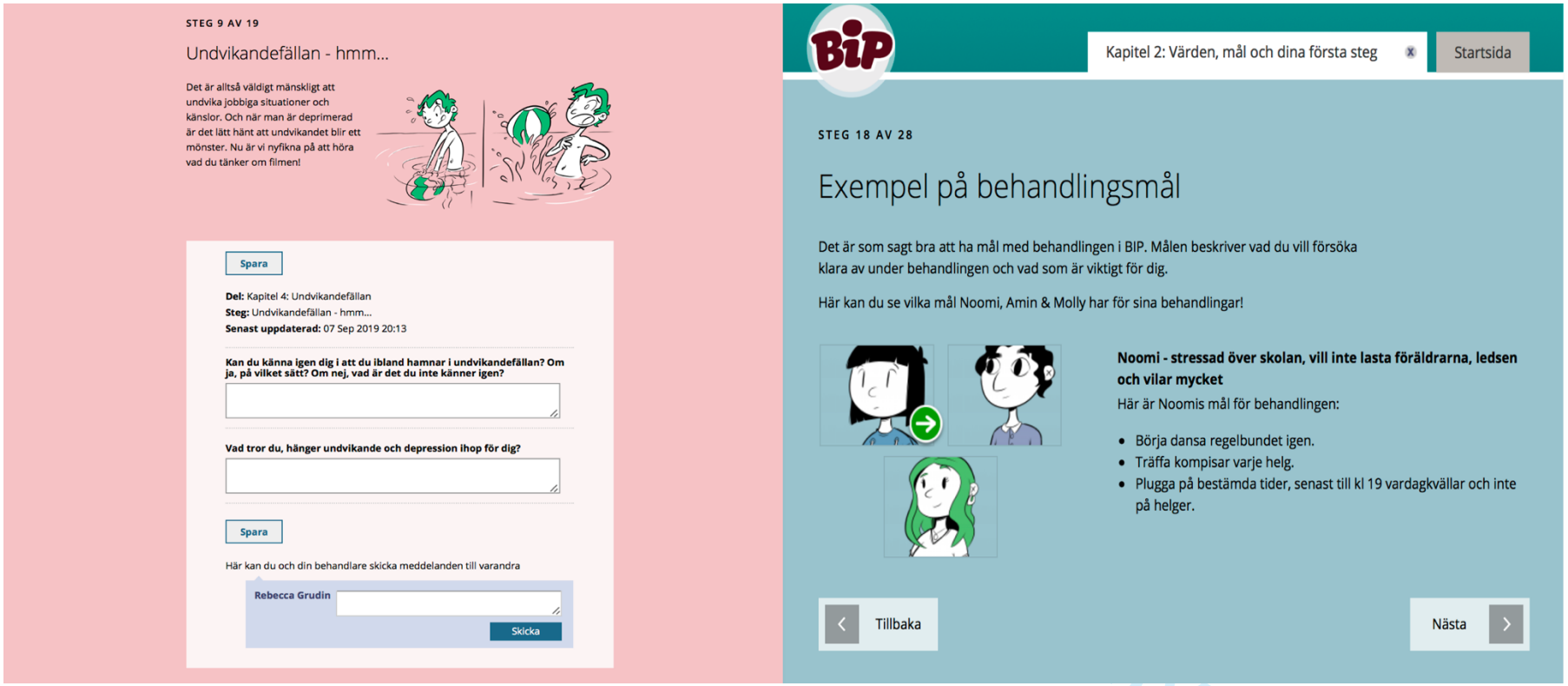
Figure S1

Screenshots of I-BA treatment

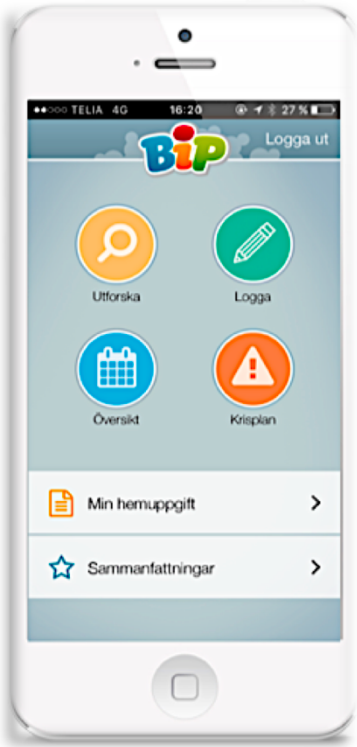
1. To the left: Overview and start page, with list of chapters (BIP Depression). To the right: A psychoeducative video about depression.



2. To the left: An exercise about the avoidance trap. To the right: The three fictional characters sharing their treatment goals.



3. To the left: The app that adolescents use for doing home assignments between chapters. To the right: Written information to the caregivers about how to validate your adolescent's emotions.



4. Encrypted messaging function which is included in guided I-BA. The psychologist responds within 1-2 days on weekdays to messages from the participant.

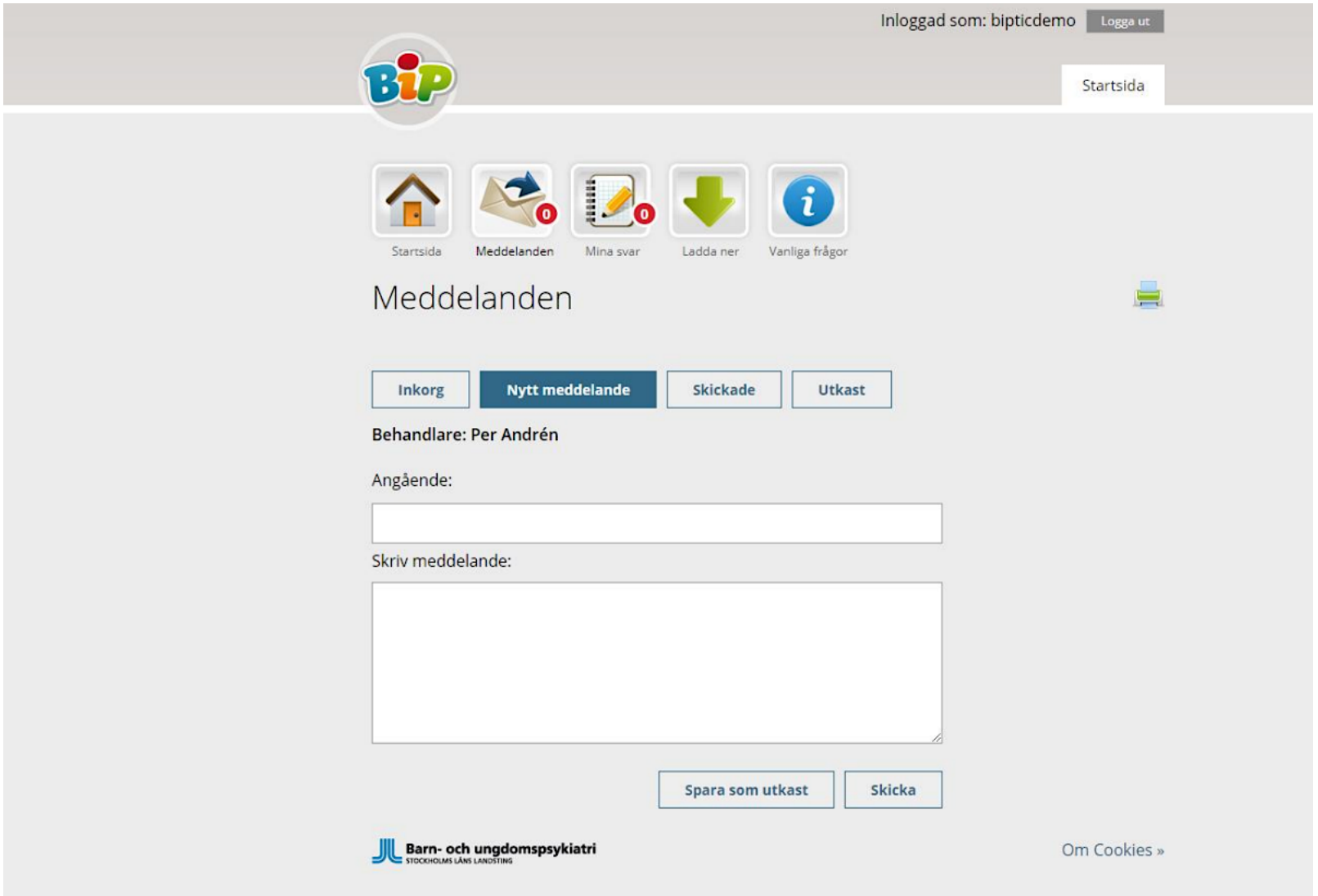


Table S1a. TAU content, including details on treatment type, intensity and provider according to interviews with parents

ID	Medications / Indication	No. of visits, incl initial psychiatric assessment	Psychological or psychosocial treatment	No. of sessions	Other intervention (no. visits)	Comments
1	Antidepressant (SSRI, 25 mg Sertraline)	–	CBT	5 sessions of CBT	–	
2	Antidepressant (SSRI, Fluoxetine, 20 mg)	–	Supportive therapy	1–2 sessions of supportive therapy	–	
3	–	2 visits (psychiatric assessment only)	–	–	–	No intervention was offered after the psychiatric assessment due to improvement.
4	Melatonine	–	CBT	10 sessions of CBT	–	
5	Melatonine + Vitamin D	–	CBT	7 sessions CBT	–	
6	–	–	Supportive therapy	10 sessions of supportive therapy	–	
7	Promethazine (Lergigan) + Melatonine	–	–	–	Neuropsychiatric assessment	
8	–	–	CBT	7 sessions	–	

9	Antidepressant + sleep medication + antihistamine (unknown types and dosage)	See comment	–	–	–	Initially this participant was referred to the CAMHS and received 1 visit (classified as psychiatric assessment), and later self-referred to primary care and received the specified medications.

Table S1b. TAU content, including details on treatment type, intensity and provider according to medical records

ID	Medications	No. of visits, incl initial psychiatric assessment	Psychological or psychosocial treatment	No. of sessions	Other intervention (no. visits)	Target for the intervention/s	Comments
1	Antidepressant (SSRI, Sertraline, 25 mg x 1)	3 visits	CBT	5 sessions of CBT	–	Social anxiety	
2	Antidepressant (SSRI, Fluoxetine 20 mg x 1)	3 visits	PDT/Supportive Therapy	5 sessions of PDT	–	Depression and unspecified anxiety	Medical records imply that it was mainly Supportive therapy, but classified as PDT according to treatment plan.
3	–	1 visit (psychiatric assessment only)	–	–	–	Depression	
4	Hydroxyzine (Atarax, 25 mg x 0,5-1) + Melatonine (Melatonine, 2 mg x 1-3)	–	CBT/Supportive therapy	8 sessions of CBT	–	Depression	No visits or telephone calls registered with a psychiatrist. The therapist seems to have consulted the doctor who initiated medical treatment without patient visist.
5	Melatonine (Melatonine, 4 mg) Vitamin D (Benferol, 800ie)	1 visit	CBT	11 sessions	–	Depression	
6	–	–	Supportive therapy	10 sessions	–	Depression	

7	Promethazine (Lergigan, 25 mg as required) + Melatonine (Melatonine, 3 mg x 3)	1 visit and 1 telephone call	–	–	Neuropsychiatric assessment, 5 visits plus 3 telephone calls	Melatonine for sleep problems, and Lergigan for unspecified anxiety; Suspected neuropsychiatric symptoms	
8	–	–	CBT	8 visits	–	Depression	
9	–	1 visit (psychiatric assessment only)	–	–	–	Depression	Psychiatric assessment included brief psychoeducation, then a referral was sent to primary care since the patient turned 18 years

Table S2. Means (SD) for all measures at the three assessment points for the three groups in the study.

Group / Measure	Guided I-BA (n=11)	Self-guided I-BA (n=10)	TAU (n=11)
Clinician-rated			
CGAS			
Baseline	56.6 (4.2)	54.7 (6.4)	52.9 (6.4)
Post	66.1 (13.3)	60.6 (11.5)	59.6 (7.8)
3-month FU §	70.6 (15.4)	63.6 (12.5)	64.3 (10.1)
CGI-S			
Baseline	3.5 (0.8)	4.1 (1.1)	3.7 (0.7)
Post	2.2 (1.3)	3.0 (1.4)	3.3 (1.2)
3-month FU §	2.0 (1.5)	2.3 (1.4)	3.0 (1.8)
Child-rated			
RCADS-S-A			
Baseline	12.5 (4.3)	14.4 (8.8)	12.7 (6.2)
Post	7.9 (5.2)	7.4 (4.6)	15.5 (10.3)
3-month FU §	8.3 (5.3)	10.1 (5.7)	12.3 (9.0)
KIDSCREEN-10-A			
Baseline	31.3 (5.3)	30.7 (4.2)	28.4 (4.2)
Post	34.4 (5.3)	36.0 (6.2)	30.4 (5.2)
3-month FU §	38.0 (5.1)	38.3 (6.0)	33.7 (4.9)
ISI			
Baseline	12.4 (6.3)	12.3 (6.2)	15.5 (3.5)
Post	6.1 (4.3)	7.6 (5.7)	14.3 (7.9)
3-month FU §	4.3 (3.6)	7.0 (4.4)	10.2 (5.5)
ARI			
Baseline	3.8 (1.8)	6.6 (4.1)	6.6 (4.1)
Post	3.4 (2.7)	3.9 (4.0)	5.5 (4.2)
3-month FU §	2.3 (1.6)	2.7 (4.4)	4.0 (3.4)
Need for further treatment			
3-month FU §	0.6 (0.8)	1.4 (1.6)	*Not assessed*
WAI-A			
3 weeks	31.6 (10.3)	31.1 (13.9)	18.0 (20.8)
Post	36.1 (5.8)	27.3 (13.7)	21.4 (13.2)
BADS-SF			
Baseline	23.1 (7.8)	23.8 (8.2)	19.7 (4.9)
Post	33.5 (8.6)	34.8 (11.3)	27.0 (11.5)
3-month FU §	36.8 (7.9)	34.9 (9.0)	28.8 (8.4)

Parent-rated			
WSAS-P			
Baseline	18.5 (8.4)	16.1 (11.0)	19.2 (7.9)
Post	13.2 (7.0)	11.7 (9.6)	21.9 (7.9)
3-month follow-up§	11.6 (9.7)	13.1 (11.1)	13.2 (8.9)
RCADS-S-P			
Baseline	10.6 (6.6)	10.3 (4.9)	10.4 (7.0)
Post	9.2 (6.4)	8.8 (4.1)	10.0 (5.3)
3-month FU §	7.7 (6.1)	6.5 (4.5)	7.9 (5.7)
KIDSCREEN-10-P			
Baseline	29.6 (4.2)	30.3 (5.6)	28.0 (5.4)
Post	31.5 (3.3)	34.8 (4.4)	31.2 (4.7)
3-month FU §	34.2 (3.4)	33.0 (8.3)	31.6 (5.0)
Need for further treatment-P			
3-month FU §	1.6 (1.4)	1.7 (1.6)	2.0 (1.2)
WAI-P			
3 weeks	38.8 (3.3)	33.0 (5.4)	23.3 (12.1)
Post	38.1 (4.4)	32.4 (9.1)	19.5 (11.5)

I-BA = Internet-delivered behavioural activation; TAU = treatment as usual; CGAS = Children's Global Assessment Scale**;** CGI-S = Clinical Global Impression – Severity; RCADS-S (A/P) = Revised Children's Anxiety and Depression Scale, short version, anxiety subscales, adolescent and parent version; KIDSCREEN-10 (A/P) = a measure for general health-related quality of life, adolescent and parent version; ISI = Insomnia Severity Index; ARI = Affective Reactivity Index; WAI = Working Alliance Inventory; BADS-SF = Behavioural Activation and Avoidance Scale Short Form; WSAS (P) = Work and Social Adjustment Scale, parent version
§Primary endpoint.

Table S3. Fixed effects and effect sizes for all measures at follow-up compared to baseline, presented separately for the three groups and types of rater.

Group / Measure	Guided I-BA (n=11)		Self-guided I-BA (n=10)		TAU (n=11)	
	Unstandardised coefficient B (95 % CI)	**Effect size (Cohen's *d*, 95 % CI)**	**Unstandardised coefficient B (95 % CI)**	**Effect size (Cohen's *d*, 95 % CI)**	**Unstandardised coefficient B (95 % CI)**	**Effect size (Cohen's *d*, 95 % CI)**
Clinician-rated						
CGI-S	-0.69 (-1.12 to -0.26)**	1.57 (0.59 to 2.55)	-0.85 (-1.24 to -0.46)***	1.94 (1.05 to 2.83)	-0.37 (-0.86 to 0.12)	0.85 (-0.26 to 1.96)
CGAS	6.86 (2.46 to 11.25)**	2.36 (0.85 to 3.87)	4.35 (1.21 to 7.50)**	1.50 (0.42 to 2.58)	5.76 (3.12 to 8.41)***	1.98 (1.07 to 2.89)
Child-rated						
RCADS-S	-2.12 (-0.92 to -3.32)***	0.66 (0.29 to 1.03)	-2.48 (–4.85 to -0.10)*	0.77 (0.03 to 1.50)	-0.29 (-2.75 to 2.16)	0.09 (-0.67 to 0.85)
ARI	-0.63 (-1.40 to 0.14)	0.35 (-0.07 to 0.77)	-2.01 (– 3.37 to -0.65)**	1.10 (0.36 to 1.85)	-1.40 (-2.40 to -0.40)**	0.77 (0.22 to 1.31)
ISI	-4.14 (-5.69 to -2.60)***	1.51 (0.94 to 2.07)	-2.64 (-4.36 to -0.92)**	0.96 (0.33 to 1.59)	-2.69 (-4.91 to -0.47)*	0.98 (0.17 to 1.79)
KIDSCREEN-10	3.03 (1.80 to 4.27)***	1.31 (0.77 to 1.84)	3.46 (1.93 to 4.99)***	1.49 (0.83 to 2.15)	2.71 (0.65 to 4.76)*	1.17 (0.28 to 2.05)
Parent-rated						
WSAS	-3.23 (-5.09 to -1.37)**	0.72 (0.31 to 1.14)	-1.50 (-3.27 to 0.27)	0.34 (-0.06 to 0.73)	-2.63 (-5.31 to 0.04)	0.59 (-0.01 to 1.19)
RCADS-S	-1.59 (-2.94 to -0.24)*	0.53 (0.08 to 0.97)	-2.20 (-3.58 to -0.82)**	0.73 (0.27 to 1.18)	-1.39 (-3.17 to 0.39)	0.46 (-0.13 to 1.05)
KIDSCREEN-10	2.16 (1.14 to 3.17)***	0.86 (0.46 to 1.27)	2.25 (0.74 to 3.76)**	0.90 (0.30 to 1.51)	1.82 (0.01 to 3.62)*	0.73 (0.00 to 1.45)

I-BA = Internet-delivered behavioural activation; TAU = treatment as usual; CGAS = Children's Global Assessment Scale**;** CGI-S = Clinical Global Impression – Severity; RCADS-S (A/P) = Revised Children's Anxiety and Depression Scale, short version, anxiety subscales, adolescent and parent version; KIDSCREEN-10 (A/P) = a measure for general health-related quality of life, adolescent and parent version; ISI = Insomnia Severity Index; ARI = Affective Reactivity Index; WSAS (P) = Work and Social Adjustment Scale, parent version

⁎p < 0.05, ⁎⁎p < 0.01, ⁎⁎⁎p < 0.001.

‡All Cohen's d effect sizes are calculated from the regression model. The 3-month follow-up effect sizes compare to baseline. Effect sizes of 0.2, 0.5 and 0.8 are considered small, moderate and large, respectively.

CONSORT checklist of information to include when reporting a pilot trial*

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	p. 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)	p. 2
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	p. 4-5
2b	Specific objectives or hypotheses	Specific objectives or research questions for pilot trial	p. 5
Methods			
Trial design:			
3a	Description of trial design (such as parallel, factorial) including allocation ratio	Description of pilot trial design (such as parallel, factorial) including allocation ratio	p. 6
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	p. 6
Participants:			
4a	Eligibility criteria for participants		p. 6
4b	Settings and locations where the data were collected		p. 6
4c		How participants were identified and consented	p. 7
Interventions:			
5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered		pp. 8-10
Outcomes:			
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	pp. 8; 11-14
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	p. 14
6c		If applicable, prespecified criteria used to judge whether, or how, to proceed with future definitive trial	N/A

Sample size:			
7a	How sample size was determined	Rationale for numbers in the pilot trial	p. 7
7b	When applicable, explanation of any interim analyses and stopping guidelines		
Randomisation:			
Sequence generation:			
8a	Method used to generate the random allocation sequence		p. 14
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)	p. 14
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		p. 14
Implementation:			
10	Who generated the random allocation sequence, enrolled participants, and assigned participants to interventions		p. 14
Blinding:			
11a	If done, who was blinded after assignment to interventions (eg, participants, care providers, those assessing outcomes) and how		p. 6; 14
11b	If relevant, description of the similarity of interventions		N/A
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	pp. 14-15
12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Not applicable	N/A
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 primary outcome	For each group, the numbers of participants who were approached and/or assessed for eligibility, randomly assigned, received intended treatment, and were assessed for each objective	p. 15 and Fig. 1
13b	For each group, losses and exclusions after randomisation, together with reasons		p. 15
Recruitment:			

14a	Dates defining the periods of recruitment and follow-up		p. 15
14b	Why the trial ended or was stopped	Why the pilot trial ended or was stopped	p. 15
Baseline data:			
15	A table showing baseline demographic and clinical characteristics for each group		Table 1
Numbers analysed:			
16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each objective, number of participants (denominator) included in each analysis. If relevant, these numbers should be by randomised group	p. 15 and Fig. 1
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	pp. 18-20
17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not applicable	N/A
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	N/A
Harms:			
19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)		p. 17
19a		If relevant, other important unintended consequences	pp. 17
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	pp. 22
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	pp. 21-23
Interpretation:			
22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Interpretation consistent with pilot trial objectives and findings, balancing potential benefits and harms, and considering other relevant evidence	pp. 21-23
22a		Implications for progression from pilot to future definitive trial, including any proposed amendments	
Other information			

Registration:			
23	Registration number and name of trial registry	Registration number for pilot trial and name of trial registry	p. 3
Protocol:			
24	Where the full trial protocol can be accessed, if available	Where the pilot trial protocol can be accessed, if available	p. 24
Funding:			
25	Sources of funding and other support (such as supply of drugs), role of funders		p. 3; 24
26		Ethical approval or approval by research review committee, confirmed with reference number	p. 24

*Here a pilot trial means any randomised study conducted in preparation for a future definitive RCT, where the main objective of the pilot trial is to assess feasibility.