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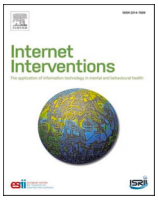

Stepped-care versus therapist-guided, internet-based cognitive behaviour therapy for childhood and adolescent anxiety: A non-inferiority trial

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ABSTRACT

Objective: This preregistered randomized trial examined whether a stepped-care approach to internet-delivered cognitive behaviour therapy (ICBT-SC) is non-inferior to therapist-guided ICBT (ICBT-TG) for child and adolescent anxiety.

Method: Participants were 137 Australians, aged 8–17 years (56 male), with a primary anxiety disorder. This randomized, non-inferiority trial compared ICBT-SC to an evidence-based, ICBT-TG program with assessments conducted at baseline, 12 weeks and 9-months after treatment commencement. All ICBT-SC participants completed the first 5 online sessions without therapist guidance. If they responded to treatment in the first 5 sessions (defined as reductions of anxiety symptoms into non-clinical range), they continued without therapist guidance for the final 5 sessions. If they did not respond to treatment in the first 5 sessions, the final five sessions were supplemented with therapist-guidance (through email). All ICBT-TG participants received therapist guidance (email) after each session, for all 10 sessions. Measures included clinical diagnostic interview (severity rating as primary outcome), as well as parent and child reported anxiety and anxiety-related interference (secondary outcomes).

Results: ICBT-SC was found to be non-inferior to ICBT-TG on primary and secondary outcomes, according to clinician, parent and young person report at 12-weeks and 9-months. Treatment satisfaction was moderate to high for both conditions. Significant clinical benefits were evident for participants in both treatments. Of participants who remained in the study, 77 % (50.7 % ITT) of ICBT-SC and 77 % (57.1 % ITT) of ICBT-TG were free of their primary anxiety diagnosis by 9-month follow-up, with no differences between conditions.

Conclusion: A stepped-care ICBT approach for clinically anxious children and adolescents may offer an acceptable treatment model that can increase access to evidence-based treatment.

1. Introduction

Less than 50 % of children and adolescents with anxiety disorders receive professional care (Lawrence et al., 2015). Internet-delivered Cognitive Behaviour Therapy (ICBT) whereby treatment programs are delivered via self-directed online sessions, circumvents problems of poor treatment access, long wait-lists, shortages of CBT-trained therapists, high costs, and stigma (Stallard et al., 2007; Sweeney et al., 2017; Sweeney et al., 2015). The efficacy of ICBT supplemented with brief online therapist guidance (ICBT-TG) has been demonstrated in several randomized controlled trials (RCT) and shows similar outcomes to face-to-face therapy for child and adolescent anxiety (Pennant et al., 2015; Podina et al., 2016; Spence et al., 2011). ICBT-TG, typically involving around 15–30 min of therapist time per session, has the benefit of time- and cost-savings compared to traditional face-to-face therapy. However, therapist guidance still incurs some cost, and workforce shortages have led to the use of fully self-guided interventions to increase treatment access by the broader community.

Two recent studies evaluating outcomes for 4425 (March et al., 2018) and 10,366 (March et al., 2021) anxious children and adolescents

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enrolled in self-guided ICBT (ICBT-SG), indicate substantial reductions in anxiety following the program, with a moderate to large effect size. For young people completing the majority of sessions, 57 % achieved recovery to a non-elevated level of anxiety, and 54 % achieved statistically reliable reductions (March et al., 2018). However, the rate of improvement was less after 6 sessions, around the time content transitioned to skill rehearsal and consolidation (March et al., 2021). Furthermore, treatment adherence was relatively weak when offered as a public, open-access service, with only 30 % completing three or more of the 10 sessions (March et al., 2018). Thus, individuals vary in their capacity to adhere to, and persist with, ICBT-SG, although some anxious young people enjoy significant benefits (March et al., 2018). A pure self-help approach may therefore be of value if combined with the option of 'stepping up' or adjusting treatment to include therapist guidance if the young person requires it.

1.1. Stepped-care and adaptive approaches

Several methods have been proposed for adjusting treatment based on need. Stepped-care aims to achieve a balance between clinical effectiveness and intensity (e.g., degree of therapist involvement or treatment duration) by 'stepping up' intervention intensity on an 'as needs' basis. The least intensive treatment is delivered first, and progress is evaluated at a specific point to determine whether a more intensive intervention is required (Salloum et al., 2016). Stepped-care may provide greater efficiency than self-help (which minimizes therapist time and increases treatment reach but lowers effectiveness) or therapist-led (which maximise therapist time and effectiveness but reduces treatment reach) approaches (van der Leeden et al., 2011). The limited research examining the benefits of stepped-care in CBT for childhood anxiety suggests that stepping up to greater intensity/dose for those who have shown insufficient response to CBT or a low-intensity intervention, may achieve reductions in anxiety, with effects equivalent to a full program of face-to-face CBT (Rapee et al., 2017). Within ICBT for child anxiety, stepped-care models have only been implemented after the completion of an entire ICBT program (e.g. Jolstedt et al., 2018; Rapee et al., 2017), with children stepped-up to face-to-face treatment with a therapist for an additional 10 sessions. Such stepped-care models have been proposed to possess inherent risks, in that many participants might be required to progress through several treatment steps (or full programs) before they experience treatment success (Forsell et al., 2019). In the case of childhood anxiety, waiting for the second treatment step means young people may become disengaged with treatment when it isn't helping, may duplicate some treatment components if only changing modality and can be particularly resource intensive.

Personalised or precision medicine has been proposed as an approach that can overcome problems of non-response by tailoring treatments to individual characteristics, that is, matching patients to optimal interventions before treatment commences (Goldberger and Buxton, 2013). Such matching is typically determined based on knowledge of patient-specific factors that might be associated with treatment outcome and has received some attention in childhood anxiety. A recent review illustrated that the most common approaches to treatment personalisation were to adapt existing therapies for specific subgroups (e.g., social anxiety disorder), and to apply modular therapy where additional modules are integrated for additional problems (e.g., depression) (Bertie and Hudson, 2021). Less common approaches included using individualised metrics such as probably of treatment benefit and risk indices to predict response to various treatment approaches. The review also highlighted the limitations of our current understanding of differential CBT response for childhood and adolescent anxiety, and noted a need for clearer evidence of predictors, moderators, and mediators to better inform modified interventions and potential personalised approaches (Bertie and Hudson, 2021). Such evidence is even more scarce when considering ICBT interventions.

Recent innovations in ICBT with adults have demonstrated that adjustments to treatment are not constrained to choices made before treatment (matching), or after treatment (stepping-up). Instead, Forsell et al. (2019) propose that treatment can be adapted during treatment in response to progress monitoring and identification of risk of non-response, in essence bringing forward the 'step-up' point to provide accelerated care. Their work demonstrated that an algorithm-based individual outcome prediction tool generated early in treatment (week 4) was successful in directing at-risk patients into adapted treatment, with improved treatment outcome compared to those who received standard treatment. In this study, adaptation aimed to intensify the treatment through level of support, materials, and messaging reminders, rather than changing treatment content. Thus, there is some support for the notion of 'stepping-up' or 'adapting' treatment intensity within an ICBT intervention, though this has not been examined in young people with anxiety.

We propose a 'stepped-care' or 'adaptive' approach for ICBT (ICBT-SC) for young people, whereby all participants begin with self-guided ICBT as the 'first step' or treatment block. Rather than a risk algorithm, we propose a model that integrates self-reported assessment and clinical judgement which can be particularly beneficial when considering both child and parent reports. Those who do not demonstrate adequate treatment gains after 5 sessions are stepped-up to ICBT-TG, while those responding well continue with the lower intensity intervention. If effective, this model of ICBT-SC would provide a viable ICBT model for integration into routine care, minimising the costs of 'stepping up' or 'adapting' support by utilising low-intensity therapist support (e.g. phone, email or videoconferencing support) rather than in-person therapy in the step-up phase. To justify its widespread use however, it is critical to demonstrate that this model of ICBT-SC does not lead to inferior treatment outcomes compared to those of existing evidence-based ICBT-TG.

1.2. The present study

This non-inferiority RCT examines whether ICBT-SC can produce the same benefits for child and adolescent anxiety as an existing, evidence-based ICBT-TG intervention that has been shown in several RCTs to be effective (March et al., 2009; Spence et al., 2011; Spence et al., 2006). It was hypothesised that ICBT-SC would be no less clinically effective than ICBT-TG (not inferior to any greater extent than the noninferiority margin), with similar reductions in anxiety severity from baseline to 12-weeks and 9-months post baseline. It was also predicted that the ICBT-SC program would be acceptable and satisfactory to participants.

2. Methods

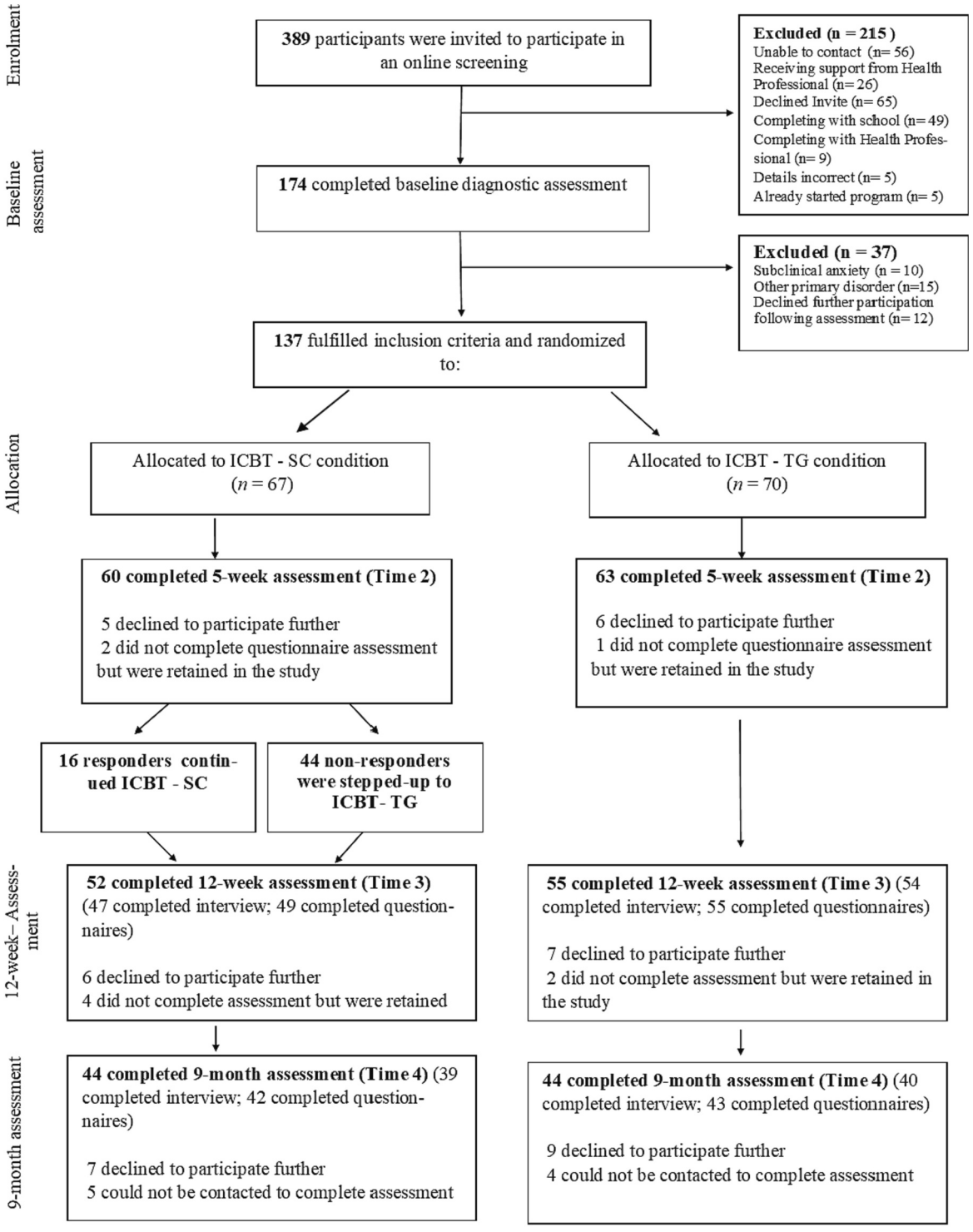
2.1. Design

This study was a two-arm non-inferiority RCT comparing ICBT-SC with evidence-based ICBT-TG (see Section 2.4) and reported in line with international recommendations for child anxiety trials (Creswell et al., 2021). Stratified block random assignment was used to control for participant age (child, teen), with an allocation ratio of 1:1 to conditions. The random sequence was generated by the lead investigator and concealed from the project manager until participants were ready to be randomized (sequence released per individual participant). Full diagnostic and questionnaire assessments were conducted at three time points: pre-intervention, and 12-weeks and 9-months (primary endpoint) after commencement of treatment. A brief assessment was conducted at mid-treatment (after Session 5 or week 7; whichever was sooner) to determine 'responder status' and the 'step-up' decision. Questionnaires were completed online, within the program. The study was conducted in accordance with the University of Southern Queensland Human Ethics Research Committee (H17REA050). The study's design, hypotheses and analysis plan were preregistered with the Australian and New Zealand Clinical Trials Registry

(ACTRN12618001415291).

2.2. Participants and procedure

Participants included 137 young people (56 male, 81 female) aged 8–17 years (M = 10.67, SD = 2.43), who registered for the BRAVE ONLINE program (an ICBT-SG intervention for child and adolescent anxiety) between September 2018 and September 2019, and who met the inclusion criteria outlined below. Participants were self-referred, or referred by general practitioners, education, or mental health professionals. Appendix A outlines the baseline demographic information of participants in each condition.



Note: "Completed assessment" includes participants who have completed any of the assessment items at this timepoint. Some participants completed interviews, but not questionnaires, and some participants completed questionnaires but not interviews. ICBT-TG = therapist-guided condition, ICBT-SC = stepped-care condition.

Fig. 1. CONSORT diagram of participants' progress through each phase of the study.

To be included in the study, participants were required to meet the following criteria: elevated levels of anxiety on the Children's Anxiety Scale-8 (CAS-8; Spence et al., 2014); a primary diagnosis of social anxiety disorder (SAD), generalised anxiety disorder (GAD), separation anxiety (SEP), or specific phobia (SP) on the Anxiety Disorders Interview Schedule for Children – Child version (ADIS-C; Silverman and Albano, 1996); aged between 8 and 17 years; access to the BRAVE ONLINE program via a computer or mobile device with an Australian IP address; able to read and write English at an age-appropriate level; and willingness to be randomized to one of the two conditions. Young people with a primary diagnosis of obsessive-compulsive disorder (OCD), posttraumatic disorder (PTSD) or panic disorder (PD) were not eligible for participation, although these diagnoses were permitted if secondary. Participants with secondary mood disorders were included if their mood disturbance had a clinician severity rating (CSR; see Section 2.3.2.1) of <6 on the ADIS-C. Participants with current suicidal ideation, self-harm, substance abuse, significant behavioural disorders, pervasive developmental disorders, learning disorders or those already receiving professional help were excluded from the study and provided with alternative appropriate referrals.

The flow of participants through each phase of the study is presented in Fig. 1. Families registering for the freely available BRAVE-ONLINE ICBT-SG intervention, and who reported elevated anxiety on the registration questionnaire (see below), were invited to take part in the RCT. As is evident from Fig. 1, 389 participants reported elevated anxiety and were invited to participate in the telephone screening assessment (see below). Of the 389 participants, 121 declined the invitation or were unable to be contacted, and 94 failed to meet the broad inclusion criteria from the screening interview. Subsequently, 174 families completed the baseline online questionnaires and diagnostic interview (see below), of whom 25 were excluded as they did not demonstrate a clinical-level anxiety disorder or had a primary disorder other than anxiety, and 12 declined further participation. As a result, 137 participants met inclusion criteria, provided informed online consent (child and parent), and were randomly allocated to either the ICBT-TG or ICBT-SC conditions. Participants were informed of the condition they were allocated to. Of the final sample, 77 % had a clinical-level comorbid anxiety disorder, with an average of 2.28 (SD = 0.99) anxiety diagnoses.

2.3. Measures

2.3.1. Demographics

Basic demographic information, including age, gender, and residential location was collected when participants began the program.

2.3.2. Diagnostic status, anxiety symptom severity, and functioning

2.3.2.1. Primary outcome measure. The Anxiety Disorders Interview Schedule for Children–Child Version (ADIS-C; Silverman and Albano, 1996) was used to determine the presence of an anxiety disorder and the associated Clinician Severity Rating (CSR) ranging from 0 (none)-8 (severely disturbing/disabling) which was the primary outcome measure in this study. The ADIS-C was conducted with the child via telephone at baseline, 12-weeks, and 9-months by trained interviewers who were blind to experimental condition and supervised by an experienced Psychologist. Information from the ADIS-C also informed the clinician rating of overall child functioning on the Children's Global Assessment Scale (CGAS; Shaffer et al., 1983), with scores ranging from 0 to 100. Scores in the 81–100 band represent normal levels of functioning, 61–80 represents slight disability, scores between 41 and 60 are indicative of moderate disability and scores from 1 to 40 indicate serious disability. The CGAS was a secondary outcome measure in the current study and has good inter-rater and test-retest reliability (Rey et al., 1995; Shaffer et al., 1983). A sample of 15 % of all interviews were coded for inter-rater reliability, with a Kappa Coefficient of 0.94 for primary diagnosis, r = 0.87 for CSR ratings attached to primary diagnosis, and r = 0.87 for overall CGAS ratings. Only the child version of the ADIS was administered in order to minimise participant burden and obtain information directly from the person completing treatment. For children under 12 years, parents either attended the interview with the child or were provided with a summary upon completion of the phone call.

2.3.2.2. Secondary outcome measures. The 8-item Children's Anxiety Scale (CAS-8; Spence et al., 2014) was completed by the young person at registration. The CAS-8 provides population-level, gender-standardized norms for comparison, with scores above the 84th percentile considered elevated (T > 60: CAS-8 score ≥ 10 for males and ≥12 for females). The Spence Children's Anxiety Scale-Child (45 items) and Parent (39 items) versions (SCAS-C&P; Nauta et al., 2004; Spence, 1998) were administered at baseline, mid-treatment, 12-weeks and 9-months as secondary outcome measures and to determine 'step-up' decisions at mid-intervention (see Section 2.4.3). Scores above the 84th percentile (T > 60) were considered elevated for each subscale and total score. The level of anxiety-induced life interference and impairment experienced by the child (as reported by children and parents), and by the parent themselves (parent report) was assessed with the Child Anxiety Life Interference Scale (CALIS; Lyneham et al., 2013) at baseline, 12-weeks and 9-months. The CAS-8, SCAS-C, SCAS-P and CALIS have shown excellent psychometric properties in previous studies (Nauta et al., 2004; Spence, 1998; Lyneham et al., 2013). The internal consistency for each of these scales is reported in Appendix B.

2.3.3. Program adherence and satisfaction

Program adherence was assessed by the number and proportion of sessions completed by 12-weeks and 9-months. Dropout status was determined by whether the participant withdrew from the study (treatment and assessments), recorded as yes/no at each assessment time point (mid-point, 12-weeks, and 9-months). Program satisfaction was measured through a 5-item scale used in our prior research (March et al., 2009; March et al., 2018). Participants were required to respond to items assessing whether they would tell a friend about the program (Item 1), how helpful the program was (Item 2), how happy they were with the program (Item 3), how much the program helped to reduce their anxiety (Item 4), and overall judgement of the program (Item 5). Responses were provided on a 5-point Likert scale, with responses for item 1 scored as 1 = Definitely Not, 3 = Maybe, and 5 = Definitely Yes; responses for items 2, 3 and 4 scored as 1 = Not at all, 3 = Quite a bit, and 5 = Very Much; and responses for item 5 coded as 1 = Very Bad, 3 = Okay, and 5 = Very Good. A total satisfaction score was calculated by summing responses for the 5 questions.

2.4. Interventions

2.4.1. ICBT-TG: BRAVE-ONLINE therapist-guided

The ICBT-TG intervention involved the child or adolescent BRAVE-ONLINE program with email therapist guidance. BRAVE-ONLINE has demonstrated efficacy across several trials (March et al., 2009; Spence et al., 2011; Spence et al., 2006), and the programs comprise 10, 45 min sessions of ICBT. Sessions 1 to 5 include evidence-based anxiety management strategies such as recognition of symptoms, relaxation, coping self-talk, cognitive restructuring, and graded exposure, and Sessions 6 to 10 include additional strategies such as problem solving, self-reinforcement, relapse prevention and ongoing skills rehearsal. The interactive sessions are completed by the young person on a computer or tablet. Each participant was assigned a therapist who monitored their progress, viewed their responses to activities, and after each session, sent guidance via email (15 min of therapist time per session). The email was created using program templates that provided reinforcement of effort and redirection, or clarification of participant responses where required. Participants also received a 30-minute phone call from their

therapist after Session 5 to assist with the construction and implementation of the exposure hierarchy.

2.4.2. ICBT-SC: BRAVE stepped-care

The ICBT-SC condition was BRAVE-ONLINE Stepped-Care, comprising two steps depending on the results of a mid-point assessment. In Step 1, all participants commenced the first 5 sessions of BRAVE-ONLINE without therapist guidance. Participants were then assessed at the mid-treatment point (after 5 sessions of BRAVE-ONLINE or 7 weeks, whichever occurred first) to determine their 'responder status' as described below. In Step 2, participants who 'responded' to Step 1 completed the remaining 5 sessions of BRAVE-ONLINE (without therapist guidance), whereas those who did not respond to Step 1 (i.e., did not demonstrate sufficient improvement) were "stepped-up" to complete the final 5 sessions of BRAVE-ONLINE supplemented with therapist guidance (identical to ICBT-TG described above). Those who were stepped-up received a 30-minute phone call after session 5 to assist with implementation of exposure. Those who were not stepped-up did not receive a phone call. The BRAVE-ONLINE program content and therapeutic strategies were identical across conditions, with the only difference being the amount of therapist-guidance provided (see March et al., 2019 for description of the stepped-care and BRAVE-ONLINE treatment content).

2.4.3. Determining responder status at mid-treatment for the stepped-care condition

Two components were considered when determining responder status, with each case assessed by a Clinical Psychologist utilising the following criteria. First, responder status for the mid-treatment "Step-Up" decision in BRAVE-ONLINE-SC was *primarily* determined by response on the SCAS-C and SCAS-P (Nauta et al., 2004; Spence, 1998), using gender-standardized cut-offs based on normative and clinical child and adolescent samples (Spence, 1998; Spence et al., 2003). Scores above the 84th percentile ($T > 60$) were considered elevated. 'Responders' were defined as those who demonstrated a reduction in anxiety into the non-elevated range on EITHER their primary anxiety subscale OR total scores on SCAS-C or SCAS-P at mid-treatment, for scales on which they were elevated at baseline. 'Non-responders' were defined as those who did not meet this criterion.

Pilot work (March et al., 2019) demonstrated that level of session adherence was not necessarily consistent with reductions in anxiety symptoms and that additional factors should be considered in the Step-Up decision. Therefore, as a second step, the Clinical Psychologist scoring the mid-treatment assessment also examined the number of sessions completed by mid-treatment, and the way the young person engaged with activities within the program. Completion of <3 sessions was deemed to be indicative of non-response at mid-treatment as were answers to program activities that indicated little thought, insight, or strategy implementation. However, completion of between 3 and 5 sessions, along with good engagement within the sessions (regular session completion, completed activities suggesting engagement with material, reported evidence of skill rehearsal and homework practice) was considered indicative of good response, if supported by the SCAS-C and/or SCAS-P data. Additional case information from baseline interviews was considered if required to resolve any discrepancies between self-report data and program engagement. Evaluation of the mid-treatment assessment was conducted by a Clinical Psychologist and recommendations discussed with the lead investigator (SM) for each case to ensure guidelines were adhered to.

Thus, overall, participants were deemed non-responders and stepped-up to Therapist-Guided if they had (i) reported SCAS scores at mid-treatment that showed no improvement on primary or total anxiety into non-elevated ranges compared to their baseline scores, (ii) completed <3 sessions in Step 1 suggesting poor treatment engagement, and reported SCAS results that were inconsistent between parent and child report, or improved on one but not all subscales, or (iii) demonstrated poor treatment engagement as measured by low levels of completion of session activities, infrequent session completion, and lack of evidence of skill rehearsal and homework practice as observed through session responses to the point that changes in SCAS scores were deemed unreliable.

Participants who did not respond to the invitation to complete the mid-treatment assessment were reminded 1 week later and the Clinical Psychologist attempted to make contact via phone. Those participants who failed to respond were able to continue with their existing program if they chose to. Two participants failed to complete the mid-treatment assessment but continued in the study.

2.4.4. Therapist training

The 7 therapists delivering guidance had completed a minimum of 4 years training in Psychology and were undergoing further Psychology education at Masters or Doctoral level. All therapists received 4 h of training in BRAVE-ONLINE and their email responses were guided by templates for email content. Therapists also participated in ongoing fortnightly supervision with a senior Clinical Psychologist.

2.5. Analytic strategy

Non-inferiority analyses were conducted for the clinician-rated and self-report measures. Following Feingold (2015) procedure, hierarchical linear models (HLM) were used to estimate the changes over time and were converted to standardized measures (i.e., Cohen's *d*). Effects estimated included changes in primary and secondary outcome measures for participants in ICBT-SC and ICBT-TG conditions across time (i.e., from baseline to 12-weeks and from baseline to 9 months), as well as the interaction between treatment condition and time (i.e., testing if the rate of change was similar or different between trial arms). HLM analysis was conducted using maximum likelihood estimation with the NLME (nonlinear mixed effects) package (Pinheiro et al., 2017) within the R statistical program (R Core Team, 2021). Confidence intervals for effect sizes were determined as described by Zaiontz (2023), using a non-central t-distribution (Goulet-Pelletier and Cousineau, 2018). Non-inferiority was supported when the lower limit of the 95 % confidence interval for the standardized mean difference was within the margin of non-inferiority.

The margin of noninferiority for the treatment effect was determined for the primary outcome measure (CSR derived from the ADIS) based on the results of previous trials comparing ICBT-TG to a waitlist control demonstrating effect sizes of $d = 0.60$, $d = 1.22$ and $d = 1.45$ at 12–14 week assessment (March et al., 2009; Spence et al., 2011; Spence et al., 2006). It is recommended that a clinically unimportant difference between two treatments should be *one half or less* of the effect size of the reference intervention (European Medicines Agency, 2005). Thus, for the CSR, the margin of non-inferiority was set to $d = 0.20$, such that if the lower bound of the 95 % confidence interval of the effect size did not exceed $d = -0.40$, ICBT-SC would be deemed as non-inferior to ICBT-TG. The same margin of non-inferiority was employed across secondary outcome measures. The power calculation was set at $\alpha = 0.05$, for a lower-bound non-inferiority margin of 0.4, to provide a power of 0.80 for primary and secondary outcomes, requiring a sample size of 58 participants per condition. The aim was to recruit 66 participants per group given an expected attrition of 15 %. The HLM approach allows for all data to be included in the analysis, including those that drop out, aligning with an intention-to-treat approach.

To examine the clinical benefits obtained by participants, diagnostic outcomes were compared between conditions using chi-square and logistic regression analyses for both completer and intent-to-treat samples. The intent-to-treat sample for the chi-square analyses was determined using the last observation carried forward method for participants who withdrew from the study or failed to complete assessment points for diagnostic outcomes only.

3. Results

3.1. Baseline characteristics and comparisons between conditions

There were no significant differences between ICBT-TG and ICBT-SC conditions on participant age, gender, living in an area of remoteness, socio-economic status of postcode, treatment expectancies, type of primary diagnosis, severity or impairment, although the sample as a whole had an over representation of the top two quartiles for socio-economic status (see Appendix A).

3.2. Program completion

There was no significant difference in the mean number of sessions completed between ICBT-SC versus ICBT-TG at the mid-point, $\bar{X} = 3.15$, $SD = 1.50$ and $\bar{X} = 3.50$ $SD = 1.50$, respectively, $t(135) = -1.39$, $p = .168$; at 12-weeks, $\bar{X} = 5.37$, $SD = 2.84$ and $\bar{X} = 5.91$, $SD = 2.95$, respectively, $t(135) = -1.02$, $p = .276$; and at 9-months, $\bar{X} = 6.69$, $SD = 3.43$ and $\bar{X} = 7.21$, $SD = 3.52$, respectively, $t(135) = -0.88$, $p = .569$. Appendix C reports the proportion of participants completing each of the 10 sessions of the program.

The proportion of participants who dropped out of the study was not significantly different by condition at the mid-treatment point, $OR = 1.04$, 95 % CI [0.35, 3.08], $p = .937$ (9.0 % vs 8.6 % for ICBT-SC vs ICBT-TG respectively), at 12-weeks, $OR = 1.16$, 95 % CI [0.48, 2.81], $p = .740$ (16.4 % vs 18.6 % for ICBT-SC vs ICBT-TG respectively), or at 9-months (26.9 % vs 31.4 %) for ICBT-SC vs ICBT-TG respectively, $OR = 0.95$, 95 % CI [0.51 1.44], $p = .557$.

3.3. Proportion of participants 'Stepped Up'

Forty-four (73 %) ICBT-SC participants were classified as 'non-responders' at mid-point assessment and subsequently stepped-up to ICBT-TG. Sixteen participants (27 %) were classified as 'responders' and continued with self-guided sessions.

3.4. Non-inferiority analysis

The difference in the rate of change between the ICBT-TG and ICBT-SC conditions from baseline to 12-weeks and from baseline to 9-months can be seen in Figs. 2 and 3 and Appendix D. The test of non-inferiority, examining the difference between conditions in the rate of change over time, indicated that the standardized 95 % CIs for Cohen's *d* were within the range of non-inferiority for all measures from baseline to 12-weeks (Fig. 2), with the exception of the CGAS, for which the upper-bound (CGAS is reverse-scored) CI (*d* 95 % CI = 0.58) exceeds the bounds of the margin of non-inferiority (*d* 95 % CI = 0.4). However, from baseline to 9-months (Fig. 3), all Cohen's *d* was within the range of non-inferiority for all measures.

3.5. Clinician- and self-reported outcomes

To further explore the benefits gained by the ICBT-SC and ICBT-TG conditions, results from the fixed effects from the HLM analyses are presented in Appendix E. Significant improvements across time were evident for all outcome measures, but no significant differences between conditions or significant condition by time interactions were evident. Table 1 reports the within subject changes from baseline to 12-weeks and from baseline to 9-months for each condition. The trajectories of change are shown in Appendix F, and estimated marginal means and standard errors for child-, parent-, and clinician-reported outcomes at each assessment occasion for each condition are show in Appendix G, along with between-condition effects at each time point. There were no significant differences between groups at each assessment point.

3.6. Diagnostic outcomes

To examine the clinical benefits of both treatments, the diagnostic outcomes are presented in Table 2. The proportion of participants free of primary and any anxiety diagnosis increased over time, and although ICBT-TG participants showed greater loss of diagnosis at each time point, there were no significant differences between conditions in the proportion of participants free of their *primary* or *any* diagnosis at 12-weeks or 9-months. Of those ICBT-SC participants in the per-protocol

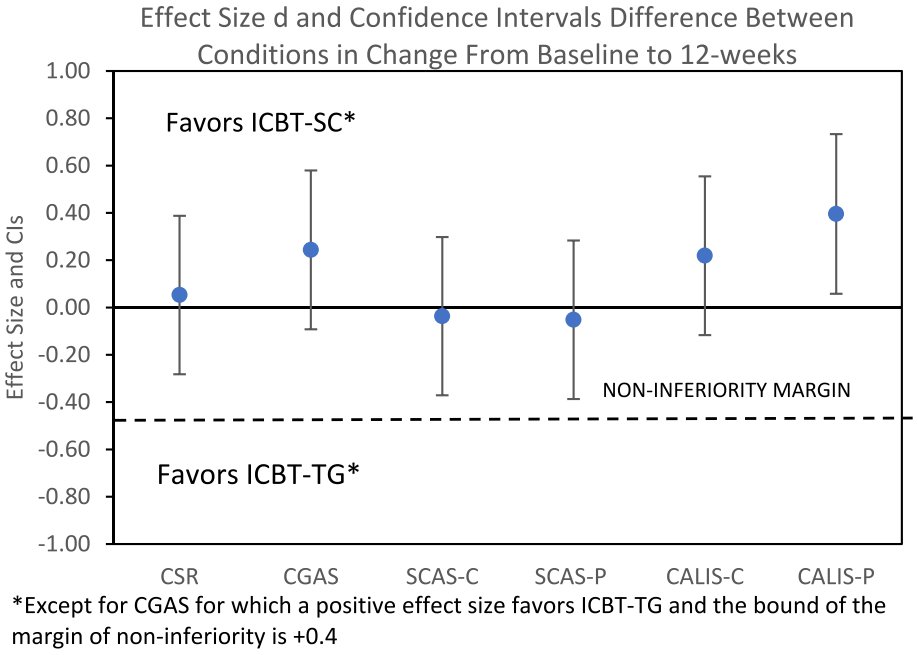


Fig. 2. Confidence intervals (95 %) for the effect size d for the difference between ICBT-SC versus ICBT-TG in changes in mean scores from baseline to 12-weeks for clinician-, child- and parent-reported outcomes.

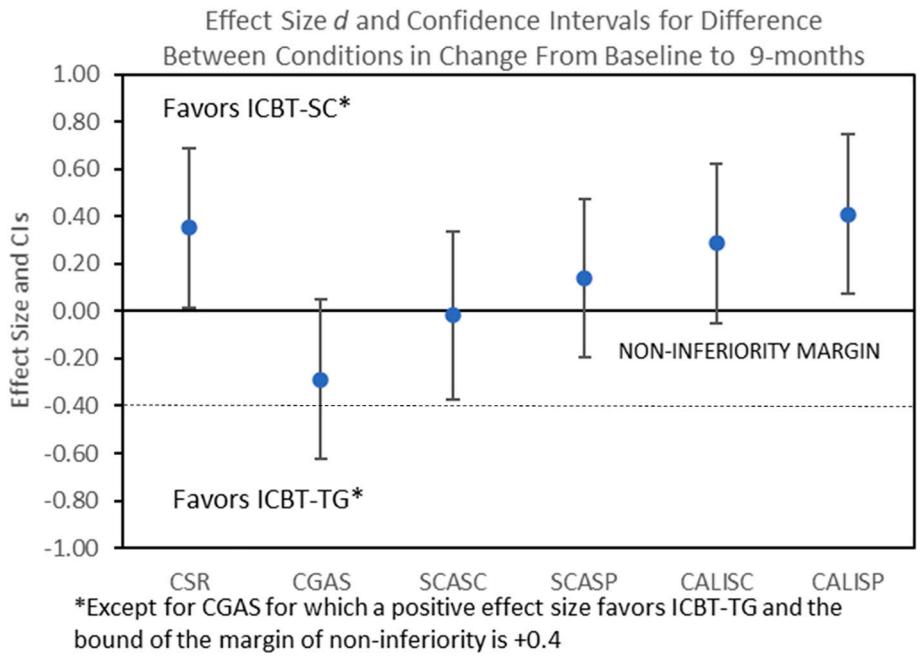


Fig. 3. Confidence intervals (95 %) for the effect size d for the difference between ICBT-SC versus ICBT-TG in changes in mean scores from baseline to 9-months for clinician-, child- and parent-reported outcomes.

Table 1
Within group treatment effects for each condition.

	ICBT-SC				ICBT-TG			
	Pre-treatment v 12-weeks		12-Weeks v 9-months		Pre-treatment v 12-weeks		12-Weeks v 9-months	
Scale	*d* [95%CI]	*p*	*d* [95%CI]	*p*	*d* [95%CI]	*p*	*d* [95%CI]	*p*
SCAS-C	1.16 [0.84, 1.47]	<.001	0.51 [0.16, 0.87]	.007	1.19 [0.91, 1.47]	<.001	0.37 [0.16, 0.59]	.001
SCAS-P	1.01 [0.75, 1.26]	<.001	0.40 [0.13, 0.67]	.004	1.04 [0.76, 1.32]	<.001	0.22 [−0.07, 0.52]	.133
CALIS-C	1.09 [0.72, 1.46]	<.001	0.28 [−0.12, 0.68]	.167	0.87 [0.54, 1.20]	<.001	0.20 [−0.14, 0.54]	.251
CALIS-P	1.17 [0.86, 1.48]	<.001	0.27 [−0.03, 0.57]	.080	0.77 [0.44, 1.09]	<.001	0.26 [−0.06, 0.57]	.110
CGAS	−2.72 [−3.25, 2.18]	<.001	−1.92 [−2.65, −1.18]	<.001	−3.01 [−3.63, −2.40]	<.001	−1.30 [−2.04, −0.57]	.001
CSR	3.58 [2.92, 4.24]	<.001	1.39 [0.59, 2.20]	.001	3.51 [2.88, 4.13]	<.001	1.09 [0.32, 1.85]	.006

Note. Positive values of *d* indicate improvement over time. Except for CGAS scores in which negative values indicate improvement over time. Estimated from MLM.

sample who were stepped up to receive therapist guidance, 60.6 % were free of their primary diagnosis at 12 weeks, compared to 57.1 % of those who were not stepped up (i.e., continued to receive self-guided sessions). At 9-months, 74.1 % of those stepped-up, compared to 90 % of those not-stepped up were free of their primary diagnosis.

3.7. Satisfaction with treatment

Total satisfaction was rated as moderate to high for both conditions. After six sessions, the difference in satisfaction between ICBT-SC and ICBT-TG approached significance, ($\bar{X} = 20.36$, SD = 4.31 vs $\bar{X}$ =19.62, SD = 3.70), $t(96) = -1.97$, $p = .052$, with stepped-care participants showing slightly higher total satisfaction scores. There was no significant difference in satisfaction after nine sessions ($\bar{X} = 20.20$, SD = 5.17 vs $\bar{X} = 20.06$, SD = 4.03, $t(53) = -0.12$, $p = .221$).

4. Discussion

This study was the first to examine if the benefits of stepped-care ICBT (ICBT-SC) for child and adolescent anxiety are equivalent to those of an empirically validated, but more labour intensive, fully therapist-guided ICBT (ICBT-TG) program. The results supported the hypotheses and demonstrated that ICBT-SC was non-inferior to ICBT-TG. This finding was evident for primary (clinician severity ratings) and secondary (parent and child anxiety reports) outcome measures, which demonstrated similar and significant improvements in anxiety over time for both conditions. The only measure that did not fall in the non-inferiority region (only at 12-weeks) was the CGAS (overall functioning), although it showed non-inferiority at 9-months. Further, ICBT-SC was well accepted by children, with moderate to high satisfaction ratings. Though non-inferiority of satisfaction was not explicitly tested, the results indicated no substantial differences between conditions. After six ICBT sessions, participants receiving stepped-care demonstrated slightly higher satisfaction ratings, though not significant, and no significant differences in satisfaction were observed between conditions after nine sessions. ICBT-SC did not result in lower levels of therapy compliance (session completion and dropout) compared to ICBT-TG. Thus, it appears that ICBT-SC offers an effective alternative mode of delivery for the treatment of child and adolescent anxiety.

When considering the clinical gains made by participants at the 9-month assessment, study completers in both conditions showed a remission rate for the *primary* anxiety disorder of ~77.0 %, with a remission rate for *any* anxiety disorder of 58.9 % for ICBT-SC and 70.0 % for ICBT-TG. These rates were lower in the intent-to-treat (ITT) sample, with 50.7 % of ICBT-SC and 57.1 % of ICBT-TG participants free of their *primary* anxiety diagnosis at 12-weeks, and 38.8 % of ICBT-SC and 48.6 % of ICBT-TG participants free of *any* anxiety diagnosis at 9-months. Given the variation in which participants complete ICBT sessions, 9-

Table 2
Diagnostic outcomes for each condition.

		Free of primary anxiety diagnosis							Free of any anxiety diagnosis						
		ICBT-SC		ICBT-TG		Statistics			ICBT-SC		ICBT-TG		Statistics		
Time	Sample	*n*	%	*n*	%	χ^2	*p*	OR	CI	*n*	%	*n*	%	χ^2	*p*	OR	CI
12-weeks	Per-protocol	28/47	59.6	36/54	66.7	0.544	.461	0.74	0.33, 1.66	20/48	41.7	29/54	53.7	2.02	.365	0.62	0.28, 1.35
	ITT	28/67	41.8	36/70	51.4	1.28	.258	0.68	0.35, 1.33	20/67	29.9	29/70	41.4	2.00	.158	0.60	0.30, 1.22
9-months	Per-protocol	30/39	76.9	31/40	77.5	0.004	.951	0.97	0.34, 2.77	23/39	58.9	28/40	70.0	1.07	.587	0.62	0.24, 1.56
	ITT	34/67	50.7	40/70	57.1	0.56	.453	0.77	0.39, 1.52	26/67	38.8	34/70	48.6	1.32	.249	0.67	0.34, 1.32

months is considered the primary endpoint for this study, and the clinical improvements observed compare favourably with other clinical trials. In their meta-analysis of CBT and ICBT studies, James et al. (2020) reported CBT remission rates for *primary* anxiety diagnosis of 49.4 % in ITT and 56.4 % in completer samples, and for *any* anxiety diagnosis, 46.8 % in ITT and 52.9 % in completer samples. Further, when considering adolescents specifically, meta-analyses of psychological therapies for adolescent anxiety have demonstrated only 36 % of ITT and 37 % of completer samples are free of their *primary* anxiety diagnosis after treatment (Baker et al., 2021). Thus, the stepped-care (and therapist-guided) intervention in the present study delivered to both children and adolescents produced excellent treatment outcomes in relation to other face-to-face and ICBT treatments with therapist guidance.

Despite the positive outcomes, there are several points worth noting. Like other ICBT studies (Podina et al., 2016), many participants were still completing treatment sessions at the 12-week assessment. Further, a substantial proportion of participants had not completed the prescribed number of sessions by mid-treatment (5 sessions prescribed for Step 1), and therefore many participants in ICBT-SC (73 %) were stepped up under our criteria. It is difficult to disentangle the reasons for non-response and it is likely that for many participants, low progress in sessions completed was linked to lack of improvement in anxiety symptoms. However, we note these rates were not different to session completion in the therapist-guided condition, which may be indicative of the overall self-guided nature of both treatments and the relatively minimal therapist support provided compared to full, face-to-face therapy programs. Nevertheless, the slow rate of treatment completion indicates that either the mid-point assessment could be delivered later, or that the efficiency of stepped-care approaches may be somewhat hindered by the large proportion of participants who need to be stepped-up from self-help programs. Other studies typically introduce the 'step-up' point at the completion of an entire intervention (Rapee et al., 2017; Salloum et al., 2016; van der Leeden et al., 2011), rather than mid-intervention, thus it difficult to compare the rates of stepping-up. However, in Rapee et al.'s (2017) study, 59 % were offered Step 2 after completing a full course of ICBT. It would be beneficial to better understand the clinical characteristics and program engagement of users progressing through such stepped-care models.

In the present study, just over a quarter of children in the ICBT-SC condition were not stepped-up and continued with self-guided sessions, which, in clinical services, could represent a large potential saving in therapist time, and free up therapists to direct resources to young people who require it most. Indeed, of those who continued with the self-guided intervention, 90 % were free of their primary anxiety diagnosis at 9 months. Future studies should examine the characteristics of individuals most likely to benefit from self-guided, stepped-care and therapist-guided approaches. They should also examine for whom low session completion is problematic. Although problems with engagement may reflect difficulty in completing treatment activities, interfering demands on time, and/or a need for greater support to increase motivation for completion and progression, poor engagement may also reflect reductions in anxiety and a reduced need for treatment.

4.1. Study limitations

This study represented the first of its kind, used a clinically diagnosed anxious sample with levels of severity and comorbidity consistent with studies elsewhere in the literature, and ensured the use of multiple informants using psychometrically valid measures. However, there were several limitations. First, although it would have been beneficial to include both child and parent diagnostic interviews, this study aimed to minimise participant burden, with interviews directed at the recipient of treatment. For children under 12, the effects of this were mitigated by allowing parents to be present during the interview or consulting with them at the end of the interview. Second, although the study was

broadly representative and included 30 % of participants residing in areas outside major cities, approximately 73 % of these areas were in the top two quartiles of socio-economic status, thus limiting the generalisability of results to lower socio-economic populations. It is also possible that the present sample is not representative of populations in other countries or cultural and socio-demographic groups and such issues need to be examined in future research. Third, we note that, as with most non-inferiority trials, the study was restricted to two active treatments with no wait-list control or non-specific control condition, and therefore we cannot be certain that the treatment effects for both conditions do not simply reflect spontaneous remission. This is unlikely, however, given that prior studies have shown the ICBT-TG intervention used here to be significantly more effective than no treatment (March et al., 2009; Spence et al., 2011) producing outcomes similar to clinic-delivered, face to face therapy. Importantly, there are also potential limitations of our chosen margin of non-inferiority which was based on our previous trials of ICBT-TG. The non-inferiority margin was calculated for the primary outcome measure (clinician diagnostic severity) and extended to other outcome measures. Future research should attempt to establish individual margins of non-inferiority for different outcome measures, to be informed by growing research.

Fourth, the drop-out rate of 29 % limited the power of the study, although such rates are not unusual in self-help online interventions (Linardon and Fuller-Tyszkiewicz, 2020), and therefore the findings are likely to be characteristic of this form of treatment. Fifth, there were limitations around the step-up criteria employed and the time point at which responder status was determined. Given that many participants did not complete the required sessions by this time, it is possible that an earlier assessment would be more beneficial in determining the need to adapt or step-up the intervention. Further, the clinical nature of the assessment means that clinician time and judgement was required to complement questionnaire scores. This limits the potential scalability of such interventions and future research should consider ways in which artificial intelligence and risk algorithms could assist in this process. Finally, the time investments of the therapists and subsequent costs of ICBT-SC were not quantified here, with a full examination of cost-effectiveness of the ICBT-SC and ICBT-TG interventions to be examined in a separate study.

5. Conclusion

To our knowledge, this is the first randomized controlled, non-inferiority trial comparing the benefits of, and satisfaction with, a stepped-care approach to ICBT for anxious children and adolescents against evidence-based therapist-guided ICBT. Overall, stepped-care was found to be non-inferior to therapist-guided ICBT, acceptable to families, and required less therapist guidance time. The findings have important implications for service delivery, suggesting that the lower-intensity stepped-care ICBT model may represent a suitable way of reducing long waiting-lists in primary care contexts or where there are insufficient numbers of clinically trained professionals to reach all those in need.

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CRediT authorship contribution statement

Sonja March (scientific conceptualisation, project leadership, supervision of staff, oversee interviews and therapy, oversee moderation, oversee analysis, preparation of data file, conduct of analysis, preparation and editing of manuscript), Caroline L Donovan (scientific conceptualisation, overseeing analysis, preparation and editing of manuscript), Susan H Spence (scientific conceptualisation, conduct of analysis, preparation and editing of manuscript), Martelle Ford (conducted diagnostic interviews, provided therapist support, conducted moderation, editing and review of manuscript), Genevieve Smith (conducted moderation, follow up data collection, data entry, data cleaning, drafted methods, manuscript review, editing and formatting), Larry Myers (conducted analyses and drafted results, manuscript review and editing).

Author note

The study's design, hypotheses and analysis plan were preregistered with the Australian and New Zealand Clinical Trials Registry (ACTRN12618001415291). The study received funding from the Financial Markets Foundation for Children Australia (2017-070). Due to limits to participant consent, a de-identified dataset is stored on a University of Southern Queensland data server and can be requested from the authors.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Authors Sonja March, Susan Spence and Caroline Donovan declare that although the intellectual property for BRAVE-ONLINE is owned by UniQuest/the University of Queensland, they may potentially benefit from royalties related to the program in the future.

Data availability

Due to the sensitive nature of the questions asked in this study, participants were assured raw data would remain confidential and would not be shared. A de-identified dataset is stored on a University of Southern Queensland data server and can be requested from the authors.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.invent.2023.100675.

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