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# Codesigned online cognitive bias modification of interpretations for anxiety and depression in children: study protocol of a randomised controlled trial

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## ABSTRACT

**Introduction** Previous research has shown that cognitive bias modification of interpretations (CBM-I) may be a promising intervention for anxiety in youth; however, results are mixed. Given the high comorbidity between anxiety and depression in youth, it is surprising that no child studies have targeted biases associated with both. This study aims to evaluate the effectiveness and acceptability of an online CBM-I intervention (Mindmaster) for children with symptom scores of anxiety or depression above a borderline or clinical threshold. The intervention has been codesigned with children, parents and mental health professionals to promote user engagement.

**Methods and analysis** The study is a randomised controlled trial, with two parallel arms. Participants are 143 children aged 8–10 years with scores of anxiety and/or depressive symptoms above a borderline or clinical threshold. They will be allocated to either the intervention group or the waitlist control group. The intervention consists of 2 weeks of online CBM-I training, with four sessions (10–15 min) per week. Outcome assessments will be conducted at baseline, 4 weeks after baseline (post-training/post-waitlist) and 8 weeks after baseline (follow-up) for the intervention group only. The primary outcome is interpretation bias. Secondary outcomes are anxiety and depressive symptoms and life interference. Analyses will be conducted within an intention-to-treat framework using mixed models for repeated measures.

**Ethics and dissemination** The study was approved by the University of New South Wales Human Research Ethics Committee (HC220758). Findings will be reported to (1) participating families; (2) presented at scientific conferences and (3) disseminated to peer-review publications. Data will be available from the corresponding author on request.

**Trial registration number** ACTRN12622001493730.

## STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Developmentally-tailored cognitive bias modification of interpretations for children targeting biases associated with anxiety and depression.
⇒ Codesigned with children, parents and mental health professionals.
⇒ Low-threshold internet-based treatment, easily accessible from home.
⇒ Results may not generalise to a clinical sample.
⇒ Study does not include an active control group.

## INTRODUCTION

Anxiety and depression are common and impairing mental health problems in children.[1] Intervention during this period is critical as this is when anxiety typically onsets and is at risk of escalating, contributing to the development of depression in adolescence.[2] Both disorders are in the top five leading causes of total disease burden in children in Australia[3] and are associated with long-lasting emotional and financial cost to individuals, their families and wider society.[2 4–6] Early, accessible and effective interventions are critically needed.

Cognitive theories highlight that maladaptive interpretation bias maintains and increases the risk of anxiety and depression.[7–9] There is ample empirical research showing that interpretation biases have a strong correlation with, and potentially predictive value of, anxiety and depressive symptoms in children and adolescents.[10–13] This research indicates that modifying these interpretation biases (reducing negative interpretation bias or promoting positive bias) might result in transdiagnostic (ie, across both anxiety and depression) symptom reduction and is a potential 'active ingredient' of treatment change.[14 15] However, current first-line treatment approaches that purport to do this, such as cognitive–behavioural therapy (CBT), vary in their efficacy, with approximately 50% of children not responding to treatment and

many relapsing.[16] Access to care is problematic and many psychologists in Australia are closed to new referrals.[17] There is a need to improve and complement current treatments in ways that are accessible to address current treatment shortages.

One promising digital approach is cognitive bias modification of interpretations (CBM-I). CBM-I was initially established to evaluate causal mechanisms between interpretation bias and symptoms[18] and subsequently has shown promise as a clinical tool.[19 20] CBM-I involves training individuals to repeatedly endorse more positive and benign interpretations of ambiguous information to directly modify interpretation biases. Thus, CBM-I can be easily administered in an online format, which means it represents a low cost and more easily disseminated intervention compared with in-person treatment, without the need for therapist input. It also appeals to children familiar with technology and represents a less intensive way for modifying interpretation bias compared with explicit cognitive restructuring strategies typically used in CBT.[21 22] The need for alternative or adjunct methods to modify interpretation biases is further highlighted by the lack of evidence showing that CBT is effective at modifying interpretation biases in children.[23]

Meta-analytical evidence has demonstrated that CBM-I has a moderate effect on improving positive interpretation bias and reducing negative interpretation bias in children and adolescents ('youth').[20 24 25] The evidence for symptom improvement for anxiety and depression outcomes is more mixed than in adults, which shows that CBM-I has small benefits for both anxiety and depression outcomes.[26] One meta-analysis found that CBM (including CBM-I) had a non-significant and small effect on youth mental health outcomes (anxiety, depression, and general distress) compared with a control condition.[24] Another meta-analysis by Krebs *et al* found that there was a small effect of CBM-I training on anxiety outcomes only in youth following training and after a stressor.[20] A more recent meta-analysis showed that CBM-I outcomes on both anxiety and depression were small and non-significant, yet there was a significant and small effect on a measure of state negative affect which included anxiety and depression items.[25] In summary, it appears that changes in bias do not always translate to changes in mental health outcomes for children and adolescents, except perhaps a small effect for anxiety and/or state negative affect.

While these results are mixed, there is a significant scope to improve CBM-I for children under 12 years.[25] First, evaluations of CBM-I have predominantly been conducted in adults and adolescents with only a handful of studies involving children.[20 25] These studies have shown that interpretation patterns can be effectively modified compared with a control condition with a small effect on anxiety symptoms. It seems likely CBM-I would have a greater effect in children with a diagnosis of or symptoms of anxious or depressive symptoms above a clinical threshold, yet only one study has been conducted in a child sample with an anxiety diagnosis, with promising findings.[27] Studies of children with a diagnosis or symptoms above a clinical threshold are much needed. Second, despite the high comorbidity between anxiety and depression, there are no child studies that have explicitly targeted biases associated with both disorders. If CBM-I is to be effective as a transdiagnostic intervention, stimuli need to be modified to be relevant to biases associated with both disorders.[28 29] While this has been done in adolescent samples,[30] with mixed success, no CBM-I studies have targeted both anxiety and depression cognitions in children.

Another reason CBM-I may not have been found to be as efficacious in children is due to the lack of motivation or engagement in the training. CBM-I for children has typically been 'extended downwards' from adult training paradigms, yet developmental differences in the capacity to engage in CBM-I necessitate an adaptation for children specifically.[22] A handful of studies have attempted to modify the training to make it relevant to children, such as the Space Odyssey programme, which contextualises training within a journey through space.[31 32] These studies found a small-to-moderate effect on interpretation bias compared with a control group, with stronger effects in high-anxious children.[31] Another set of studies presented two alternative explanations for each scenario (one positive and one negative/neutral), replacing the need for the oft-used word fragment in adult studies that may not be suitable for use in children due to its reliance on spelling.[33–36] In adult and adolescent CBM-I studies, game-design principles have been included to increase engagement, such as the use of embedding scenarios within a narrative context (eg, in adults[37]) and a points system based on performance and progress (eg, in adolescents[30 38]), however, these methods have not been used specifically for children. Further, previous studies have typically applied the same set of training scenarios to all participants in a one-size-fits-all approach. Given the variety of anxiety and depressive symptoms across children, it is important to increase the relevance of the training to match symptom domains, known as 'content specificity'.[23 27] While methods to adapt the training to make CBM-I more engaging is commendable, it is unknown whether these methods contribute to the presence or absence of a training effect, or whether these approaches are considered acceptable to children or lead to better rates of adherence. One way to promote engagement of a new intervention is to involve end-users in the design process,[39–42] which has been shown to lead to interventions that are feasible, acceptable and effective,[41 42] yet this has never been done for child CBM-I interventions. We describe a CBM-I treatment protocol that has undergone a rigorous codesign process with children, parents and mental health professionals. The online version of the CBM-I training in the current study differs from previous CBM-I interventions for children in four main ways: (1) the training is tailored to the child's primary concern (ie, a greater number of scenarios match

the child's primary symptom subtype); (2) the training is delivered online and completed in home settings (vs in a school or laboratory setting); (3) the training is flexibly administered over a period of 2–3 weeks (vs daily or on a scheduled timetable) and (4) includes a range of gamification and engagement features.

This protocol is reported following Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines.[43] The aim of this randomised controlled trial is to evaluate the effectiveness and acceptability of a developmentally tailored and codesigned digital CBM-I training (known as 'Mindmaster') for children aged 8–10 years with anxiety and/or depressive symptoms above a borderline or clinical threshold. Children will be randomised to either the intervention or a waitlist control group (WL). We chose a waitlist control group as the first step to evaluate the clinical effectiveness of Mindmaster as it incorporates several features which have not been combined and evaluated previously in a sample of children with clinically elevated symptoms, including tailoring scenarios to the child's primary concern and incorporating gamification features. A waitlist control is deemed an appropriate first step to establish clinical effectiveness in CBM-I whereas sham or neutral training is useful for establishing specificity of intervention effects.[19 25] We hypothesise that Mindmaster will reduce negative interpretation bias, increase positive interpretation bias and reduce anxiety and depressive symptoms and life interference compared with a WL at postintervention and that these gains will be maintained at the 1-month follow-up. We will also explore engagement and usage data to establish the acceptability of the intervention for children.

## METHODS

### Study design

The study is a parallel two-arm randomised controlled trial. Data will be collected at screening (T0), baseline (T1), post-training/post-waitlist (T2) and follow-up (T3; intervention group only) assessment points. The screening and baseline assessments will occur prior to random allocation and the post-training/post-waitlist assessment will occur 4 weeks after baseline. The follow-up assessment will occur 8 weeks after baseline. After the post-waitlist assessment, participants in the WL will be granted access to the CBM-I training. We will not be conducting follow-up assessments for the WL group due to time and resourcing constraints.

### Study setting

The study will be conducted online. Data will be collected from participants residing in Australia using the online Qualtrics survey platform.

### Eligibility criteria

Eligible participants (1) are aged 8–10 years; (2) have symptoms of anxiety and/or depression reported by parents with scores above a borderline or clinical threshold; (3) have a primary carer consent to their participation; (4) reside in Australia; (5) are fluent in English and able to read independently at grade 2 level and (6) have access to an internet-enabled device. Participants are not eligible if they (1) report life-threatening suicidal ideation or have had serious suicidal ideation in the last month or (2) have an impairment that prevents them using a computer, tablet or smartphone.

Eligibility criteria will be assessed at the screening assessment. The inclusion criteria 1 and 3–6 and the exclusion criteria 1 and 2 will be assessed using parent report yes/no questions. Symptoms above a borderline or clinical threshold (inclusion criteria 2) will be determined by t-scores above the cut-off value (≥65) on either the anxiety and/or depression subscales of the Revised Children's Anxiety and Depressive Scale 25-Parent report (RCADS-25-P[44]). T-scores of 65 and higher indicate scores at the borderline clinical threshold and t-scores above 70 indicate scores above a clinical threshold according to normative data.[44] Participants will also be required to score at least one point on questions of child symptomatic interference to be eligible to participate assessed by two questions (see the 'Secondary outcomes' section for further detail).

### Patient and public involvement

The protocol for this study was developed with extensive engagement of children (aged 8–12 years; n=7), young people (aged 12–26 years; n=7), parents (n=8) and mental health professionals (n=4). Across a series of workshops and interviews between October and March 2021, the group highlighted that there was a need for evidence-based digital interventions for children with anxiety and depression to support healthier ways of thinking about situations. They also highlighted that the intervention would only be effective if their child was engaged in using it. Accordingly, outcomes were focused on both symptom and bias outcomes, and a research question and measures of acceptability were incorporated.

The group was extensively engaged in the design of Mindmaster. This process was facilitated with the use of online whiteboards and discussion. The codesign process involved four stages including identifying users' needs and preferences, defining intervention features, designing content and visual features and testing prototypes in accordance with recommended guidelines.[39 40] Design and intervention features were incorporated into the final intervention described below. Outcomes from the codesign sessions were disseminated to the group via email. The potential burden of the intervention was assessed by the group and the administration of the sessions was adapted based on this feedback. The group will not be involved in the recruitment or conduct of the study.

### Intervention

The intervention is CBM-I delivered on a website called 'Mindmaster'. It is based on previous effective treatment

protocols[27 35] adapted specifically for this study. Adaptations were based on patient and public involvement outlined above, in collaboration with a team of researchers, user experience designers, psychologists and information technology specialists.

The intervention comprises of eight sessions with each session lasting approximately 10–15 min. In each session, participants are presented with 15 scenarios in a fixed order (120 in total). Each scenario consists of 2–3 sentences that describe an ambiguous situation they may experience. The training scenarios are based on existing scenarios[27 29 38 45] and adapted or created by the study authors (one clinical psychologist (GS), one provisional psychologist (ED) and a primary school teacher (TH)) so that they fit within a narrative structure. Scenarios relate to situations and cognitions specific to the most common anxiety subtypes in children (social situations, generalised anxiety situations, separation situations) and depression (see online supplemental material).

Novel to this study, the intervention is tailored so that 40% (n=48) of the scenarios relate to the participant's primary concern (ie, social anxiety, generalised anxiety, separation anxiety or depression). Primary concerns are identified based on a basic algorithm of subscale scores (ie, the highest t-score) on the symptom questionnaire measures. A random selection of 40 scenarios (one-third of the total scenarios) were pilot tested with a clinical psychologist (AT) for relevance to anxiety subtypes and depression in the target population. Changes were made based on feedback.

Following each scenario, participants are presented with two alternative interpretations: one describing a positive or benign resolution to the ambiguous scenario, and the other describing a negative outcome. Children are instructed that the goal is to choose the interpretation that is positive or neutral, rather than the negative interpretation. Children read the scenario (with the help of a parent if needed) and select from two interpretations. If the child selects the positive or benign interpretation, they will be provided with positive feedback such as 'That's correct!' and a restatement of the correct interpretation. If they select the negative interpretation, they will be provided with neutral feedback such as 'No, but good try' and a statement of the positive or benign interpretation (see online supplemental material).

Design features identified in the patient and public involvement phase were included in the programme to promote user engagement. These include (1) embedding the scenarios within a narrative structure about a protagonist going on a quest to restore 'balance' in an alternative world, with short pieces of narrative text in between some of the scenarios to provide additional context; (2) choice of an 'avatar' character; (3) vibrant and simple illustrations to support the story; (4) gamification and rewards and (5) simple and clear instructions about what CBM-I is (see online supplemental material).

### Control condition

This study uses a WL condition. We chose a WL, rather than a neutral or sham training group, as WL is considered more relevant to assessing clinical efficacy or effectiveness rather than testing specificity of effects.[20 26] Participants allocated to the WL will wait 4 weeks to begin the intervention. Participants in the WL will have access to the intervention following the post-waitlist assessment but no further data will be collected or analysed from the WL group following this point and they will have no further contact with the research team.

### Procedure and participant timeline

Figure 1 outlines the study flow and table 1 outlines the schedule of enrolments, interventions and assessments.

Interested parents will be directed to the study website, where they can access information about the study. If they wish to proceed, parents will be directed to read the online consent forms. Parents who provide informed consent (see online supplemental material for a copy of the consent form) for their child to participate will complete the online screening survey. Parents of eligible participants will register their contact details. Parents of children who do not pass screening will be provided with mental health service information.

Following registration, parents will be directed to a baseline assessment. Children will be asked to provide consent before completing the child-report sections of the baseline assessment. Participants who fail to complete the baseline assessment within 7 days will be automatically withdrawn from the study. Following the baseline assessment, participants will be randomly assigned to either the CBM-I intervention or the WL. Following randomisation, parents in the intervention group will receive an email with information about the programme and how to register on the website. Parents will be encouraged to assist their child with logging onto the programme and selecting rewards. Once registered, the participant can start the intervention. We will recommend that the parents and children complete session one together, and that children can then complete the remaining sessions independently, with parental reminders, if they choose to. Two emails will be sent to participants to remind them to register and/or continue with the intervention (days 3 and 5). Participants will be asked to complete eight sessions in a 2-week period (four sessions per week) but will have up to 3 weeks. Participants will be restricted to complete one session per day to enable spacing of sessions. The research team will email parents in the intervention group weekly to offer to provide a phone call to help with session scheduling or using the website. Parents who reply to the email will be provided with a phone call, however contact with the participants will not be therapeutic in nature.

At 4 weeks postbaseline, participants will be invited to complete the online assessments. Participants will have 14 days to complete each assessment and will be sent two reminders (days 3 and 7). Participants in the intervention

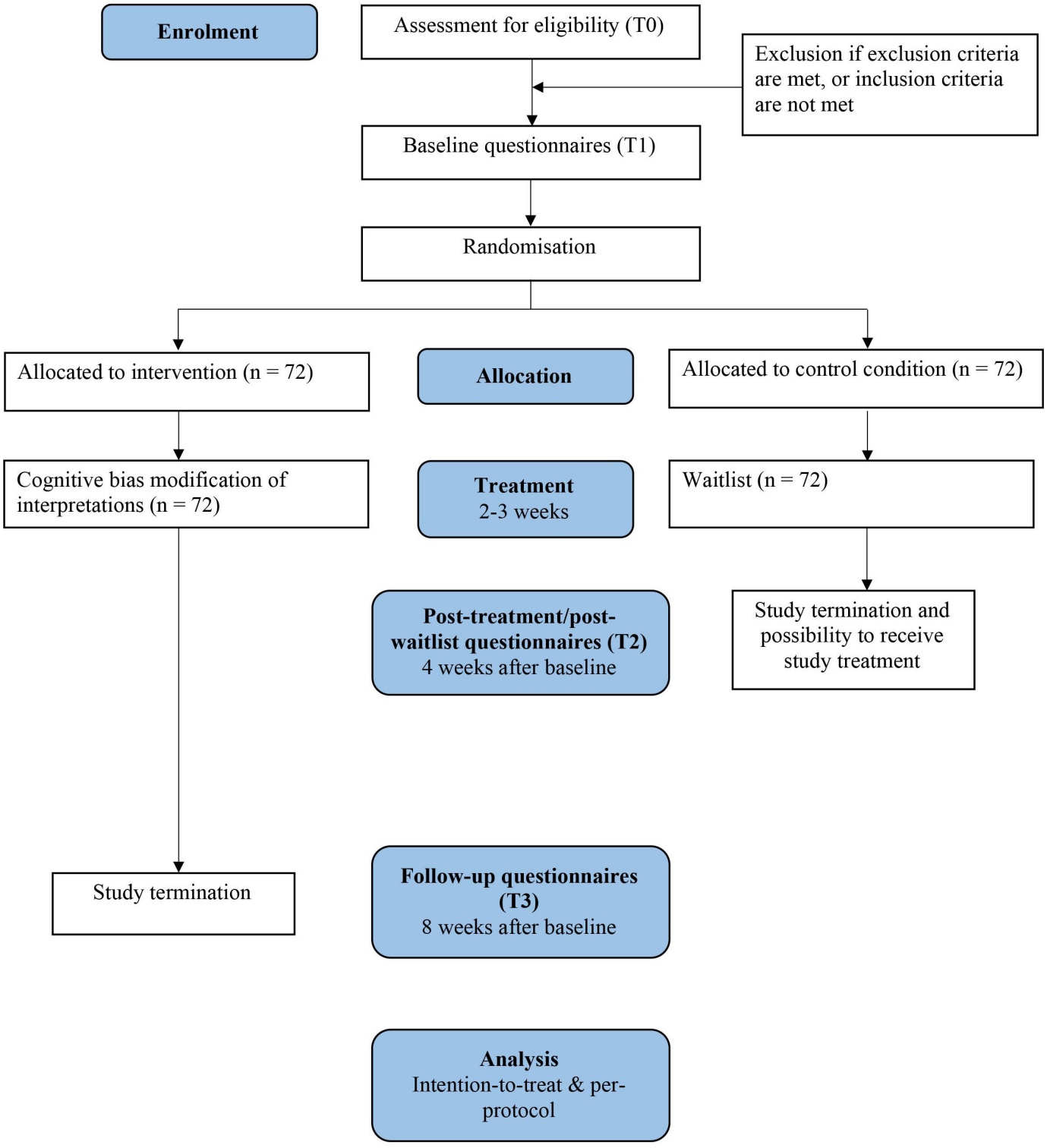


**Figure 1** Study flow.

group only will be invited via email to complete the same assessments at 8 weeks postbaseline. Participants in the control group will receive an email with the programme's instructions and log-in details after they have completed the post-waitlist assessments.

Participants will be reimbursed $A20 (electronic gift voucher emailed to parents) for each study assessment completed. Discontinuation of the allocated intervention will occur if the participant withdraws from the trial.

### Primary outcomes

The primary outcome will be positive and negative interpretation bias, measured using the Ambiguous Scenarios Task for children (AST-C). The AST-C will be used to

Table 1 Schedule of enrolment, interventions and assessments

| | Study period | | | |
|---|---|---|---|---|
| | Enrolment | Allocation | Postallocation | |
| Time point | Screener (T0) | Baseline (T1) | Post-treatment/post-waitlist (T2) | Follow-up - intervention group only (T3) |
| **Enrolment** | | | | |
| Informed consent | X | | | |
| Registration | X | | | |
| Demographics | | X | | |
| Eligibility screen | X | | | |
| Allocation | | X | | |
| **Interventions** | | | | |
| Cognitive bias modification of interpretations | | — | | |
| Waitlist | | — | | |
| **Assessments** | | | | |
| AST | | X | X | X |
| RCADS-25-P | X | | X | X |
| RCADS-25-C | | X | X | X |
| SCAS-P | | X | X | X |
| SCAS-C | | X | X | X |
| CADLIS-P | | X | X | X |
| CADLIS-C | | X | X | X |
| Interference supplement | X | | X | X |
| VAS (anxiety and mood) | | — | | |
| Barriers Questionnaire | | | X | |
| Digital Satisfaction Questionnaire-Parent | | | X | |
| Digital Satisfaction Questionnaire-Child | | | X | |
| Intervention usage data | | — | | |

AST-C, Ambiguous Scenarios Task for children; CADLIS-P/C, Child Anxiety and Depression Life Interference Scale-Parent and Child report; RCADS-25-P/C, Revised Children's Anxiety and Depression Scale-Parent and Child report; SCAS-P/C, Spence Children's Anxiety Scale - Parent and Child report; VAS, Visual Analogue Scale.

examine whether the intervention produces the proposed changes in interpretation bias. The AST-C is based on previous measures[27–29 46] and has been adapted for the current study by (1) modifying scenarios for relevance to anxiety and depression in children and (2) modifying the wording of the question to be appropriate for a child sample. The AST-C uses 16 ambiguous scenarios which relate to social situations, generalised anxiety situations, separation situations and depressive situations.[27 28 33] Two sets of eight scenarios are used: one set for the baseline and follow-up assessments, and one set for the post-training/post-waitlist assessments. For each scenario, there is a positive ending and negative ending. Children are asked to rate the chance that each ending could occur on a 4-point Likert scale (1=very small; 4=very great). Scores are summed to create a positive bias score (range: 8–32; higher scores indicate higher levels of positive bias) and a negative bias score (range: 8–32; higher scores indicate higher levels of negative bias). An example of an item on the AST-C is provided in online supplemental material. As this was a modified measure, no psychometric properties for the current version exist (but will be reported on), however, psychometric properties of the original measures are acceptable.[28 29 46]

## Secondary outcomes

The secondary outcomes will be child anxiety and depressive symptoms and life interference. Anxiety and depressive symptoms will be reported by parents and children using the RCADS-25-P/C[44 47]. The RCADS-25-P/C is a 25-item scale with two subscales that measure anxiety (15 items) and low mood (10 items). Items are scored on a 4-point Likert scale (0=never; 3=always). The baseline assessment of the RCADS-25-P (Parent-report) will also be used to determine eligibility into the study (t-score≥65 on either the anxiety or depression

subscale). The RCADS-25-P/C has demonstrated good internal consistency in community and clinical samples (alphas range 0.70–0.82), and the subscales have shown good internal consistency, test–retest reliability, criterion validity and construct validity,[44 48] but structural validity has been demonstrated for the anxiety subscale only.[48] Life interference will be measured using the Children's Anxiety and Depression Life Interference Scale-Parent and Child report (CADLIS-P/C; O'Gradey-Lee and Hudson, 2023, 'The Psychometric Properties of the Child Anxiety and Depression Life Interference Scale (CADLIS)' (Manuscript submitted for publication)). The CADLIS-P/C will be used to examine whether potential changes resulting from the intervention translate into meaningful improvements in life interference and functioning. The CADLIS-P/C is adapted from the Children's Anxiety Life Interference Scale[49] to be relevant to life interference associated with both anxiety and depression (O'Gradey-Lee and Hudson, 2023). The CADLIS-P has 16 items that assess symptomatic interference with both the parent's and child's everyday life, whereas the CADLIS-C has nine items that assess symptomatic interference with the child's life. Items are scored on a 5-point Likert scale (0=not at all; 4=a great deal). Two questions which assess symptomatic interference in relation to child distress and impairment to the family will also be asked to determine eligibility into the study (score of 1 or higher). The CADLIS has demonstrated excellent internal consistency, good convergent and divergent validity, good inter-rater correlations and was able to differentiate between children with and without clinical levels of anxiety and depressive symptoms (O'Gradey-Lee and Hudson, 2023).

### Other measures

Other measures include demographics, anxiety subtype symptoms, state anxiety and mood, recent mental healthcare and acceptability and participant satisfaction.

Demographic information will be collected at baseline. Items from the Spence Children's Anxiety Scale-Parent and Child report (SCAS-P/C[50 51]) will be administered at baseline to calculate the subscale scores for social, separation and generalised anxiety. The baseline subscale scores will be converted to t-scores to determine the allocation of scenarios relevant to the child's primary anxiety concern. At the post and follow-up time points, the SCAS-P/C subscale scores will be used to assess anxiety symptom change relevant to the primary anxiety concern. The SCAS-P/C has six items for each of the subscales, which assess anxiety symptoms relevant to the anxiety domains. Items are scored on a 4-point scale ranging from 0 ('never') to 3 ('always'). The SCAS-P/C has demonstrated strong reliability and validity across a large range of child samples.[52] Participants in the intervention group only will be asked to rate their current (state) mood and worry on a 5-point Likert scale (1=not at all worried/sad; 5=extremely worried/sad) at the beginning and end of each session during the intervention to track changes in states during the intervention. State mood and worry items will be summed and analysed to determine mean change in scores before and after each session on a session-by-session basis.

Parents will be asked whether their child has ever been diagnosed with anxiety or depression by a health professional, and about their recent mental healthcare (including treatments accessed, waitlist status for treatments and medication usage) at all assessment points.

The Digital Satisfaction Questionnaire (DSQ-P/C; Parent and Child report), and the Barriers Questionnaire (BQ; Parent report) will be administered to the intervention group at postintervention. The DSQ is a 13-item measure adapted from previous digital research to be relevant to Mindmaster.[53] The first 10 items of the DSQ are statements relating to ease of use and perceived usefulness of the online intervention, in which participants answer either 'agree' or 'disagree'. Participants then rate the overall helpfulness of the programme on a 5-point Likert scale (1=extremely unhelpful; 5=extremely helpful). The final two free response questions examine how the intervention was helpful (eg, 'In what ways did Mindmaster help your child/you?') and to provide suggestions for improvement (eg, 'What would make Mindmaster better?'). The BQ is a 17-item measure, adapted from previous digital research,[53] which has statements relating to personal, intervention-specific and technical barriers (eg, 'I/my child didn't have time to use Mindmaster'). Participants respond to the statements by selecting either 'yes' or 'no' to indicate whether they experienced each problem.

We will also collect the following data associated with participants' engagement and use of the intervention: log-in attempts (total frequency and frequency per day), actual usage (time spent logged into website), pages visited (home page, sessions, rewards), page visit usage time, number of visits (frequency of visits on each page), avatar selected, rewards selected, badges redeemed, rewards redeemed.

### Sample size

Previous CBM-I studies in youth have found moderate effect sizes for interpretation bias ranging between g=0.52–0.70.[20 24] Based on a power of 0.8, alpha 0.025 and assuming a correlation of 0.50 between baseline and post-training assessments, a moderate effect size d=0.60 requires 55 participants per group (total minimum sample size=110). Allowing for a 30% attrition rate between baseline and post-training based on previous online intervention trials targeting children and adolescents and delivered in a home setting[27 42 54] a sample size of 143 (72 per group) is anticipated.

### Recruitment

Participants will be recruited through the Black Dog Institute (BDI), Sydney, Australia, a not-for-profit medical research institute affiliated with the University of New South Wales (UNSW). Study advertisements will be published on the BDI website and distributed

to subscribers of internal and external communication newsletters and databases. We will use paid and organic advertising campaigns on social media platforms. We will contact relevant mental health organisations and services, parent and youth groups, and independent schools to invite them to advertise the study. Recruitment will continue once the minimum sample size is reached.

### Randomisation and blinding

Random allocation will occur after the baseline assessment and before the intervention start. Participants will be individually randomised using stratification to ensure balance across the conditions (intervention, control) based on their gender identity (male, female, non-binary/other) and their primary concern (anxiety, depression, both) using an automatic randomisation procedure within Qualtrics. Due to using an WL condition, participants will not be blinded. The research team will also not be blinded to allow for monitoring and contact with participants. The statistician (AM) involved in examining the effects of the conditions on primary and secondary outcomes at post-training will be blinded to treatment condition.

### Data collection, management and statistical analysis

Participant data will be collected and securely stored on UNSW OneDrive. Participant email addresses will be used to link surveys across assessment points and to usage data. Participant email addresses will be deleted when data is downloaded from Qualtrics for analysis purposes and each participant will be assigned a randomly created user ID for deidentification purposes.

Analyses will be undertaken on an intention-to-treat basis and will include all participants in the group to which they were randomised (regardless of actual receipt or uptake of the intervention or withdrawal from the study). Mixed-model repeated measures analysis will be used for the primary outcome and continuously scaled secondary outcome variables. The model will include factors of study condition (intervention or control group), occasion of measurement (baseline, postintervention and follow-up) and their interaction. Analyses will include the effect of the stratification variables, gender and primary symptom domain, with associated model parameters being retained if they are statistically significant.

The primary outcome will be assessed by a planned comparison of the difference between groups in change of the primary outcome variables (positive and negative interpretation bias) from baseline to post-training. A false discovery rate will be calculated using the Benjamini-Hochberg procedure.[55] An unstructured residual variance-covariance matrix will accommodate within-participant dependency. Tests of significance will use the Kenward-Roger method of df adjustment based on the observed information matrix.

Analyses of secondary outcome variables (anxiety and depressive symptoms, life interference) will follow the same methods as the primary outcome. Secondary analyses will also include change in the primary and other outcome variables from baseline to follow-up to inform the outcome pertaining to retention of learning. Change in the intervention group over this period cannot be compared with the waitlist as the latter group will be provided with access to the intervention after the wait period. The magnitude of change within the intervention group post-training to follow-up will be also estimated to reflect retention of any benefit of training. Mediation analysis will establish the plausibility of a causal pathway of the intervention's effect on clinical outcomes (anxiety and depression) being via change in interpretation bias.

Acceptability of the intervention will be explored using descriptives of the DSQ-P/C, BQ and engagement and usage data. Participant attributes that predict usage will also be investigated.

### Monitoring

The trial is overseen by the principal investigator (GS) and the trial management group. Day-to-day trial oversight will occur by the project manager involved with data collection (ED) who will meet with the principal investigator on a weekly basis. All adverse events and serious adverse events and broader safety monitoring will be documented and reported to the trial management group by the project manager and reported in the primary outcomes paper. If there are concerns for participant safety, based on (but not limited to) a higher than anticipated rate at one of the postintervention or follow-up points, or a higher than anticipated rate of adverse events during the trial, the trial management group may recommend pausing or terminating the trial.

Suicide risk will be assessed at the screener using a parent report question which asks, 'Has your child ever had any serious thoughts or intentions of suicide?'. Parents who report that their child has experienced recent risk of suicide are not eligible to participate in the study and will be redirected to a list of information, resources, alternative online treatment programmes and crisis support services.

If a participant contacts the research team to report an adverse event or distress from using the intervention, a registered psychologist from the team will arrange for a follow-up phone call, which includes a brief suicide risk assessment. If the participant is assessed as at risk of suicide, a referral to further care will be implemented. All parents are directed to mental health resources and supports via email following the call. Adverse events and phone calls will be discussed by members of the research team, and the events and responses logged in a register and reported to the ethics committee if appropriate.

The follow-up assessment will assess for deterioration in symptoms resulting from the study (one question), recent hospitalisation due to mental health symptoms (one question), and symptom scores above a borderline or clinical threshold (t-score≥65 on the anxiety or depression subscale of the RCADS-25-P/C reported by either children or parents[44 47]). If any of these conditions are

met, parents will be provided with a list of information, resources and crisis support services and invited to participate in a phone call from a psychologist. A psychologist will conduct a brief risk assessment and if determined to be at risk of suicide, a referral to further care will be implemented. An email with further mental health information and support services will also be sent.

## Ethics and dissemination

The University of New South Wales is the sponsor of this clinical trial and ethics approval was provided by the University of New South Wales Human Research Ethics Committee (HC220758). This trial was prospectively registered with the Australian New Zealand Clinical Trials Registry (29 November 2022 ACTRN12622001493730; see online supplemental material). The findings arising from the study protocol will be reported to participating families, presented at scientific conferences and disseminated by publications submitted to peer-reviewed journals. The data set used and/or analyses will be available from the corresponding author on reasonable request.

## DISCUSSION

This protocol described the design of a parallel two-arm randomised controlled trial to examine the effectiveness of an online CBM-I intervention at two follow-up assessment points and to evaluate its acceptability. To our knowledge, it is the first study to investigate the effects of CBM-I targeting both anxiety and depressive symptoms in children. The intervention is delivered digitally in a home setting, in which it is most likely to be implemented. So far, CBM-I for children has mostly targeted biases associated with anxiety in a lab setting. The intervention has been codesigned with children, parents and clinicians to increase engagement and relevance to children. The additional features included in the CBM-I intervention may encourage treatment adherence and potential effectiveness if it is implemented outside of research trials in the future. If proven effective, online CBM-I could easily be implemented as a low intensity, early intervention for children with anxiety and depressive symptoms above a clinical threshold, possibly while they are on a waitlist for conventional, therapist-based CBT.

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**Patient and public involvement** Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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