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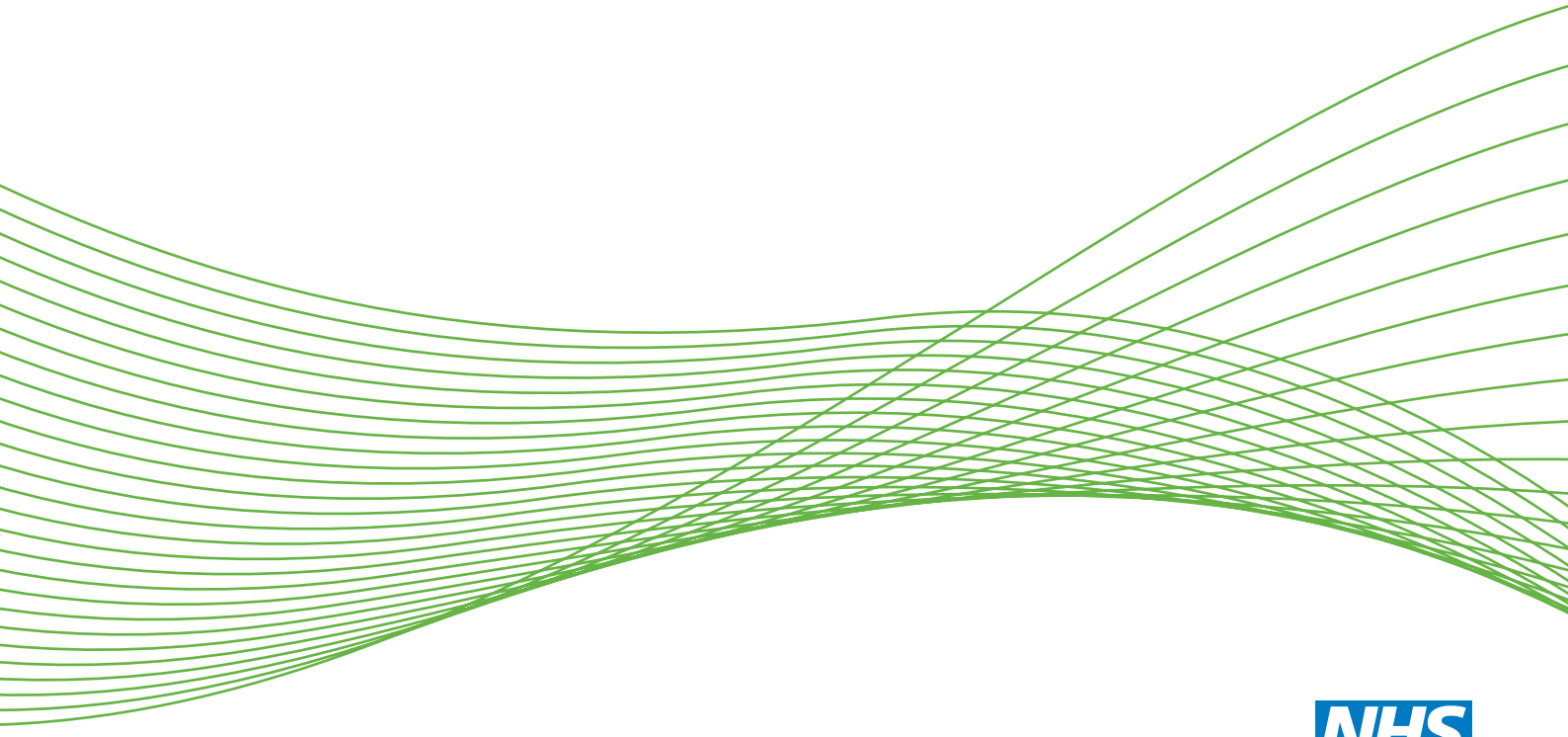

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Treatment of childhood anxiety disorder in the context of maternal anxiety disorder: a randomised controlled trial and economic analysis

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Abstract

Treatment of childhood anxiety disorder in the context of maternal anxiety disorder: a randomised controlled trial and economic analysis

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Background: Cognitive–behavioural therapy (CBT) for childhood anxiety disorders is associated with modest outcomes in the context of parental anxiety disorder.

Objectives: This study evaluated whether or not the outcome of CBT for children with anxiety disorders in the context of maternal anxiety disorders is improved by the addition of (i) treatment of maternal anxiety disorders, or (ii) treatment focused on maternal responses. The incremental cost-effectiveness of the additional treatments was also evaluated.

Design: Participants were randomised to receive (i) child cognitive–behavioural therapy (CCBT); (ii) CCBT with CBT to target maternal anxiety disorders [CCBT + maternal cognitive–behavioural therapy (MCBT)]; or (iii) CCBT with an intervention to target mother–child interactions (MCIs) (CCBT + MCI).

Setting: A NHS university clinic in Berkshire, UK.

Participants: Two hundred and eleven children with a primary anxiety disorder, whose mothers also had an anxiety disorder.

Interventions: All families received eight sessions of individual CCBT. Mothers in the CCBT + MCBT arm also received eight sessions of CBT targeting their own anxiety disorders. Mothers in the MCI arm received 10 sessions targeting maternal parenting cognitions and behaviours. Non-specific interventions were delivered to balance groups for therapist contact.

Main outcome measures: Primary clinical outcomes were the child's primary anxiety disorder status and degree of improvement at the end of treatment. Follow-up assessments were conducted at 6 and 12 months. Outcomes in the economic analyses were identified and measured using estimated quality-adjusted life-years (QALYs). QALYS were combined with treatment, health and social care costs and presented within an incremental cost–utility analysis framework with associated uncertainty.

Results: MCBT was associated with significant short-term improvement in maternal anxiety; however, after children had received CCBT, group differences were no longer apparent. CCBT + MCI was associated with a reduction in maternal overinvolvement and more confident expectations of the child. However, neither CCBT + MCBT nor CCBT + MCI conferred a significant post-treatment benefit over CCBT in terms of child anxiety disorder diagnoses [adjusted risk ratio (RR) 1.18, 95% confidence interval (CI) 0.87 to 1.62, $p = 0.29$; adjusted RR CCBT + MCI vs. control: adjusted RR 1.22, 95% CI 0.90 to 1.67, $p = 0.20$, respectively] or global improvement ratings (adjusted RR 1.25, 95% CI 1.00 to 1.59, $p = 0.05$; adjusted RR 1.20, 95% CI 0.95 to 1.53, $p = 0.13$). CCBT + MCI outperformed CCBT on some secondary outcome measures. Furthermore, primary economic analyses suggested that, at commonly accepted thresholds of cost-effectiveness, the probability that CCBT + MCI will be cost-effective in comparison with CCBT (plus non-specific interventions) is about 75%.

Conclusions: Good outcomes were achieved for children and their mothers across treatment conditions. There was no evidence of a benefit to child outcome of supplementing CCBT with either intervention focusing on maternal anxiety disorder or maternal cognitions and behaviours. However, supplementing CCBT with treatment that targeted maternal cognitions and behaviours represented a cost-effective use of resources, although the high percentage of missing data on some economic variables is a shortcoming. Future work should consider whether or not effects of the adjunct interventions are enhanced in particular contexts. The economic findings highlight the utility of considering the use of a broad range of services when evaluating interventions with this client group.

Trial registration: Current Controlled Trials ISRCTN19762288.

Funding: This trial was funded by the Medical Research Council (MRC) and Berkshire Healthcare Foundation Trust and managed by the National Institute for Health Research (NIHR) on behalf of the MRC–NIHR partnership (09/800/17) and will be published in full in *Health Technology Assessment*; Vol. 19, No. 38.

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List of abbreviations

A&E	accident and emergency
ADIS-C/P	Anxiety Disorder Interview Schedule for DSM-IV – child and parent report
ADIS-IV	Anxiety Disorder Interview Schedule for DSM-IV
CAIS	Child Anxiety Impact Scale
CAIS-c	Child Anxiety Impact Scale – child report
CAIS-p	Child Anxiety Impact Scale – parent report
CAMHS	Child and Adolescent Mental Health Services
CAS-t	Child Adjustment to School – teacher report
CBT	cognitive–behavioural therapy
CCBT	child cognitive–behavioural therapy
CEAC	cost-effectiveness acceptability curve
CGI-I	Clinical Global Impression – Improvement
CI	confidence interval
CSR	clinical severity rating
CUA	cost–utility analysis
DASS-21	Depression Anxiety Stress Scale
DSM-IV	*Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition
EQ-5D	European Quality of Life-5 Dimensions
FH	family health
GAD	generalised anxiety disorder
HCHS	Hospital and Community Health Service
ICC	intraclass correlation
ICER	incremental cost-effectiveness ratio
ITT	intention to treat
MCBT	maternal cognitive–behavioural therapy
MCI	mother–child interaction
NDC	non-directive counselling
NICE	National Institute for Health and Care Excellence
NMB	net monetary benefit
OLS	ordinary least squares
PD	panic disorder
PP	per protocol
PSWQ	Penn State Worry Questionnaire
QALY	quality-adjusted life-year
RCT	randomised controlled trial
RPI	Retail Price Index
RR	risk ratio
SAD	separation anxiety disorder
SCAS	Spence Child Anxiety Scale
SCAS-c	Spence Child Anxiety Scale – child report
SCAS-p	Spence Child Anxiety Scale – parent report
SCAS-t	Spence Child Anxiety Scale – teacher report
SD	standard deviation
SDQ	Strengths and Difficulties Questionnaire
SDQ-c	Strengths and Difficulties Questionnaire – child report
SDQ-p	Strengths and Difficulties Questionnaire – parent report
SDQ-t	Strengths and Difficulties Questionnaire – teacher report
SES	socioeconomic status

SIAS	Social Interaction Anxiety Scale	SMFQ-p	Short Mood and Feelings Questionnaire – parent report
SMFQ	Short Mood and Feelings Questionnaire	SPS	Social Phobia Scale
SMFQ-c	Short Mood and Feelings Questionnaire – child report	TSC	Trial Steering Committee

Plain English summary

Anxiety disorders are characterised by a level of fear and avoidance that interferes in day-to-day life. They are among the most common emotional difficulties experienced by children and present a risk for ongoing emotional difficulties in later life. A talking therapy called cognitive–behavioural therapy (CBT) is effective for the treatment of childhood anxiety disorders; however, if parents also have an anxiety disorder children often do not benefit as much as they should. We set out to establish whether or not supplementing CBT for the child (child cognitive–behavioural therapy; CCBT) with (i) CBT focused on maternal anxiety disorders, or (ii) an intervention focused on maternal parenting responses, would lead to better child treatment outcomes than CCBT alone.

A total of 211 children were randomly allocated to (i) CCBT and CBT for the maternal anxiety disorder (CCBT + maternal CBT); (ii) CCBT and an intervention focused on how the mother interacted with her child [CCBT + mother–child interaction (MCI)]; or (iii) CCBT alone.

In terms of children's anxiety disorder diagnoses, severity and symptoms, there was only limited evidence that supplementing individual CBT for children with anxiety disorders with either intervention significantly improved treatment outcomes. However, when the cost and relative benefits of treatment to the child were taken into account, the intervention focused on the MCI was good value for money compared with CCBT alone.

These findings suggest that, in the context of maternal anxiety disorders, adding treatment focused on how mothers respond to their child, but not treatment focused on maternal anxiety disorders, may be a cost-effective approach to treatment.

Scientific summary

Background

Anxiety disorders are among the most common psychological disorders in childhood and are associated with adverse outcomes throughout the life course. Psychological treatments [specifically cognitive–behavioural therapy, (CBT)] have established effectiveness; however, one group who have not been found to benefit as much as others are children with anxiety disorders who have a parent who also has an anxiety disorder.

There has been limited consideration of how to improve treatment outcomes for children with anxiety disorders in the context of parental anxiety disorder. Two trials have delivered CBT for the parental disorder alongside CBT for the child; however, in both these cases the parental CBT was brief and did not significantly improve parental anxiety. It remains unclear whether or not successful treatment of parental anxiety would lead to benefits in child anxiety outcomes following CBT.

An alternative explanation for the relatively poor outcomes for children with anxiety disorders in the context of parental anxiety is that particular parenting responses (that are more common among highly anxious parents) may reinforce child anxiety disorder and, thus, militate against good treatment outcomes. Particular parental responses that have been implicated in the maintenance of child anxiety disorders include an overprotective parenting style, expressed anxiety when the child faces a challenge, and negative expectations about the child's competence and coping.

The aim of the trial was to establish the relative clinical effectiveness and cost-effectiveness of treatments of (i) maternal anxiety, and (ii) key parenting responses, for children with anxiety disorders who have a primary-caregiving mother with a current anxiety disorder.

Objectives

This randomised controlled trial (RCT) for child anxiety disorder occurring in the context of maternal anxiety disorder, set out to address the following principal questions:

1. Is the impact of child cognitive–behavioural therapy (CCBT) enhanced by first providing CBT to the mother for her own anxiety disorder?
2. Is the impact of CCBT enhanced by the addition of therapeutic measures designed to target maternal parenting responses?

In addition the following secondary questions were addressed:

i. Is sustained improvement in child anxiety significantly associated with a reduction in maternal anxiety?
ii. Is sustained improvement in child anxiety significantly associated with improvements in maternal modelling, encouragement, overcontrolling/overprotective behaviour and associated cognitions?

Methods

We carried out a RCT in which we compared CCBT with (i) CBT focused on the maternal anxiety disorder in addition to CCBT, and (ii) an intervention focused on promoting positive maternal responses to the child in addition to CCBT. The randomisation ratio was 1 : 1. The randomisation was carried out with a remote facsimile system and was minimised for child age, gender, primary anxiety disorder diagnosis, and baseline severity of the child and the mother's primary anxiety disorder.

Participants were recruited from referrals to NHS Child and Adolescent Mental Health Services across Berkshire.

The inclusion criteria for children were age (7–12 years) and primary diagnosis of a current anxiety disorder according to the *Diagnostic and Statistical Manual of Mental Disorders,* Fourth Edition (DSM-IV) (American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*. 4th edn. Washington, DC: American Psychiatric Association; 2000). The inclusion criteria for mothers were that the mother was the primary carer and had a current DSM-IV anxiety disorder. Exclusion criteria for children were significant and intellectual impairment, a current prescription of psychotropic medication that had not been at a stable dose for at least 1 month and without agreement to maintain a stable dose for the duration of the study, and previous receipt of six or more sessions of CBT. Exclusion criteria for mothers were significant intellectual impairment, a severe comorbid disorder (that would interfere with the mothers ability to participate in treatment sessions), or a current prescription of psychotropic medication that had not been at a stable dose for at least 1 month and without agreement to maintain a stable dose for the duration of the study.

The primary outcomes were the number of children who were free of their primary anxiety disorder diagnosis, and the number who were classified as 'much' or 'very much' improved on the Clinical Global Impression – Improvement scale immediately after the treatment phase. Further follow-ups were conducted 6 and 12 months after the end of treatment. Secondary outcomes were the severity of the child's primary diagnosis, the number of children who were free of all their anxiety diagnoses, child- and mother-reported child anxiety symptoms, impact and comorbid symptoms, and teacher-reported anxiety and adjustment at school.

Outcomes for the economic analyses were identified and measured using quality-adjusted life-years (QALYs), estimated on the basis of child reports on the European Quality of Life-5 Dimensions at all assessments from baseline to the 12-month follow-up. Costs associated with each treatment arm were based on patient-level resource use data, collected as an integral part of the trial data collection process on the basis of mother and therapist report.

All children received individual CBT over eight weekly sessions. Mothers randomised to the maternal cognitive–behavioural therapy (MCBT) treatment arm received eight weekly individual CBT sessions focused on their own difficulties with anxiety. Mothers in the other two arms received a non-specific intervention [non-directive counselling (NDC)] to balance for therapist contact. Mothers in the CCBT + mother–child interaction (MCI) arm received 10 therapeutic sessions (over 8 weeks; eight with the mother alone and two with the mother and child) which were designed to target potentially anxiogenic maternal parenting behaviours. Those in the other two treatment arms received a non-specific intervention to balance for therapist contact (family health; FH). All therapists followed written manuals, received regular supervision and audio-recorded treatment sessions so that adherence to treatment protocols could be evaluated.

Results

A total of 676 potential participants were assessed for eligibility. Of these, 435 participants did not meet eligibility criteria (in the majority of cases because the mother did not have a concurrent anxiety disorder) and 30 eligible families did not give consent to participate. A total of 211 children were randomised, with 84% assessed at the post-treatment assessment, and 72% and 65% at 6- and 12-month follow-up assessments, respectively.

At baseline 69 participants were randomised to the MCBT + CCBT arm, 71 participants to MCI + CCBT and 71 participants to CCBT + non-specific interventions. The three randomised groups were comparable at baseline. Analysis of audio-recordings of treatment sessions showed that there were no significant differences in adherence to the CCBT treatment protocol across the three treatment arms. The content of the targeted and non-specific interventions were significantly different in the case of both MCBT and NDC, and MCI and FH, in both cases indicating that the content of the treatments differed as intended. There was also evidence that both the MCBT and MCI interventions were associated with some change in the variables that they were targeting. Immediately after the MCBT intervention, mothers in the CCBT + MCBT arm were 1.63 times more likely to have recovered from their primary diagnosis and 2.51 times more likely to have recovered from all their anxiety diagnoses compared with mothers in the CCBT arm. However, there were no significant differences on maternal self-report questionnaire scores. Furthermore, by the later assessment points maternal recovery rates improved for all treatment arms and differences between arms were no longer significant. In comparison to those in the CCBT arm, mothers who received CCBT + MCI showed a greater change in observed overprotection and expectations relating to how scared and in control their child would be compared with the CCBT arm. Significant differences were not found on any other measures of parenting response.

The primary analysis indicated that, for the number of children free of their primary diagnosis, although the CCBT + MCBT and CCBT + MCI arms were associated with better outcomes, these were not significantly different from the CCBT arm [CCBT + MCBT risk ratio (RR) 1.21, 95% confidence interval (CI) 0.86 to 1.71, $p = 0.280$; CCBT + MCI vs. CCBT RR 1.24, 95% CI 0.88 to 1.74, $p = 0.219$]. This was also the case for the number 'much' or 'very much' improved (CCBT + MCBT RR 1.24, 95% CI 0.99 to 1.57, $p = 0.065$; CCBT + MCI RR 1.18, 95% CI 0.93 to 1.50, $p = 0.179$). At the 6- and 12-month follow-up assessments CCBT + MCI (but not CCBT + MCBT) continued to be associated with relatively high recovery rates, but neither of the groups differed significantly from CCBT. Significantly more children (92%) in the CCBT + MCI arm, compared with the CCBT arm (73%), showed a reduction in severity of their primary diagnosis 6 months post treatment [$\chi^2(1) = 6.19$; $p = 0.013$]. A similar pattern was found at the 12-month follow-up; however, this was not statistically significant. No significant differences were found on child, mother or teacher between treatment arms at any assessment point.

Analysis of the secondary research questions yielded inconsistent results, both across reporters and assessment time points. There was not a consistent pattern of association between change in maternal anxiety or parenting responses and change in child outcomes, so clear conclusions about mechanisms of change cannot be drawn at this stage.

The economic evaluations suggested that from a health service perspective only, the mean health cost of the CCBT + MCBT arm was on average £233.55 (95% CI –£6.81 to £473.92) higher than the CCBT arm, whereas mean child QALY gain was 0.033 (95% CI –0.101 to 0.035) lower. Similarly, incremental health-care costs in the CCBT + MCI arm were on average £233.16 (95% CI –£6.81 to £473.92) higher than the CCBT arm, with the child QALY gain 0.028 (95% CI –0.030 to 0.086) higher. The cost-effectiveness acceptability curve (CEAC) for the CCBT + MCBT arm suggested that, given the distribution of the incremental cost-effectiveness ratios, CCBT + MCBT is highly unlikely to be cost-effective at current willingness-to-pay thresholds for an extra QALY (£20,000–30,000) with a probability lower than 0.1. The CEAC for the CCBT + MCI arm, however, revealed that the probability that CCBT + MCI is cost-effective in comparison with CCBT alone is around 75%. These results should, however, be interpreted in light of an

important limitation of the data, namely the high percentage of missing values in some of the follow-up resource use and outcome variables. This shortcoming was dealt with using appropriate data imputation techniques; however, imputation cannot account for potentially non-random reasons for missing data.

Conclusions

Implications for health care

- The novel intervention that focused on modifying maternal parenting responses was associated with some benefit to children and mothers with anxiety disorders, and is likely to be cost-effective. Incorporating effective measures to address maternal cognitions and behaviours when interacting with her child may improve health outcomes for children with anxiety disorders in the context of maternal anxiety disorder.
- We can be confident that supplementing individual CCBT with CBT to target the maternal anxiety disorder is unlikely to confer substantial health benefits and is unlikely to be cost-effective. Given the intensity of this intervention and its general lack of effectiveness we think it is unlikely that supplementing CCBT with this intervention will improve child outcomes.

Future research implications

- Given that CCBT alone was sufficient for the majority of patients, it is possible that any benefits from the MCI and MCBT interventions may be enhanced in particular contexts; for example, in the context of particular maternal or child anxiety disorders or high levels of severity. Future research that directly addresses these possibilities is warranted.
- The relatively low level of association between change in maternal anxiety and responses and child anxiety, may suggest that other factors may account for the modest treatment outcomes typically found among children with anxiety disorders who have mothers with anxiety disorders (such as genetic or broader social/environmental factors). Future research is warranted to address these issues.
- The economic evaluation provides insight as to the broad range of services accessed by this client group, hence it is recommended that future economic evaluations in this area incorporate data collection on this full range of services in order to capture the full impact of new interventions for this client group.

Trial registration

This trial is registered as ISRCTN19762288.

Funding

This trial was funded by the Medical Research Council (MRC) and Berkshire Healthcare Foundation Trust and managed by the National Institute for Health Research (NIHR) on behalf of the MRC–NIHR partnership (09/800/17) and will be published in full in *Health Technology Assessment*; Vol. 19, No. 38.

Chapter 1 Introduction

Scientific background

Anxiety disorders are among the most common psychological disorders in childhood, affecting 2.6–5.2% of children under the age of 12 years.[1,2] These disorders adversely affect children's functioning in personal, social and academic domains,[3,4] raise the risk for disorders in adolescence and adulthood,[5] and carry a substantial health and social cost.[6] Following advances in the development of successful cognitive–behavioural therapies (CBTs) for adult anxiety disorders,[7] CBT for child anxiety disorders has now been developed. Although there is still some uncertainty over the optimal form of such an intervention, recent systematic reviews of outcome research indicate that the general CBT approach produces significant therapeutic benefit in this patient group, with, on average, 59% of anxious children no longer meeting criteria for their primary anxiety disorder following CBT.[8] However, it is clear from these reviews, and from the individual treatment trials, that the outcome is highly variable, with a significant proportion (40.6%) of patients retaining their anxiety diagnoses following treatment.[8]

Parental anxiety disorders are associated with poor treatment outcomes

One way of further improving children's responses to treatment is to identify predictors of poor outcome which are amenable to therapeutic change. One of these is parental emotional distress, in particular parental anxiety disorder, which has been found to be associated with up to a 50% reduction in child recovery following treatment.[6,9–13] This is of great significance given that the rate of anxiety disorder among the parents of anxious children is raised.[14,15] Indeed, in a consecutive series of children referred for treatment of an anxiety disorder in our clinic, two-thirds of the mothers were found to have a current *Diagnostic and Statistical Manual of Mental Disorders*, Fourth Edition (DSM-IV)[16] anxiety disorder (with no elevated rate of current disorder among the fathers), almost three times the base rate.[17]

Two studies to date have examined whether or not targeting parental anxiety might benefit child treatment outcome. Cobham and colleagues[9] found that supplementing child cognitive–behavioural therapy (CCBT) with parent anxiety management was associated with significantly improved diagnostic outcomes for children with anxiety disorders whose parents had elevated trait anxiety; however, this group did not maintain a specific benefit from the parent anxiety management treatment at a 3-year follow-up.[18] More recently, Hudson and colleagues[19] used a similar design but classified groups according to parental anxiety disorder status. In this study, CCBT + parent anxiety management did not confer a significant benefit over CCBT post teatment or at a 6-month follow-up assessment. Notably, both studies administered brief treatments for parental anxiety which did not have an overall impact on parental anxiety symptoms or disorder. The question therefore remains open as to whether or not successful treatment of parental anxiety might benefit child outcome.

Other mechanisms associated with poor outcomes

An alternative possibility is that it might not be parental anxiety, per se, that is prognostically significant for child response to treatment but, rather, the parenting practices associated with high levels of parental anxiety that themselves reinforce or maintain the child disorder. Specific parenting responses have been implicated in the maintenance of child anxiety, in particular an overcontrolling and overprotective parental style, expressed anxiety when the child is faced with challenge, [20,21] and associated parental cognitions and expectations about child competence.[22] These behaviours are known to obtain significantly more in anxious than in non-anxious parents of children with anxiety disorder,[23,24] as are associated cognitions characterised by elevated expectations that the child will be frightened and feel out of control in the face of a challenge.[23] Recent studies have suggested that targeting parental anxiety may be pertinent only insofar as it changes behaviours that are likely to interfere with the child's treatment.[25] These studies suggest, therefore, that targeting parenting cognitions and behaviours, rather than parental anxiety,

may be of most benefit in bringing about improvement in anxious children's response to treatment in the context of parental anxiety disorders.

Implications for optimal treatment outcomes

Cognitive–behavioural therapy treatments of child anxiety disorder commonly require the day-to-day prosecution of treatment regimes to be managed by the parent (e.g. parents are typically required to model positive responses to fear provoking stimuli and to prompt and reinforce their child's positive responses), so it is likely that the parent's own anxiety and the associated disturbances in parenting responses may militate against optimal treatment delivery. Although the CBT treatments developed to date for the treatment of child anxiety do acknowledge the importance of both parental anxiety and parenting,[26–29] there has been no systematic evaluation of an intervention in which both parental anxiety and parenting responses are specifically addressed. There is, therefore, a need for the development and evaluation of a CBT treatment for child anxiety disorder in which parental anxiety and associated patterns of parental responses to the child are systematically targeted.

Rationale for the research

The outcome from CBT for children with anxiety disorders is highly variable. Major factors contributing to this are likely to be the presence of parental anxiety and associated disturbances in how parents respond to their children when they are faced with challenges. Where parental anxiety has been addressed in treatment research,[26–29] for several methodological reasons, it has been difficult to assess its contribution to child outcome. Two studies have systematically targeted parental anxiety in the treatment of child anxiety disorders. In one,[9] child anxiety outcome was better where therapeutic measures to address parental anxiety symptoms were included, and in the other[19] children's outcomes were not improved. In both cases, as the treatment did not significantly alter levels of parental anxiety, it remains unclear what aspect of the treatment effected the clinical improvement in the children. Similarly, where therapeutic measures to address parenting responses have been included,[30] it has not been possible to determine the specific role of such measures in the complex treatment package employed. A controlled trial in which both factors – treatment of parental anxiety and measures to alter parenting responses – are systematically varied, would produce data of both clinical utility and scientific importance. The study was determined on this basis, and there was no patient or public input at this stage.

Although paternal behaviours are likely to contribute to the maintenance of child anxiety disorder, this study focused on mothers for the following reasons: (i) it has been suggested that the parental responses that may promote anxiety among children differ for mothers and fathers;[31] (ii) anxiety disorders are more common among women than men[32] and, also, more common among mothers of children with anxiety disorders than fathers;[17] (iii) mothers are most commonly the primary caregiving parent in the study region and are more likely to attend treatment sessions for their child (e.g. in a recent study in the same region, 98% of parents nominated as primary caregivers in order to attend treatment were mothers[33]).

Aims

The aim of the trial was to establish the relative clinical effectiveness and cost-effectiveness of treatments of (i) maternal anxiety and (ii) key maternal parenting responses for children with anxiety disorders who have a mother with current anxiety disorder.

Research questions

In a randomised controlled trial (RCT) for child anxiety occurring in the context of maternal anxiety, the principal questions are:

1. Is the impact of CCBT enhanced by first providing CBT to the mother for her own anxiety?
2. Is the impact of CCBT enhanced by the addition of therapeutic measures designed to address potentially anxiogenic maternal parenting responses?

Secondary questions are:

1. Is sustained improvement in child anxiety significantly associated with a reduction in maternal anxiety?
2. Is sustained improvement in child anxiety significantly associated with improvements in maternal modelling, encouragement, overcontrolling/overprotective behaviour and associated cognitions?

Chapter 2 Trial design and methods

Study design

The trial was set up to evaluate the benefit of supplementing individual CCBT with either treatment of maternal anxiety disorder or treatment that targeted maternal responses when interacting with her child, for children with anxiety disorders whose mothers also had a current anxiety disorder. A three-arm trial was conducted in which children received individual CCBT in all three arms, supplemented by either CBT for the maternal anxiety disorder [CCBT + maternal cognitive–behavioural therapy (MCBT)] or a mother–child interaction (MCI) focused intervention. Non-specific interventions were also delivered in all treatment arms in order to balance therapist contact. The main trial was supplemented with an economic evaluation to consider the cost-effectiveness of the CCBT and MCI interventions.

Ethical approval and research governance

Ethical approval for the study was given by Berkshire Research Ethics Committee (07/H0505/156) and the University of Reading Research Ethics Committee (07/48). The trial was registered with the International Standard Randomised Controlled Trial Register under the reference number 19762288.

Participants

Participants were 211 children, aged 7–12 years [mean age 10.22 years, standard deviation (SD) 1.58], with a current anxiety disorder, together with their mothers. As noted above, the study focused on mothers as (i) intergenerational associations for anxiety disorders are most commonly found between mothers and their children;[17] (ii) mothers are most commonly the primary caregivers in the study region; and (iii) paternal behaviours may have different associations with childhood anxiety.[34] Participants were all referred to Berkshire Child Anxiety Clinic, run jointly by Berkshire Healthcare NHS Foundation Trust and the University of Reading, by a health or educational professional. Participants were recruited between June 2008 and May 2011, with the last follow-up assessment in February 2013.

Inclusion criteria

Child

i. Age 7–12 years.
ii. Primary diagnosis of DSM-IV generalised anxiety disorder (GAD), social phobia, separation anxiety disorder (SAD), panic disorder (PD)/agoraphobia or specific phobia (if comorbid with another anxiety disorder).

Mother

i. Primary carer.
ii. Current maternal DSM-IV anxiety disorder.

Exclusion criteria

Participants were not eligible if any of the following criteria are met.

Child

i. Significant physical (where it would impede treatment delivery) or intellectual impairment (including autistic spectrum disorders) (determined by registration with local learning disability services).
ii. Current prescription of psychotropic medication that had not been at a stable dose for at least 1 month and without agreement to maintain that dose throughout the study.
iii. Previously received six or more sessions of systematically administered CBT for an anxiety disorder.

Mother

i. Significant intellectual impairment (determined by registration with local learning disability services).
ii. Severe comorbid disorder (e.g. severe major depressive disorder, psychosis, substance/alcohol dependence that would interfere with the mothers ability to participate in treatment).
iii. Prescription of psychotropic medication that had not been at a stable dose for at least 1 month and without agreement to maintain that dose throughout the study.

If participating mothers were having any ongoing treatment, this did not preclude them from participating in the trial, but ideally, any psychotherapeutic treatment should have finished prior to initiating this trial.

Six children were recruited to the trial (two in each treatment arm) who were assigned a primary diagnosis of anxiety disorder not otherwise specified. Following consultation with the trial management team it was decided to include these children as the anxiety disorder not otherwise specified diagnosis reflected a slight variation from meeting diagnostic criteria for GAD. One child was recruited to the trial (CCBT + MCI arm) on the basis of having a primary diagnosis of selective mutism; and in this case the trial management group agreed to inclusion as the selective mutism was comorbid with, and was considered to be a manifestation of, social anxiety disorder. Four children were outside the specified age range at the point of randomisation. One child was 6 years old but was due to turn the age of 7 years before initiating treatment (CCBT + MCI arm); three turned 13 years of age between the initial assessment and randomisation.

Recruitment procedure

The recruitment schedule is shown in *Figure 1*.

Informed consent

Participants were given a complete description of the study orally and in writing prior to written informed consent being obtained from participating mothers and assent from participating children. As shown in *Figure 2*, 676 children were referred and assessed for eligibility. A total of 435 families did not meet the inclusion criteria (24 children and 311 mothers because they did not meet criteria for a current anxiety disorder). Assent/consent was not given by 30 families.

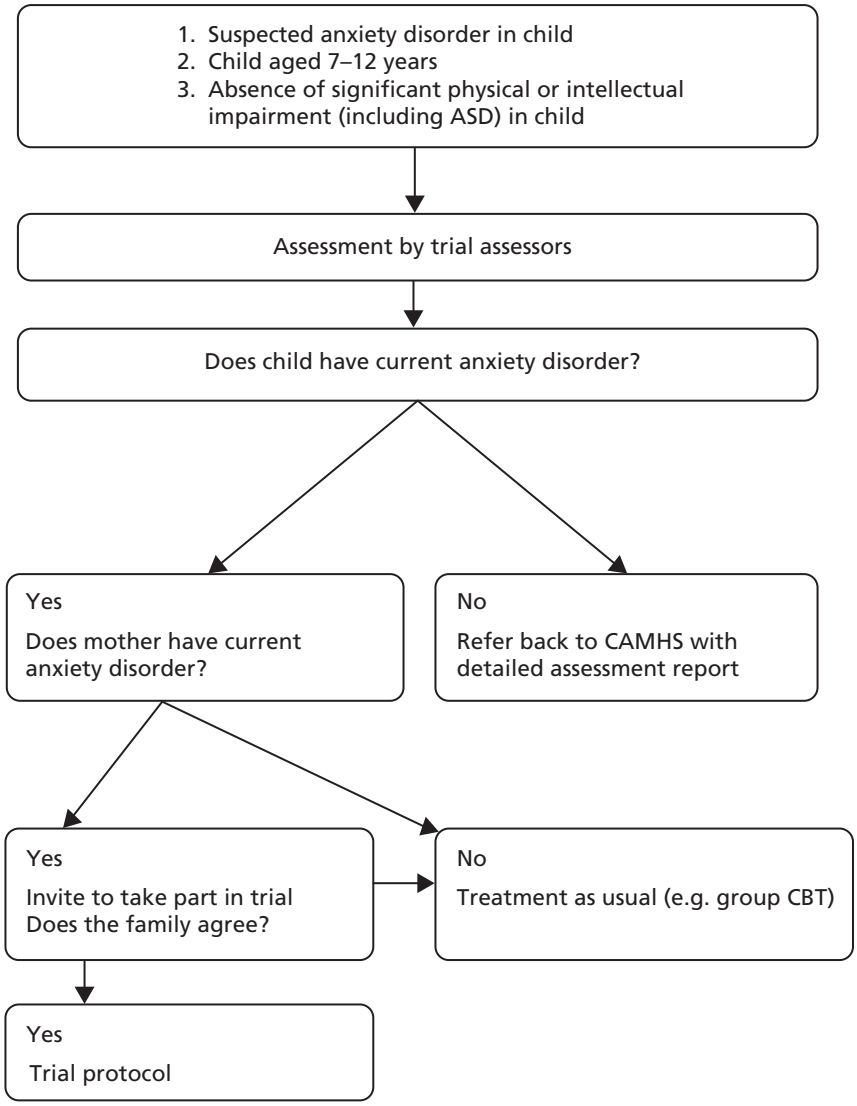
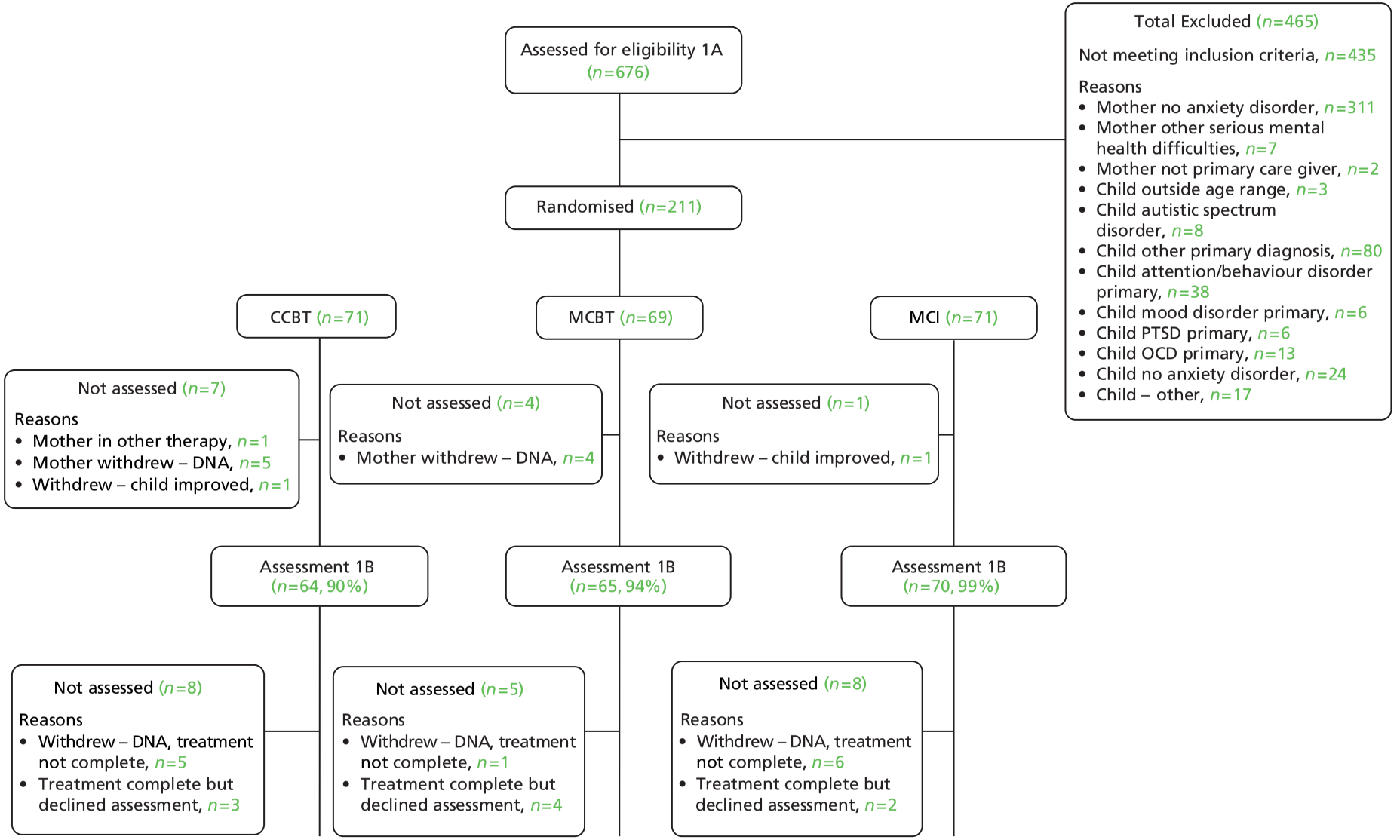


FIGURE 1 Flow chart outlining recruitment schedule. ASD, autistic spectrum disorder; CAMHS, Child and Adolescent Mental Health Services.


Assessed for eligibility 1A (n=676)
Total Excluded (n=465)
Not meeting inclusion criteria, n=435
Reasons
• Mother no anxiety disorder, n=311
• Mother other serious mental health difficulties, n=7
• Mother not primary care giver, n=2
• Child outside age range, n=3
• Child autistic spectrum disorder, n=8
• Child other primary diagnosis, n=80
• Child attention/behaviour disorder primary, n=38
• Child mood disorder primary, n=6
• Child PTSD primary, n=6
• Child OCD primary, n=13
• Child no anxiety disorder, n=24
• Child – other, n=17
Randomised (n=211)
CCBT (n=71)
MCBT (n=69)
MCI (n=71)
Not assessed (n=7)
Reasons
• Mother in other therapy, n=1
• Mother withdrew – DNA, n=5
• Withdrew – child improved, n=1
Not assessed (n=4)
Reasons
• Mother withdrew – DNA, n=4
Not assessed (n=1)
Reasons
• Withdrew – child improved, n=1
Assessment 1B (n=64, 90%)
Assessment 1B (n=65, 94%)
Assessment 1B (n=70, 99%)
Not assessed (n=8)
Reasons
• Withdrew – DNA, treatment not complete, n=5
• Treatment complete but declined assessment, n=3
Not assessed (n=5)
Reasons
• Withdrew – DNA, treatment not complete, n=1
• Treatment complete but declined assessment, n=4
Not assessed (n=8)
Reasons
• Withdrew – DNA, treatment not complete, n=6
• Treatment complete but declined assessment, n=2

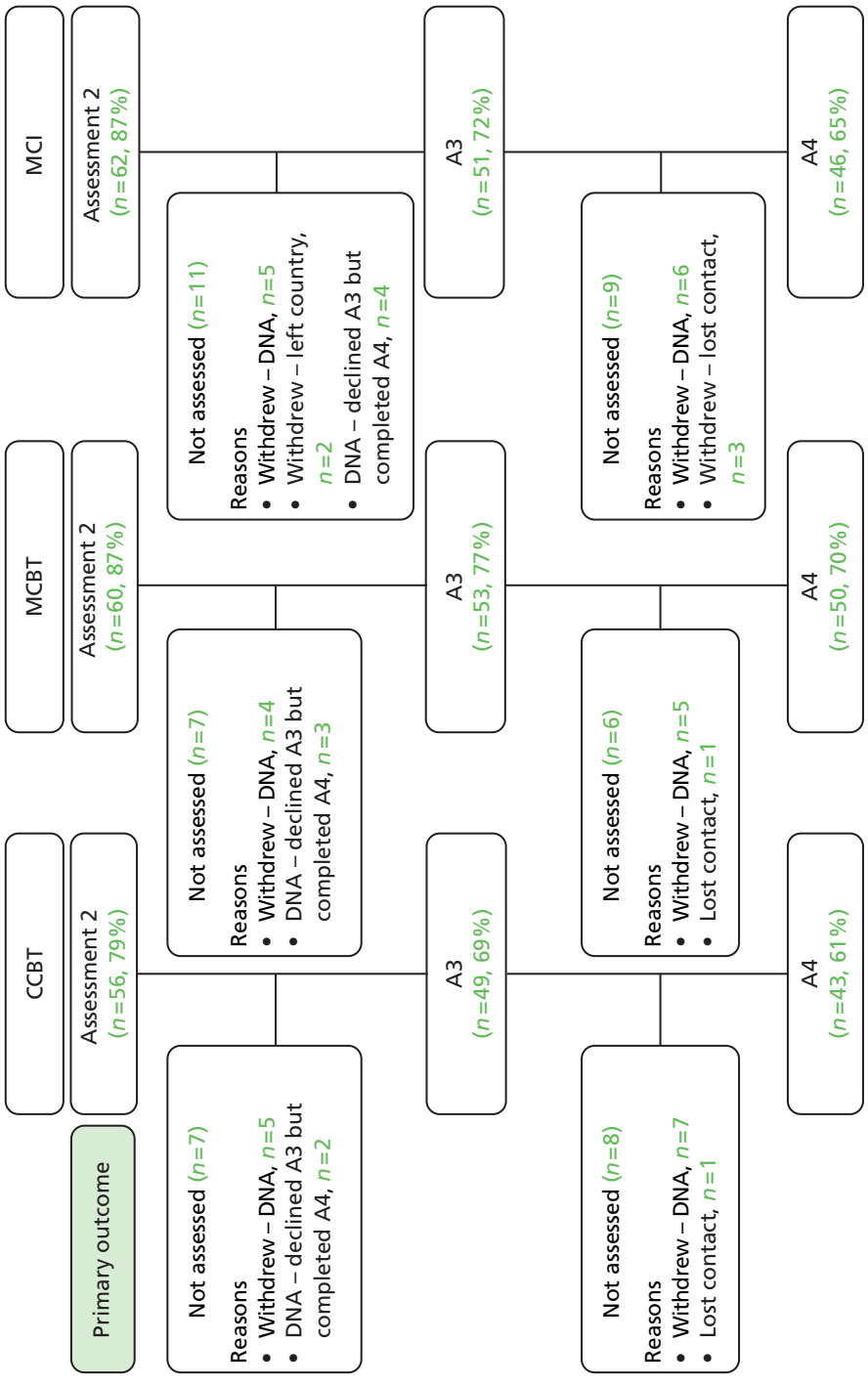


FIGURE 2 Consolidated Standards of Reporting Trials diagram. A3, assessment 3; A4, assessment 4. DNA, did not attend; OCD, obsessive–compulsive disorder; PTSD, post-traumatic stress disorder.

Randomisation, concealment and blinding

Participants were randomised to one of three treatment conditions: (i) CCBT; (ii) CCBT plus CBT for maternal anxiety disorder (CCBT + MCBT); or (iii) CCBT plus treatment focused on the MCI (CCBT + MCI). Each of the three conditions included non-specific therapeutic interventions to balance the treatment arms for therapist contact with both children and mothers. These were non-directive counselling (NDC; for mothers not receiving MCBT, i.e. groups i and iii) and a family health (FH) intervention (for those not receiving MCI, i.e. groups i and ii), see *Table 1*.

Randomisation was performed externally at the Centre for Statistics in Medicine (University of Oxford, UK) on receipt of anonymised participant information by fax. Patients were randomised with a 1 : 1 : 1 ratio and minimisation was used to ensure balanced allocation across the treatment groups for child age, gender and type of child anxiety disorder, and baseline severity of the child's and mother's primary anxiety disorder. The trial manager was informed of randomisation and allocated participants to therapists for treatment. All assessors and coders remained blind to treatment group for the duration of the study.

Treatment group allocation

The order of treatment delivery is shown in *Table 1*. MCBT/NDC was delivered first, then the CCBT and MCI/FH interventions were delivered in parallel. Each phase of treatment (MCBT/NDC, CCBT, MCI/FH) was delivered by a different therapist.

Child cognitive–behavioural therapy

All children, in all treatment arms, received eight 1-hour weekly sessions of individual CBT delivered by 1 of 10 qualified clinical psychologists or cognitive–behaviour therapists (graduate therapists who held postgraduate certificates/diplomas in CBT), following a manual adapted from the widely used 'Cool Kids' programme[35] to be used on an individual rather than group basis. Core components of the treatment include psychoeducation, identification and modification of anxious thoughts, and graded exposure to feared situations/stimuli. The adaptations involved reducing the number of sessions to eight (from nine) as the content could be covered more quickly on an individual basis, and altering exercises and practices so that they worked well on an individual basis using strategies from the 'Coping Cat' programme.[36] Sessions took place in

TABLE 1 Overview of design

Condition	CCBT	CCBT + MCBT	CCBT + MCI
Assessment 1: pre treatment	Diagnostic assessment (mother and child) + laboratory observation of MCI		
Treatment 1	NDC (8)	MCBT (8)	NDC (2)
Assessment 1B: mid-treatment (number of sessions)	Diagnostic assessment (mother and child)		
Treatment 2 (number of sessions)	CCBT (8) + FH (mother: 2; child + mother: 2)	CCBT (8) + FH (mother: 2; child + mother: 2)	CCBT (8) + MCI (mother: 8; child + mother: 2)
Assessment 2: post treatment	Diagnostic assessment (mother and child) + laboratory observation of MCI		
Assessment 3: 6 months post treatment	Diagnostic assessment (child)		
Assessment 4: 12 months post treatment	Diagnostic assessment (child)		
Total therapy sessions	Mother: 10	Mother: 10	Mother: 10
	Child: 8	Child: 8	Child: 8
	Child + mother: 2	Child + mother: 2	Child + mother: 2

the participants' local Child and Adolescent Mental Health Services (CAMHS), at the University of Reading Child Anxiety Clinic or within the child's home. The focus of treatment was on helping children to identify and challenge negative thinking styles, gradually increase exposure to feared stimuli and develop problem-solving skills. Mothers were included briefly in giving and receiving feedback at the beginning and end of each session (for approximately 5 minutes). To ensure therapist adherence to the CCBT treatment manual was equivalent across condition, 75 treatment sessions (25 from each condition) were rated for adherence to the manual (in terms of therapist stance, coverage of general and specific content) by blind raters (minimum Bachelor of Science psychology) trained to acceptable levels of reliability [therapist stance: intraclass correlation (ICC) = 0.76–76; general content: ICC = 0.73–0.82; specific content: ICC = 0.81–0.89]. Treatment adherence for CCBT did not differ across the three conditions [therapist stance: $F(2,72) = 1.83$, $p = 0.17$; general content: $F(2,72) = 0.80$, $p = 0.92$; specific content: $F(2,72) = 0.23$, $p = 0.80$].

Maternal cognitive–behavioural therapy

Maternal cognitive–behavioural therapy consisted of eight 1-hour weekly sessions delivered by one of seven clinical psychologists or cognitive–behaviour therapists (all supervised by a highly experienced clinical psychologist who was a British Association of Behavioural & Cognitive Psychotherapies-accredited cognitive–behaviour therapist) following a manualised transdiagnostic treatment for adult anxiety disorders.[37] A transdiagnostic approach was applied on the basis that mothers presented with various anxiety disorders; the effectiveness of a transdiagnostic approach to anxiety disorders has been established in similar contexts.[38] This treatment used cognitive–behavioural methods to reverse the putative maintaining mechanisms identified through individual formulation. Treatment was delivered in the participants' local CAMHS, at the University of Reading Child Anxiety Clinic or within the family's home.

Groups that did not receive MCBT received a non-specific intervention (NDC), in which mothers received a supportive individual intervention that was not focused specifically on reducing symptoms of anxiety but involved supportive non-directive listening for clients to facilitate self-reflection and to clarify and focus on feelings within an accepting, non-judgemental, empathic environment, following the manual of Borkovec and Costello.[39] NDC was provided by one of five qualified counsellors (all accredited by the British Association for Counselling & Psychotherapy), supervised by a highly experienced counsellor/psychotherapist with senior British Association for Counselling & Psychotherapy accreditation.[39] To ensure fidelity of the two treatments, the content of therapist utterances from 100 treatment sessions (50 MCBT, 50 NDC) was allocated by independent raters (psychology graduates), trained to a high level of reliability, to categories considered as allowed or not allowed within each treatment condition (reliability of proportion of allowable utterances, MCBT ICC = 0.73; NDC, ICC = 0.73). The proportion of MCBT allowable utterances was significantly higher in MCBT than in NDC [$t(98) = 6.25$; $p < 0.001$] and the proportion of NDC allowable utterances was significantly higher in NDC than in MCBT [$t(98) = 4.40$; $p < 0.001$], indicating that the content of the two treatments differed as intended. As shown in *Table 1*, MCBT and NDC were delivered first, before the delivery of CCBT.

Mother–child interaction treatment

The MCI intervention consisted of 10 sessions delivered over 8 weeks by one of seven qualified clinical psychologists or cognitive–behaviour therapists (supervised by an experienced clinical psychologist): eight sessions were with the mother alone and two were with the mother and child together. This was a novel intervention designed to target potentially anxiogenic maternal parenting behaviours. Specifically, it aimed to enhance maternal autonomy promoting cognitions (such as confidence in her child's ability to face challenge) and behaviours and reduce potentially anxiogenic behaviours. This was achieved through a combination of specific strategies from existing family interventions for childhood anxiety,[30,35] with the addition of video-feedback techniques developed and piloted by the trial investigators.[40,41] Sessions took place in the participants' local CAMHS, at the University of Reading Child Anxiety Clinic or within the family's home. The two mother and child sessions were conducted within the laboratory at the University of Reading, as these involved the mother and child completing structured tasks which were video-recorded for feedback purposes.

To balance therapist contact, those groups that did not receive the MCI intervention received sessions that focused on the promotion of a healthy lifestyle (see *Table 1*). A manual was developed for this intervention that principally focused on following a healthy diet and participating in regular exercise using a number of worksheets, games and activities based on existing interventions applied within school settings (FH).[42–54] The FH intervention was delivered by 1 of 10 therapists [qualified clinical psychologists, cognitive–behaviour therapists and one psychology graduate (Bachelor of Science) with extensive experience of delivering behavioural interventions, under supervision of an experienced clinical psychologist (LW)].

Mother–child interaction/FH were delivered in parallel with CCBT for all participants. To ensure treatment fidelity, raters who were blind to treatment condition rated audio-recordings of 40 therapy sessions on the degree to which session content focused on the MCI or FH. Inter-rater reliability was excellent (ICC = 0.98). MCI sessions were rated significantly higher than FH sessions on the degree to which sessions focused on MCI (Mann–Whitney *U*-test = 6.01; $p < 0.0001$), and FH sessions were rated significantly higher on the degree to which session focused on FH (Mann–Whitney *U*-test = 5.90; $p < 0.0001$) indicating that the content of the two treatments differed as intended.

Data collection and management

Trial data were entered into an International Business Machine Corporation Statistical Package for the Social Sciences database (IBM SPSS, version 17; IBM Corporation, Armonk, NY, USA) and monitoring and tracking information was entered onto a Microsoft Access 2003 database (Microsoft Corporation, Redmond, WA, USA). A range of data validation checks were carried out in Access, SPSS and Stata Software Release 12 (StataCorp LP, College Station, TX, USA) to minimise erroneous or missing data.

Assessments of maternal anxiety disorder and parenting were made before and immediately following the interventions. Assessments of child anxiety disorder status and severity were conducted before and following treatment, as well as at 6 and 12 months after treatment. All assessors were blind to treatment group allocation throughout the trial.

Baseline assessment

Baseline assessment for the trial comprised diagnostic interviews conducted with children and their mothers to ascertain whether or not both the child and his/her mother met diagnostic criteria for a current anxiety disorder. All of the follow-up measures were also administered at baseline. All baseline assessments were conducted between May 2008 and May 2011.

Follow-up

As shown in *Table 1*, follow-up data collection was scheduled to take place 'mid-treatment' [i.e. after the initial maternal intervention, MCBT/NDC (assessment 1B)], then 'post treatment' [i.e. after the CCBT and MCI/FH intervention (assessment 2)], and 6 and 12 months from the post-treatment assessment. Diagnostic assessments were conducted to establish whether or not interventions had successfully altered maternal anxiety at the 'mid-treatment' (1B) and 'post-treatment' (2) assessments. To establish whether or not the interventions had successfully altered maternal responses, observational and parent-reported measures were administered at the 'post-treatment' assessment. Child diagnostic and symptom outcomes were assessed at all time points.

All follow-up data were collected between September 2008 and February 2013. A flow chart showing all recruitment and retention is given in *Figure 2*.

Measures

Primary outcomes

The primary outcomes were (i) the status of the child's primary anxiety disorder and (ii) the extent of child improvement at the post-treatment assessment. This second primary outcome was added to the primary outcomes identified in the original protocol following its inclusion as the primary outcome in a recent major multicentre trial for the treatment of anxiety disorders,[55] with approval from the Trial Steering Committee (TSC).

Structured diagnostic interviews with children and parents

Children were assigned diagnoses on the basis of the Anxiety Disorder Interview Schedule for DSM-IV for children, child and parent versions (Anxiety Disorders Interview Schedule – child and parent report; ADIS-C/P).[56] For the ADIS-C/P, as is standard, overall diagnoses and clinical severity ratings (CSRs) were assigned if the child met diagnostic criteria on the basis of either the child or parent report, and the higher CSR of the two was taken. Following convention, only those with a CSR of ≥ 4 (moderate psychopathology) on a scale from 0 (complete absence of psychopathology) to 8 (severe psychopathology) were considered to meet diagnostic criteria. The assessors, all psychology graduates, were trained to administer and score the ADIS-C/P through verbal instruction, listening to assessment audio-recordings, role-play and participating in diagnostic consensus discussions. Each of the assessor's first 20 interviews were discussed with a consensus team, led by a consultant clinical psychologist (LW). The assessor and the consensus team independently allocated diagnoses and CSRs. Once assessors achieved reliability of at least 0.85, they discussed one in six interviews with the consensus team (to prevent rater drift). Reliability for presence or absence of child diagnosis on the ADIS-C/P was $\kappa = 0.98$ (child report) and $\kappa = 0.98$ (mother report), and CSR ICC = 0.99 (child report) and CSR ICC = 0.99 (mother report).

Clinical Global Impression – Improvement scale[57]

Overall improvement in child anxiety was assessed using the Clinical Global Impression – Improvement (CGI-I) scale, a 7-point scale from 1 = very much improved to 7 = very much worse; scores of 1 and 2 are accepted to represent treatment success. Inter-rater reliability was established using the same procedures as for the ADIS-C/P. Overall mean inter-rater reliability for the assessment team was high (ICC = 0.96).

Secondary outcomes

Maternal anxiety and maternal interactive responses were assessed to establish whether or not MCI and MCBT effectively changed these factors. Secondary outcomes included (i) the severity of the child's primary anxiety diagnosis; (ii) if the child was or was not free of all of their anxiety diagnoses (as assessed by the ADIS-C/P above); (iii) child- and mother-reported child anxiety symptoms and impact and comorbid difficulties; and (iv) teacher-reported symptoms of anxiety and adjustment to school at the post-treatment assessment. Finally, outcomes included all of the primary and secondary measures at the 6- and 12-month follow-up assessments.

Maternal anxiety disorder

The presence or absence of a current maternal anxiety disorder was assigned on the basis of the ADIS-IV,[58] a structured diagnostic assessment designed to assess the presence and severity of DSM-IV anxiety, mood and somatoform disorders. CSRs for each disorder present are made and range from 0 (not at all severe) to 8 (extremely severe/distressing). A rating of 4 is considered to be the cut-off for a clinically significant disorder. Procedures for training assessors and ensuring inter-rater reliability followed those of the ADIS-C/P. Reliability for presence or absence of maternal diagnosis on the ADIS-IV was $\kappa = 0.97$; and for the CSR ICC = 0.99.

Maternal symptoms of anxiety and depression

The Depression Anxiety Stress Scale (DASS-21)[59] was administered to all participating mothers to assess self-reported symptoms. The DASS-21 has demonstrated good internal consistency and concurrent validity.[60] Maternal symptoms of worry were assessed using the Penn State Worry Questionnaire (PSWQ),[61] a 16-item self-report inventory designed to assess the pathological worry characteristic of GAD. Maternal symptoms of

social anxiety were also measured using the Social Interaction Anxiety Scale (SIAS) and the Social Phobia Scale (SPS).[62] The SIAS is a 20-item self-report inventory designed to assess anxiety experienced while interacting with others. The SPS is a 20-item self-report inventory designed to assess fear of scrutiny when performing a task or being observed by others. Internal reliability for the scales was good across assessment time points (DASS-21 anxiety $\alpha = 0.80–0.87$; DASS-21 depression $\alpha = 0.90–0.92$; PSWQ $\alpha = 0.92–0.93$; SIAS $\alpha = 0.92–0.93$; SPS $\alpha = 0.91–0.94$).

Maternal parenting and parental expectations

Maternal behaviours in interaction with the child was assessed by laboratory observation under conditions of mild social, performance and physical threat.[23] The social threat task involved the child preparing and delivering a speech to a research assistant with a hand-held video camera with their mother's support. The performance task involved the child attempting difficult tangram puzzles following the procedure of Hudson and Rapee.[63] The physical threat task required children to investigate the content of four chambers within a mysterious 'black box'. To account for prior experience, the assessment was modified at the post-treatment assessment point; for social stress the child was required to present to a panel rather than a single research assistant, the tangram puzzles were more difficult and the black box was accompanied by sound effects (e.g. rustling/scratching).

Observers who were blind to treatment condition coded parental behaviours on scales developed by Murray and colleagues[64] and adapted by Creswell and colleagues[23] to be suitable for children aged 7–12 years and for the specific tasks. Ratings were given for each minute of the interaction on 5-point scales (1 = none, 5 = pervasive/strong). As interactions varied somewhat in duration, mean scores for each task were summed to give total scores across the full range of tasks. For the current study the following behaviours were considered: maternal expressed anxiety; control (overprotection and intrusiveness); positivity (warmth and encouragement); promotion of avoidance; and the general quality of the relationship. See *Table 2* for a description of each type of parenting behaviour. For each coder, in each task, a second coder independently scored a random sample of 25 videotapes. ICCs showed good agreement across all indices (range 0.60–1.00; mean 72). The constructs of encouragement and warmth overlap and these scales correlated highly ($p = 0.56–0.58$) so were combined to form as single measure of 'positive behaviours'.

Mothers also completed the parental overprotection measure (OP)[65] to assess parenting behaviours that restrict a child's exposure to perceived threat or harm (e.g. 'when playing in the park I keep my child within a close distance of me'). This parent-reported measure has been found to correlate significantly with observations of parent behaviours,[65,66] and has been found to be reliable and valid for children aged 7–12 years.[66] Internal consistency was good across the assessment time points ($\alpha = 0.87–0.89$).

TABLE 2 Observed parenting behaviours

Negative behaviour	
Expressed anxiety	Modelling of anxiety: anxiety in facial expression (e.g. fearful expression, biting lip), body movements (e.g. rigid posture, wringing hands), and speech (e.g. rapid, nervous, or inhibited)
Overprotection	Initiates emotional and/or practical support that is not required (stroking/kissing/offering unnecessary help while child manages independently)
Intrusiveness	Interferes, verbally or physically, cutting across child behaviour, attempts to take over and impose own agenda
Promotion of avoidance	Actively encourages/supports child avoidance of task (e.g. saying 'you don't have to do it')
Positive behaviour	
Encouragement (autonomy–promotion)	Provides positive motivation to child to engage in the task, showing enthusiasm regarding both task and child capacity/efforts
Warmth	Affectionate, expresses positive regard for child, both verbally and physically
Quality of relationship	Sense of relatedness and mutual engagement between mother and child (e.g. talking, listening, laughing and joking with each other)

Maternal expectations were assessed before initiating the challenge tasks. Immediately after receiving the instructions for each task, mothers were taken to a separate room where they were asked to provide ratings regarding their child's response.[23] In the current study we were interested in their responses regarding (a) how their child would feel about doing the task (0 not scared at all, 10 extremely scared); (b) how they would feel while their child was doing the task (0 not anxious at all, 10 extremely anxious); (c) how much their child could do about how the task went (0 nothing at all, 10 a lot); and (d) how much they could do about their child's feelings and behaviours during the task (0 nothing at all, 10 a lot). Ratings were combined across the three tasks to represent their expectations across a range of challenge contexts.

Symptoms of child anxiety

The Spence Child Anxiety Scale (SCAS)[29,67] assessed child- and parent-reported child anxiety symptoms. The child version [Spence Child Anxiety Scale – child report (SCAS-c)] requires children to rate how often they experience each of 38 anxiety symptoms, presented alongside six positive filler items. The SCAS-c and Spence Child Anxiety Scale – parent report (SCAS-p) have demonstrated high internal reliability and concurrent validity with other well-known anxiety measures.[29,67]

Impact of child anxiety

The Child Anxiety Impact Scale (CAIS) was used to measure the extent to which anxiety interferes in a child's life.[68] The Child Anxiety Impact Scale – child report (CAIS-c) and Child Anxiety Impact Scale – parent report (CAIS-p) covers three psychosocial domains (school, social activities and family functioning) and consists of 34 items, each rated on a 4-point scale to indicate how much anxiety has caused problems (not at all, just a little, pretty much, very much). The CAIS-c and CAIS-p have demonstrated good reliability and validity.[68,69]

Symptoms of child comorbid difficulties

The Short Mood and Feelings Questionnaire (SMFQ)[70] assessed child- and parent-reported symptoms of child low mood. The Short Mood and Feelings Questionnaire – child report (SMFQ-c) and Short Mood and Feelings Questionnaire – parent report (SMFQ-p) are brief, 13-item measures which require children or parents to report how often in the past 2 weeks they have experienced a number of symptoms. The SMFQ-c has demonstrated high internal reliability and concurrent validity with other well-known measures of symptoms of depression.[70] The conduct problems scale from the Strengths and Difficulties Questionnaire (SDQ)[71] was used to assess child- and parent-reported behavioural disturbance. The Strengths and Difficulties Questionnaire – child report (SDQ-c) and Strengths and Difficulties Questionnaire – parent report (SDQ-p) are known to have good psychometric properties and scores correlate highly with other well-known scales.[71]

Internal reliability for all these scales was good across assessment time points (SCAS-c $\alpha = 0.92$–0.94; SCAS-p $\alpha = 0.88$–0.93; CAIS-p $\alpha = 0.69$–0.91; SMFQ-c $\alpha = 0.89$–0.94; SMFQ-p $\alpha = 0.90$–0.93), with the exception of the SDQ conduct scales where internal reliability was marginal (SDQ-p $\alpha = 0.54$–0.68; SDQ-c $\alpha = 0.55$–0.69), although this may reflect the relatively low number of items, and the CAIS-c at the initial assessment ($\alpha = 0.52$), although for this scale internal reliability was higher at subsequent assessments ($\alpha = 0.88$–0.96).

Teacher-reported child symptoms and adjustment

Teacher reports were collected in an attempt to provide an objective assessment of child adjustment in the school domain before and after treatment. To assess teacher perceptions of child anxiety symptoms they completed an adapted version of the SCAS (Spence Child Anxiety Scale – teacher report; SCAS-t). This comprised the 30 items that it was felt that teachers would be in a position to comment on (i.e. removing items about, for example, sleep, heights, animal fears). Teachers also completed the conduct scale of the parent/teacher report form of the SDQ (Strengths and Difficulties Questionnaire – teacher report; SDQ-t)[71] which comprised five items. Finally, teachers completed a new measure of the child's adjustment to school (Child Adjustment to School – teacher report; CAS-t), which focused on avoidance or worry about common

school-based activities, such as showing things to the class, participating in group activities, speaking to the teacher. This comprised eight items that were rated on a 3-point scale from 0 (not true) to 2 (certainly true), see *Appendix 4*. Internal reliability for all these scales was acceptable across assessment time points (SCAS-t $\alpha = 0.91–0.96$; SDQ-t $\alpha = 0.64–0.78$; CAS-t $\alpha = 0.89–0.92$).

Sample size

The study was powered to provide 90% power at the 5% (two-sided) significance level to detect a 30% difference in the proportion of children who recovered from their primary anxiety disorder post treatment in the CCBT + MCI or CCBT + MCBT conditions compared with the CCBT condition, with an estimated remission rate for the CCBT group of 40%.[9] Although the effects of the non-specific treatment on child outcomes were not clear, using the 40% remission rate from Cobham and colleagues[9] was considered reasonable to account for the effect of CCBT plus any non-specific intervention, given the substantially briefer form of CCBT delivered in the current trial.

A difference of 30% in the proportion of anxiety-free children following completion of the treatment was considered to be the minimum that would be clinically worthwhile taking into account the increased resources required and change to service delivery that would be required if either of these interventions were found to be effective and implemented in practice. The required sample size of 56 children per group was increased to allow for an estimated 20% loss to follow-up. The sample size was estimated as if two independent trials were conducted, with no adjustment for multiple testing, as recommended by Machin and colleagues.[72]

Statistical analysis

A comprehensive statistical analysis plan was prepared before embarking on the analysis. All primary and secondary analyses, apart from the per-protocol (PP) sensitivity analyses, were conducted on the intention-to-treat (ITT) population. The primary end points (recovery from primary diagnosis and overall improvement in anxiety (CGI-I ratings) at post treatment and other binary end points were analysed using a modified Poisson regression approach with robust error variance adjusting for the minimisation factors [child age, child gender, type of child anxiety disorder (GAD, social phobia, SAD, other)], baseline severity of the child's and the mother's primary anxiety disorder (ADIS-IV CSR). The modified Poisson regression approach described by Zou[73] is an alternative to logistic regression which allows for estimation of risks ratios (RRs) rather than odds ratios. Sensitivity analyses of the primary end points included (i) no adjustment for minimisation criteria; (ii) PP population (this included those participants who had received at least half of the treatment sessions and had data for the post-treatment assessments, with the exception of one mother in the MCBT condition who also received the MCI intervention in error, rather than the FH control; data from this family was also removed for the PP analyses); and (iii) multiple imputation analysis. Missing data for the primary end points were multiply imputed by chained equations methods.[74] All results from sensitivity analyses were very similar to the primary results. Interim analyses were conducted by the trial statistician when 156 participants had been recruited following a request from the funders. The interim results were kept confidential from the trial manager, all assessors, therapists and their supervisors.

Questionnaire scores, maternal behaviours and maternal cognitions were modelled using linear regression models with the change from baseline as the dependent variable, adjusted for baseline score and minimisation factors. There were outliers present in some of the regression models; however, these were reviewed and were not considered to be due to incorrect completion of the questionnaires. Furthermore, their removal did not change the conclusions from the regression.

All analyses were conducted using Stata software.

Chapter 3 Trial results

Patient flow and numbers analysed

Patient flow is shown in *Figure 2*. The number of available participants for each treatment arm were as follows:

- post treatment: CCBT $n = 56$ (79%), CCBT + MCBT $n = 60$ (87%), CCBT + MCI $n = 62$ (87%)
- 6 months post treatment: CCBT $n = 49$ (69%), CCBT + MCBT $n = 53$ (77%), CCBT + MCI $n = 51$ (72%)
- 12 months post treatment: CCBT $n = 43$ (61%), CCBT + MCBT $n = 50$ (70%), CCBT + MCI $n = 46$ (65%).

Baseline data

Baseline characteristics were well balanced across treatment groups (*Table 3*).

TABLE 3 Baseline characteristics by treatment allocation

Baseline characteristic	Category	CCBT, *n* (%)	CCBT + MCBT, *n* (%)	CCBT + MCI, *n* (%)
Child ethnicity	White British	67 (94.4)	58 (84.1)	55 (77.5)
	White Irish	1 (1.4)		1 (1.4)
	Any other white background		5 (7.2)	7 (9.9)
	White and black Caribbean	1 (1.4)		
	White and black African			1 (1.4)
	White and Asian		2 (2.9)	
	Any other mixed background	1 (1.4)		
	Indian			1 (1.4)
	Pakistani		2 (2.9)	1 (1.4)
	Any other Asian background		1 (1.4)	2 (2.8)
	Caribbean			1 (1.4)
	Any other ethnic group		1 (1.4)	
	Did not wish to state ethnicity			1 (1.4)
	Not recorded	1 (1.4)		1 (1.4)
Child gender	Male	34 (47.9)	35 (50.7)	32 (45.1)
	Female	37 (52.1)	34 (49.3)	39 (54.9)
Martial status	Single, never married	2 (2.8)	5 (7.2)	5 (7.0)
	Married (first time)	28 (39.4)	41 (59.4)	38 (53.5)
	Remarried	8 (11.3)	3 (4.3)	5 (7.0)
	Divorce/separated	21 (29.6)	11 (15.9)	12 (16.9)
	Living with partner	11 (15.5)	9 (13.0)	8 (11.3)
	Not recorded	1 (1.4)		3 (4.2)

continued

TABLE 3 Baseline characteristics by treatment allocation (*continued*)

Baseline characteristic	Category	CCBT, *n* (%)	CCBT + MCBT, *n* (%)	CCBT + MCI, *n* (%)
Employment mother	Unemployed	21 (29.6)	23 (33.3)	18 (25.4)
	Part time	33 (46.5)	33 (47.8)	37 (52.1)
	Full time	14 (19.7)	8 (11.6)	13 (18.3)
	Not recorded	3 (4.2)	5 (7.2)	3 (4.2)
Employment father	Unemployed	1 (1.4)	6 (8.7)	5 (7.0)
	Part time		1 (1.4)	1 (1.4)
	Full time	50 (70.4)	50 (72.5)	53 (74.6)
	NA	5 (7.0)	1 (1.4)	1 (1.4)
	Not recorded	15 (21.1)	11 (15.9)	11 (15.5)
Overall SES	Higher professional	29 (40.8)	39 (56.5)	38 (53.5)
	Other employed	29 (40.8)	16 (23.2)	26 (36.6)
	Unemployed	2 (2.8)		1 (1.4)
	Not recorded	11 (15.5)	14 (20.3)	6 (8.5)
Mother education	School completion	21 (31.3)	11 (17.7)	22 (33.9)
	Further education	34 (50.8)	32 (51.6)	27 (41.5)
	Higher education	7 (10.5)	12 (19.4)	12 (18.5)
	Postgraduate qualification	5 (7.5)	7 (11.3)	4 (6.2)
Father education	School completion	17 (34.7)	12 (22.6)	23 (39.7)
	Further education	17 (34.7)	20 (37.7)	20 (34.5)
	Higher education	9 (18.4)	15 (28.3)	11 (19.0)
	Postgraduate qualification	6 (12.2)	6 (11.3)	4 (6.9)
Child ADIS-C/P primary diagnosis	SAD	19 (26.8)	16 (23.2)	21 (29.6)
	Social phobia	16 (22.5)	18 (26.1)	14 (19.7)
	GAD	22 (31.0)	20 (29.0)	24 (33.8)
	Other	14 (19.7)	15 (21.7)	12 (16.9)
	Specific phobia	8 (11.3)	11 (15.8)	5 (7.0)
	PD without agoraphobia	1 (1.4)		
	PD with agoraphobia			1 (1.4)
	Agoraphobia without PD	3 (4.2)	2 (2.9)	3 (4.2)
	Selective mutism			1 (1.4)
	Anxiety disorder not otherwise specified	2 (2.8)	2 (2.9)	2 (2.8)
Child ADIS-C/P primary diagnosis CSR	Moderate 4	6 (8.5)	5 (7.2)	5 (7.0)
	Moderate 5	21 (29.6)	19 (27.5)	19 (26.8)
	Severe 6	36 (50.7)	37 (53.6)	40 (56.3)
	Severe 7	8 (11.3)	8 (11.6)	7 (9.9)
Child mood disorder (major depressive disorder/dysthymia)	No diagnosis	62 (87.3)	62 (89.9)	67 (94.4)
	Diagnosis	9 (12.7)	7 (10.1)	4 (5.6)

TABLE 3 Baseline characteristics by treatment allocation (*continued*)

Baseline characteristic	Category	CCBT, *n* (%)	CCBT + MCBT, *n* (%)	CCBT + MCI, *n* (%)
Child age (years)	6		1 (1.4)	
	7	4 (5.6)	5 (7.2)	7 (9.9)
	8	12 (16.9)	7 (10.1)	13 (18.3)
	9	9 (12.7)	12 (17.4)	12 (16.9)
	10	17 (23.9)	17 (24.6)	13 (18.3)
	11	18 (25.4)	16 (23.2)	13 (18.3)
	12	10 (14.1)	11 (15.9)	11 (15.5)
	13	1 (1.4)		2 (2.8)
Mother's ADIS-IV primary disorder	Specific phobia	12 (16.9)	17 (24.6)	9 (12.7)
	GAD	37 (52.1)	35 (50.7)	40 (56.3)
	Social phobia	9 (12.7)	14 (20.3)	11 (15.5)
	PD	1 (1.4)		1 (1.4)
	Agoraphobia	2 (2.8)	1 (1.4)	2 (2.8)
	OCD	1 (1.4)		
	PTSD	1 (1.4)		
	Major depressive disorder	5 (7.0)		
	Hypochondriasis	2 (2.8)		
	Anxiety disorder not otherwise specified	1 (1.4)	2 (2.9)	8 (11.3)
Mother ADIS-IV CSR of primary disorder	Moderate 4	20 (28.2)	18 (26.1)	18 (25.4)
	Moderate 5	22 (31.0)	25 (36.2)	21 (29.6)
	Severe 6	22 (31.0)	22 (31.9)	24 (33.8)
	Severe 7	6 (8.5)	4 (5.8)	8 (11.3)
	Very severe 8	1 (1.4)		
Mother mood disorder (major depressive disorder/dysthymia)	No diagnosis	57 (80.3)	58 (84.1)	56 (78.9)
	Diagnosis	14 (19.7)	11 (15.9)	15 (21.1)

NA, not applicable; OCD, obsessive–compulsive disorder; PTSD, post-traumatic stress disorder; SES, socioeconomic status.

Manipulation checks: effects of the interventions on maternal anxiety and responses

Manipulation checks were conducted to evaluate whether or not the MCBT and MCI interventions successfully altered maternal anxiety and maternal responses, respectively.

Change in maternal anxiety

Recovery from maternal primary diagnosis at assessment 1B

As shown in *Table 4*, from the CCBT group eight mothers had missing data for their primary ADIS-IV diagnosis at the mid-treatment assessment (assessment 1B, i.e. after the MCBT intervention), for the CCBT + MCBT group this was four mothers and for CCBT + MCI this was one mother.

TABLE 4 Presence of pre-treatment ADIS-IV primary diagnosis at assessment 1B (including missing data)

Treatment allocation	Missing, *n* (%)	No diagnosis, *n* (%)	Diagnosis, *n* (%)	Total, *n* (%)
CCBT	8 (11.3)	23 (32.4)	40 (56.3)	71
CCBT + MCBT	4 (5.8)	38 (55.1)	27 (39.1)	69
CCBT + MCI	1 (1.4)	30 (42.3)	40 (56.3)	71
Total	13	91	107	211

As shown in *Table 5*, at assessment 1B, 23 mothers (37%) in the control group had recovered from their primary diagnosis. In the CCBT + MCBT group 38 mothers (59%) had recovered and in the CCBT + MCI group 30 mothers (43%) had recovered.

Mothers in the CCBT + MCBT group were 1.63 times more likely to recover from their ADIS-IV primary diagnosis by assessment 1B than those in the CCBT group [adjusted RR 1.63, 95% confidence interval (CI) 1.13 to 2.36; $p = 0.009$]. The adjusted RR for CCBT + MCI versus CCBT is 1.22 (95% CI 0.83 to 1.81; $p = 0.314$) (*Table 6*).

Recovery from all anxiety diagnoses at assessment 1B

As shown in *Table 7*, the CCBT group had the largest per cent of missing data for mothers at assessment 1B with 13%, the CCBT + MCBT group had 6% and the CCBT + MCI group had 1%.

As shown in *Table 8*, in the CCBT group 10 mothers (16%) had recovered from all anxiety diagnoses by assessment 1B. However, in the CCBT + MCBT group there were 25 recovered mothers (39%) and in the CCBT + MCI group there were 22 recovered mothers (31%).

TABLE 5 Presence of pre-treatment ADIS-IV primary diagnosis at assessment 1B

Treatment allocation	No diagnosis, *n* (%)	Diagnosis, *n* (%)	Total, *n* (%)
CCBT	23 (36.5)	40 (63.5)	63
CCBT + MCBT	38 (58.5)	27 (41.5)	65
CCBT + MCI	30 (42.9)	40 (57.1)	70
Total	91	107	198

TABLE 6 Analysis of mothers' recovery from pre-treatment ADIS-IV primary diagnosis at assessment 1B

Parameter		Adjusted RR[a]	95% CI	*p*-value[b]
Treatment	CCBT	Ref.		
	CCBT + MCBT	1.63	1.13 to 2.36	0.009
	CCBT + MCI	1.22	0.83 to 1.81	0.314

Ref., reference category.

a Adjusted for child age, child gender, type of child anxiety disorder (GAD, social phobia, SAD, other), baseline severity (ADIS-C/P CSR) of the child's primary anxiety disorder and baseline severity (ADIS-IV mother self-report) of the mother's primary anxiety disorder.

b Analysis conducted using the modified Poisson regression framework with robust error variance.

TABLE 7 Presence of any ADIS-IV anxiety diagnosis in mothers at assessment 1B (including missing data)

Treatment allocation	Missing, *n* (%)	No diagnosis, *n* (%)	Diagnosis, *n* (%)	Total, *n* (%)
CCBT	9 (12.7)	10 (14.1)	52 (73.2)	71
CCBT + MCBT	4 (5.8)	25 (36.2)	40 (58.0)	69
CCBT + MCI	1 (1.4)	22 (31.0)	48 (67.6)	71
Total	14	57	140	211

TABLE 8 Presence of any ADIS-IV anxiety diagnosis in mothers at assessment 1B

Treatment allocation	No diagnosis, *n* (%)	Diagnosis, *n* (%)	Total, *n* (%)
CCBT	10 (16.1)	52 (83.9)	62
CCBT + MCBT	25 (38.5)	40 (61.5)	65
CCBT + MCI	22 (31.4)	48 (68.6)	70
Total	57	140	197

Mothers receiving CCBT + MCBT or CCBT + MCI were more than twice as likely to have recovered from all anxiety diagnoses by assessment 1B than mothers in the control group CCBT + MCBT (RR 2.51, 95% CI 1.43 to 4.40; $p = 0.001$) and CCBT + MCI (RR 2.15, 95% CI 1.21 to 3.81; $p = 0.009$) (*Table 9*).

Change in maternal self-reported symptoms at assessment 1B

Table 10 shows the results of analyses looking at the change from baseline to assessment 1B scores of questionnaires completed by mothers about themselves. There were no significant differences between treatment groups. Summary scores are shown in *Appendix 5*, *Table 123*.

Recovery from maternal primary diagnosis at assessment 2 (end of all treatment)

As shown in *Table 11*, missing data was similar at the end of treatment (assessment 2) for mothers in the CCBT and CCBT + MCBT groups (24% and 20%, respectively). In the CCBT + MCI group it was 13%.

TABLE 9 Analysis of recovery from any ADIS-IV anxiety diagnosis in mothers at assessment 1B

Parameter		RR[a]	95% CI	*p*-value[b]
Treatment	CCBT	Ref.		
	CCBT + MCBT	2.51	1.43 to 4.40	0.001
	CCBT + MCI	2.15	1.21 to 3.81	0.009

Ref., reference category.
a Adjusted for child age, child gender, type of child anxiety disorder (GAD, social phobia, SAD, other), baseline severity (ADIS-C/P CSR) of the child's primary anxiety disorder and baseline severity (ADIS-IV mother self-report) of the mother's primary anxiety disorder.
b Analysis conducted using the modified Poisson regression framework with robust error variance.

TABLE 10 Adjusted analysis of change in mothers' self-report questionnaires at assessment 1B

Questionnaire	Treatment	*n*	Adjusted[a] mean change (95% CI)	Adjusted[a] mean difference (95% CI)	*p*-value
PSWQ total score	CCBT	40	–2.91 (–5.91 to 0.10)	Ref.	
	CCBT + MCBT	42	–4.96 (–7.90 to –2.01)	–2.05 (–6.31 to 2.21)	0.342
	CCBT + MCI	44	–3.72 (–6.59 to –0.84)	–0.81 (–5.03 to 3.40)	0.704
SIAS total score	CCBT	41	–0.86 (–3.37 to 1.66)	Ref.	
	CCBT + MCBT	44	–1.24 (–3.67 to 1.18)	–0.39 (–3.92 to 3.15)	0.829
	CCBT + MCI	47	–0.49 (–2.84 to 1.86)	0.37 (–3.12 to 3.85)	0.835
SPS total score	CCBT	41	–0.77 (–3.19 to 1.64)	Ref.	
	CCBT + MCBT	45	–0.21 (–2.52 to 2.10)	0.56 (–2.81 to 3.94)	0.742
	CCBT + MCI	46	0.07 (–2.22 to 2.36)	0.84 (–2.53 to 4.22)	0.622
DASS-21 depression subscale	CCBT	38	–1.54 (–3.28 to 0.21)	Ref.	
	CCBT + MCBT	43	–2.11 (–3.74 to –0.49)	–0.58 (–3.00 to 1.85)	0.638
	CCBT + MCI	45	–1.70 (–3.30 to –0.11)	–0.17 (–2.57 to 2.23)	0.890
DASS-21 anxiety subscale	CCBT	38	–0.38 (–2.36 to 1.60)	Ref.	
	CCBT + MCBT	44	–1.95 (–3.79 to –0.11)	–1.57 (–4.32 to 1.18)	0.259
	CCBT + MCI	45	–1.99 (–3.81 to –0.18)	–1.61 (–4.34 to 1.10)	0.243
DASS-21 stress subscale	CCBT	41	–0.90 (–2.88 to 1.08)	Ref.	
	CCBT + MCBT	45	–1.76 (–3.65 to 0.13)	–0.86 (–3.63 to 1.91)	0.539
	CCBT + MCI	45	–1.28 (–3.18 to 0.61)	–0.38 (–3.16 to 2.40)	0.786

Ref., reference category.
a Adjusted for child age, child gender, type of child anxiety disorder (GAD, social phobia, SAD, other), baseline severity (ADIS-C/P CSR) of the child's primary anxiety disorder, baseline severity (ADIS-IV mother self-report) of the mother's primary anxiety disorder and baseline questionnaire score.

TABLE 11 Presence of pre-treatment ADIS-IV primary diagnosis at assessment 2 (including missing data)

Treatment allocation	Missing, *n* (%)	No diagnosis, *n* (%)	Diagnosis, *n* (%)	Total, *n* (%)
CCBT	17 (23.9)	28 (39.4)	26 (36.6)	71
CCBT + MCBT	14 (20.3)	36 (52.2)	19 (27.5)	69
CCBT + MCI	9 (12.7)	41 (57.8)	21 (29.6)	71
Total	40	105	66	211

As shown in *Table 12*, there were 36 mothers (66%) in the MCBT group and 41 mothers (66%) in the CCBT + MCI group who recovered from their primary diagnosis by assessment 2 compared with 28 mothers (52%) from the CCBT group.

The results from log-linear regression of the mothers' recovery from their primary ADIS-IV diagnosis by assessment 2, adjusted for minimisation factors, are shown in *Table 13*. There were no significant differences between CCBT + MCBT and CCBT or between CCBT + MCI and CCBT. The adjusted RR for the effect of CCBT + MCBT on recovery from maternal primary diagnosis was 1.23 (95% CI 0.90 to 1.68; $p = 0.201$). Similarly, the adjusted RR for the effect of CCBT + MCI on recovery was 1.27 (95% CI 0.93 to 1.74; $p = 0.126$).

Recovery from all anxiety diagnoses at assessment 2

Missing data was similar at assessment 2 for mothers in the CCBT and CCBT + MCBT groups (24% and 20%, respectively). In the CCBT + MCI group it was 13% (*Table 14*).

TABLE 12 Presence of pre-treatment ADIS-IV primary diagnosis at assessment 2

Treatment allocation	No diagnosis, *n* (%)	Diagnosis, *n* (%)	Total, *n* (%)
CCBT	28 (51.9)	26 (48.1)	54
CCBT + MCBT	36 (65.5)	19 (34.5)	55
CCBT + MCI	41 (66.1)	21 (33.9)	62
Total	105	66	171

TABLE 13 Analysis of mothers' recovery from pre-treatment ADIS-IV primary diagnosis at assessment 2

Parameter		Adjusted RR[a]	95% CI	*p*-value[b]
Treatment	CCBT	Ref.		
	CCBT + MCBT	1.23	0.90 to 1.68	0.201
	CCBT + MCI	1.27	0.93 to 1.74	0.126

Ref., reference category.
a Adjusted for child age, child gender, type of child anxiety disorder (GAD, social phobia, SAD, other), baseline severity (ADIS-C/P CSR) of the child's primary anxiety disorder and baseline severity (ADIS-IV mother self-report) of the mother's primary anxiety disorder.
b Analysis conducted using the modified Poisson regression framework with robust error variance.

TABLE 14 Presence of any ADIS-IV anxiety diagnosis in mothers at assessment 2 (including missing data)

Treatment allocation	Missing, *n* (%)	No diagnosis, *n* (%)	Diagnosis, *n* (%)	Total, *n* (%)
CCBT	17 (23.9)	19 (26.8)	35 (49.3)	71
CCBT + MCBT	14 (20.3)	26 (37.7)	29 (42.0)	69
CCBT + MCI	9 (12.7)	29 (40.9)	33 (46.5)	71
Total	40	74	97	211

As can be seen in *Table 15*, 29 mothers (47%) in the CCBT + MCI group had recovered from all ADIS-IV anxiety diagnoses at assessment 2 and 26 (47%) from the CCBT + MCBT group. Nineteen mothers (35%) had fully recovered from the CCBT group.

Table 16 shows the results from log-binomial regression of the mothers' recovery from all ADIS-IV anxiety diagnoses adjusted for minimisation factors. There were no significant improvements for the CCBT + MCBT group (RR 1.32, 95% CI 0.85 to 2.04; $p = 0.210$) or the CCBT + MCI group (RR 1.35, 95% CI 0.87 to 2.10; $p = 0.179$).

Change in maternal self-reported symptoms at assessment 2

The regression results from the change in mothers' self-report questionnaires can be seen in *Table 17*. There were no significant differences between the CCBT + MCBT and CCBT groups or between the CCBT + MCI and CCBT groups.

TABLE 15 Presence of any ADIS-IV anxiety diagnosis in mothers at assessment 2

Treatment allocation	No diagnosis, *n* (%)	Diagnosis, *n* (%)	Total, *n* (%)
CCBT	19 (35.2)	35 (64.8)	54
CCBT + MCBT	26 (47.3)	29 (52.7)	55
CCBT + MCI	29 (46.8)	33 (53.2)	62
Total	74	97	171

TABLE 16 Analysis of recovery from any ADIS-IV anxiety diagnosis in mothers at assessment 2

Parameter		RR[a]	95% CI	*p*-value[b]
Treatment	CCBT	Ref.		
	CCBT + MCBT	1.30	0.84 to 2.01	0.244
	CCBT + MCI	1.35	0.87 to 2.10	0.180

Ref., reference category.
a Adjusted for child age, child gender, type of child anxiety disorder (GAD, social phobia, SAD, other), baseline severity (ADIS-C/P CSR) of the child's primary anxiety disorder and baseline severity (ADIS-IV mother self-report) of the mother's primary anxiety disorder.
b Analysis conducted using the modified Poisson regression framework with robust error variance.

TABLE 17 Adjusted analysis of change in mothers' self-report questionnaires at assessment 2

Questionnaire	Treatment	*n*	Adjusted[a] mean change (95% CI)	Adjusted[a] mean difference (95% CI)	*p*-value
PSWQ total score	CCBT	35	–7.14 (–10.67 to –3.60)	Ref.	
	CCBT + MCBT	41	–6.71 (–10.00 to –3.42)	0.43 (–4.47 to 5.32)	0.863
	CCBT + MCI	35	–6.43 (–10.01 to –2.86)	0.70 (–4.40 to 5.81)	0.785
SIAS total score	CCBT	34	–3.52 (–6.77 to –0.27)	Ref.	
	CCBT + MCBT	40	–4.80 (–7.82 to –1.79)	–1.28 (–5.79 to 3.22)	0.574
	CCBT + MCI	36	–4.75 (–7.93 to –1.58)	–1.23 (–5.84 to 3.37)	0.597
SPS total score	CCBT	35	–3.91 (–6.15 to –1.67)	Ref.	
	CCBT + MCBT	41	–4.03 (–6.12 to –1.94)	–0.12 (–3.24 to 2.99)	0.937
	CCBT + MCI	36	–2.20 (–4.65 to –2.16)	1.71 (–1.49 to 4.91)	0.291
DASS-21 depression subscale	CCBT	32	–2.83 (–5.11 to –0.55)	Ref.	
	CCBT + MCBT	36	–3.89 (–6.05 to –1.73)	–1.06 (–4.24 to 2.13)	0.511
	CCBT + MCI	33	–2.59 (–4.87 to –0.31)	0.24 (–3.05 to 3.54)	0.884
DASS-21 anxiety subscale	CCBT	32	–0.62 (–2.80 to 1.57)	Ref.	
	CCBT + MCBT	36	–2.75 (–4.85 to –0.65)	–2.13 (–5.21 to 0.94)	0.171
	CCBT + MCI	33	–2.40 (–4.61 to –0.19)	–1.79 (–4.95 to 1.38)	0.266
DASS-21 stress subscale	CCBT	34	–3.60 (–5.82 to –1.39)	Ref.	
	CCBT + MCBT	41	–2.45 (–4.48 to –0.42)	1.15 (–1.88. 4.19)	0.453
	CCBT + MCI	35	–2.77 (–4.98 to –0.56)	0.83 (–2.36 to 4.02)	0.606

Ref., reference category.
a Adjusted for child age, child gender, type of child anxiety disorder (GAD, social phobia, SAD, other), baseline severity (ADIS-C/P CSR) of the child's primary anxiety disorder, baseline severity (ADIS-IV mother self-report) of the mother's primary anxiety disorder and baseline questionnaire score.

Change in parenting responses

Parenting behaviours

Change in maternal parenting behaviours was analysed using linear regression. Analysis in *Table 18* shows the adjusted mean change from baseline to assessment 2, for each of the seven areas in each treatment group. The mean score over three tasks is used for each parenting behaviour. The adjusted mean difference compares the CCBT + MCBT group with CCBT and also the CCBT + MCI group with CCBT. A summary of scores is given in *Appendix 5*, *Table 122*.

The only significant difference was for CCBT + MCI versus CCBT in the 'overprotection' scores ($p = 0.026$). The difference between the CCBT + MCI and CCBT arms also approached significance for maternal self-report overprotection ($p = 0.057$).

Parenting cognitions

Maternal expectations were assessed before the behavioural tasks. These ratings were recorded at baseline and at assessment 2. The following analysis, shown in *Table 19*, looks at the change scores from baseline to assessment 2, analysed using adjusted linear regression.

TABLE 18 Adjusted analyses of behavioural change scores at assessment 2 (ITT analysis)

Questionnaire	Treatment	*n*	Adjusted[a] mean change (95% CI)	Adjusted[a] mean difference (95% CI)	*p*-value
Positive behaviour (–)	CCBT	42	0.042 (–0.058 to 0.141)	Ref.	
	CCBT + MCBT	45	–0.009 (–0.104 to 0.086)	–0.050 (–0.190 to 0.090)	0.478
	CCBT + MCI	49	0.067 (–0.024 to 0.158)	0.026 (–0.112 to 0.163)	0.714
Over-protection (+)	CCBT	42	–0.016 (–0.036 to 0.005)	Ref.	
	CCBT + MCBT	45	–0.035 (–0.055 to –0.016)	–0.020 (–0.048 to 0.009)	0.174
	CCBT + MCI	49	–0.048 (–0.066 to –0.029)	–0.032 (–0.060 to –0.004)	0.026
Promotion of avoidance (+)	CCBT	42	–0.019 (–0.045 to 0.007)	Ref.	
	CCBT + MCBT	45	–0.024 (–0.049 to 0.001)	–0.004 (–0.041 to 0.033)	0.813
	CCBT + MCI	49	–0.042 (–0.066 to –0.019)	–0.023 (–0.059 to 0.013)	0.207
Intrusiveness (+)	CCBT	42	–0.058 (–0.163 to 0.046)	Ref.	
	CCBT + MCBT	45	0.015 (–0.085 to 0.116)	0.074 (–0.074 to 0.221)	0.324
	CCBT + MCI	49	–0.108 (–0.205 to –0.012)	–0.050 (–0.195 to 0.195)	0.499
Anxiety (+)	CCBT	42	–0.005 (–0.106 to 0.097)	Ref.	
	CCBT + MCBT	45	0.034 (–0.063 to 0.132)	0.039 (–0.103 to 0.182)	0.589
	CCBT + MCI	49	–0.013 (–0.107 to 0.080)	–0.009 (–0.149 to 0.131)	0.901
Quality of relationship (–)	CCBT	42	0.023 (–0.074 to 0.121)	Ref.	
	CCBT + MCBT	45	0.050 (–0.044 to 0.142)	0.026 (–0.111 to 0.163)	0.712
	CCBT + MCI	49	0.003 (–0.086 to 0.092)	–0.020 (–0.155 to 0.114)	0.763
POI total score (+)	CCBT	34	–5.83 (–9.07 to –2.59)	Ref.	
	CCBT + MCBT	38	–6.41 (–9.51 to –3.31)	–0.58 (–5.06 to 3.89)	0.7974
	CCBT + MCI	34	–10.32 (–13.60 to –7.04)	–4.49 (–9.12 to 0.14)	0.0573

–, shows that a low score indicates dysfunction and hence an increase indicates an improvement; +, shows that a high score indicates dysfunction and hence a decrease indicates an improvement; POI, Parent Over-Involvement Questionnaire; ref., reference category.

a Adjusted for child age, child gender, type of child anxiety disorder (GAD, social phobia, SAD, other), baseline severity (ADIS-C/P CSR) of the child's primary anxiety disorder, baseline severity (ADIS-IV mother self-report) of the mother's primary anxiety disorder and baseline questionnaire score.

TABLE 19 Adjusted analyses of cognition change scores at assessment 2 (ITT analysis)

Questionnaire	Treatment	*n*	Adjusted[a] mean change (95% CI)	Adjusted[a] mean difference (95% CI)	*p*-value
Pre-task 'child scared' (+)	CCBT	40	–0.69 (–1.12 to –0.26)	Ref.	
	CCBT + MCBT	45	–1.22 (–1.62 to –0.82)	–0.53 (–1.12 to 0.07)	0.083
	CCBT + MCI	46	–1.36 (–1.76 to –0.96)	–0.67 (–1.26 to –0.07)	0.029
Pre-task 'mother anxious' (+)	CCBT	40	–0.87 (–1.32 to –0.42)	Ref.	
	CCBT + MCBT	45	–1.43 (–1.85 to –1.01)	–0.56 (–1.18 to 0.07)	0.079
	CCBT + MCI	46	–1.43 (–1.85 to –1.02)	–0.56 (–1.18 to 0.06)	0.077
Pre-task 'child in control' (–)	CCBT	40	0.25 (–0.12 to 0.63)	Ref.	
	CCBT + MCBT	45	0.75 (0.40 to 1.10)	0.50 (–0.03 to 1.02)	0.063
	CCBT + MCI	46	0.78 (0.44 to 1.13)	0.53 (0.01 to 1.05)	0.046
Pre-task 'mother in control' (+/–)	CCBT	40	–0.28 (–0.80 to 0.23)	Ref.	
	CCBT + MCBT	45	–0.07 (–0.55 to 0.41)	0.21 (–0.51 to 0.93)	0.564
	CCBT + MCI	46	–0.08 (–0.55 to 0.39)	0.20 (–0.50 to 0.91)	0.569

–, shows that a low score indicates dysfunction and hence an increase indicates an improvement; +, shows that a high score indicates dysfunction and hence a decrease indicates an improvement; +/–, shows that it is unclear whether a high score or a low score indicates dysfunction; ref., reference category.

a Adjusted for child age, child gender, type of child anxiety disorder (GAD, social phobia, SAD, other), baseline severity (ADIS-C/P CSR) of the child's primary anxiety disorder, baseline severity (ADIS-IV mother self-report) of the mother's primary anxiety disorder and baseline questionnaire score.

For the pre-task 'scared' rating and pre-task 'child in control' rating there were significant differences between CCBT + MCI and CCBT ($p = 0.029$ and $p = 0.046$, respectively). A summary of mean scores is provided in *Appendix 5*, *Table 125*.

Primary outcomes

Missing data

Nine (13%) participants allocated to CCBT + MCBT and nine (13%) participants allocated to CCBT + MCI were not able to be measured for the primary end points. These rates of missing data were slightly lower than for participants allocated to CCBT (21%). Baseline characteristics of participants with or without missing primary outcomes are given in *Tables 20–22*.

TABLE 20 Presence of pre-treatment ADIS-C/P primary diagnosis at assessment 2: child

Treatment allocation	Missing, *n* (%)	No diagnosis, *n* (%)	Diagnosis, *n* (%)	Total, *n* (%)
CCBT	15 (21.1)	27 (38.0)	29 (40.9)	71
CCBT + MCBT	9 (13.0)	35 (50.7)	25 (36.2)	69
CCBT + MCI	9 (12.7)	37 (52.1)	25 (35.2)	71
Total	33	99	79	211

TABLE 21 Clinical Global Impression: child – Improvement at assessment 2

Treatment allocation	Missing, *n* (%)	Much/very much improved, *n* (%)	Not much/very much improved, *n* (%)	Total, *n* (%)
CCBT	15 (21.1)	36 (50.7)	20 (28.2)	71
CCBT + MCBT	9 (13.0)	48 (69.6)	12 (17.4)	69
CCBT + MCI	9 (12.7)	47 (66.2)	15 (21.1)	71
Total	33	131	47	211

TABLE 22 Baseline characteristics by whether or not missing ADIS-C/P assessment at assessment 2

		Assessment 2	
Baseline characteristic	Category	Completed, *n* (%)	Missing, *n* (%)
Gender	Male	84 (83.2)	17 (16.8)
	Female	94 (85.5)	16 (14.5)
Marital status	Single, never married	7 (58.3)	5 (41.7)
	Married (first time)	90 (84.1)	17 (15.9)
	Remarried	13 (81.3)	3 (18.8)
	Divorce/separated	39 (88.6)	5 (11.4)
	Living with partner	25 (89.3)	3 (10.7)
	Not recorded	4 (100.0)	
Employment mother	Unemployed	48 (77.4)	14 (22.6)
	Part time	89 (86.4)	14 (13.6)
	Full time	30 (85.7)	5 (14.3)
	Not recorded	11 (100.0)	
Employment father	Unemployed	10 (83.3)	2 (16.7)
	Part time	2 (100.0)	
	Full time	128 (83.7)	25 (16.3)
	NA	4 (57.1)	3 (42.9)
	Not recorded	34 (91.9)	3 (8.1)
Overall SES	Higher professional	93 (87.7)	13 (12.3)
	Other employed	57 (80.3)	14 (19.7)
	Unemployed	3 (100.0)	
	Not recorded	25 (80.6)	6 (19.4)
ADIS-C/P primary diagnosis (initial assessment)	SAD	45 (80.4)	11 (19.6)
	Social phobia	42 (87.5)	6 (12.5)
	GAD	51 (77.3)	15 (22.7)
	Other	40 (97.6)	1 (2.4)

TABLE 22 Baseline characteristics by whether or not missing ADIS-C/P assessment at assessment 2 (*continued*)

Baseline characteristic	Category	Assessment 2	
		Completed, *n* (%)	Missing, *n* (%)
ADIS-C/P primary diagnosis CSR (initial assessment)	Moderate 4	12 (75.0)	4 (25.0)
	Moderate 5	50 (84.7)	9 (15.3)
	Severe 6	97 (85.8)	16 (14.2)
	Severe 7	19 (82.6)	4 (17.4)
ADIS-C/P primary diagnosis CSR at assessment 1B	No diagnosis	3 (100.0)	
	Mild 3	6 (100.0)	
	Moderate 4	25 (92.6)	2 (7.4)
	Moderate 5	52 (85.2)	9 (14.8)
	Severe 6	86 (91.5)	8 (8.5)
	Severe 7	5 (71.4)	2 (28.6)
	Very severe 8	1 (100.0)	
	Not recorded		12 (100.0)
Child age (years)	6		1 (100.0)
	7	11 (68.8)	5 (31.3)
	8	27 (84.4)	5 (15.6)
	9	28 (84.8)	5 (15.2)
	10	41 (87.2)	6 (12.8)
	11	43 (91.5)	4 (8.5)
	12	25 (78.1)	7 (21.9)
	13	3 (100.0)	

NA, not applicable; SES, socioeconomic status.

Unadjusted analyses: primary end points

As shown in *Table 23* and *Figure 3*, 48% of the children in the CCBT arm were free of their primary diagnosis status at assessment 2 compared with 58% of children in the CCBT + MCBT and 60% of children in the CCBT + MCI arms.

The unadjusted RR for the effect of CCBT + MCBT versus CCBT on recovery from primary ADIS-C/P diagnosis by assessment 2 was 1.21 (95% CI 0.86 to 1.71; $p = 0.280$). This was very similar to the unadjusted estimate of the effect of CCBT + MCI versus CCBT, RR 1.24 (95% CI 0.88 to 1.74; $p = 0.219$).

The unadjusted RR for the effect of CCBT + MCBT versus CCBT on CGI-I by assessment 2 was 1.24 (95% CI 0.99 to 1.57; $p = 0.065$) and for the effect of CCBT + MCI versus CCBT the RR was 1.18 (95% CI 0.93 to 1.50; $p = 0.179$). Frequencies are displayed in *Table 24* and *Figure 4*.

TABLE 23 Presence of pre-treatment ADIS-C/P primary diagnosis at assessment 2: child

Treatment allocation	No diagnosis, *n* (%)	Diagnosis, *n* (%)	Total, *n* (%)
CCBT	27 (48.2)	29 (51.8)	56
CCBT + MCBT	35 (58.3)	25 (41.7)	60
CCBT + MCI	37 (59.7)	25 (40.3)	62
Total	99	79	178

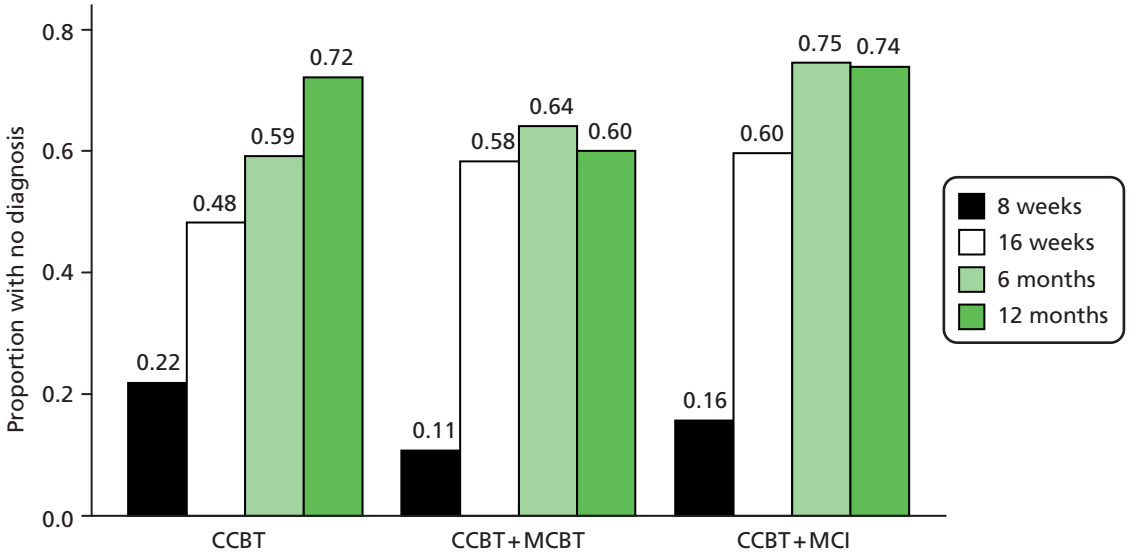


FIGURE 3 Presence of pre-treatment ADIS-C/P child primary diagnosis.

TABLE 24 Clinical Global Impression: child – Improvement at assessment 2

Treatment allocation	Much/very much improved, *n* (%)	Not much/very much improved, *n* (%)	Total, *n* (%)
CCBT	36 (64.3)	20 (35.7)	56
CCBT + MCBT	48 (80.0)	12 (20.0)	60
CCBT + MCI	47 (75.8)	15 (24.2)	62
Total	131	47	178

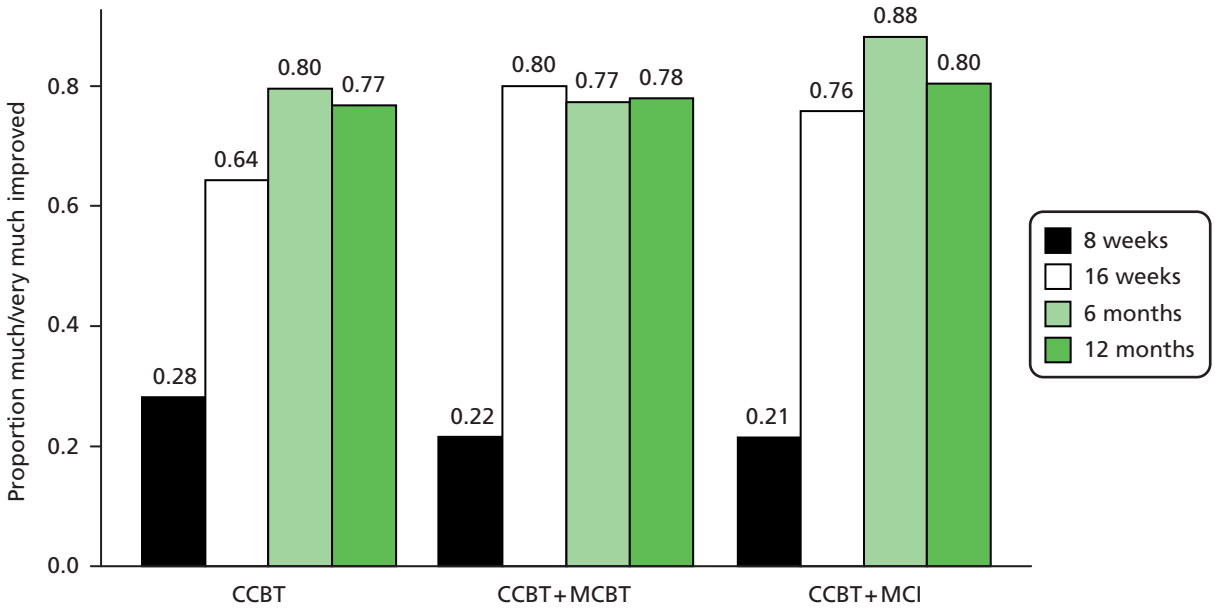


FIGURE 4 Child CGI-I.

Multiple imputation analyses

Multiple imputations were used to account for missing data for the two primary end points. Twenty imputed data sets were developed using the Stata 'ice' function for multiple imputation with chained equations. Imputation models were developed using variables for treatment allocation, minimisation factors [child age, child gender, type of child anxiety disorder (GAD, social phobia, SAD, other), baseline severity (ADIS-C/P CSR) of the child's primary anxiety disorder and baseline severity (ADIS-IV mother self-report) of the mother's primary anxiety disorder] as well as assessment of ADIS-C/P CSR at assessment 1B, assessment of ADIS-C/P primary diagnosis at assessment 1B, CGI-I at assessment 1B and baseline mother's depression (DASS-21 – depression), child depression symptoms (SMFQ-c), child behavioural problems (SDQ-conduct) and presence of child social phobia.

Results from multiple imputation analyses, which were the primary analyses, along with adjusted RRs are presented in *Table 25*. Adjusted analyses for log-binomial regression models did not converge (as is often the case), therefore the modified Poisson regression framework with robust error variance was used as specified in the analysis plan, which gives almost identical CIs.

Confidence intervals for all estimates remained similar regardless of the method of analysis.

TABLE 25 Results for primary end points (unadjusted, adjusted and multiple imputation analyses)

Assessment 2	RR[a]	95% CI	*p*-value
ADIS-C/P primary diagnostic status: child			
Unadjusted			
CCBT	Ref.		
CCBT + MCBT	1.21	0.86 to 1.71	0.280
CCBT + MCI	1.24	0.88 to 1.74	0.219
Adjusted[a]			
CCBT	Ref.		
CCBT + MCBT	1.22	0.88 to 1.67	0.228
CCBT + MCI	1.21	0.88 to 1.65	0.243
Multiple imputation[a]			
CCBT	Ref.		
CCBT + MCBT	1.18	0.827 to 1.62	0.285
CCBT + MCI	1.22	0.90 to 1.67	0.203
CGI-I: child			
Unadjusted			
CCBT	Ref.		
CCBT + MCBT	1.24	0.99 to 1.57	0.065
CCBT + MCI	1.18	0.93 to 1.50	0.179
Adjusted[a]			
CCBT	Ref.		
CCBT + MCBT	1.25	0.99 to 1.57	0.058
CCBT + MCI	1.18	0.93 to 1.50	0.173
Multiple imputation[a]			
CCBT	Ref.		
CCBT + MCBT	1.26	1.00 to 1.59	0.054
CCBT + MCI	1.20	0.95 to 1.53	0.133

Ref., reference category.

a Adjusted for child age, child gender, type of child anxiety disorder (GAD, social phobia, SAD, other), baseline severity (ADIS-C/P CSR) of the child's primary anxiety disorder and baseline severity (ADIS-IV mother self-report) of the mother's primary anxiety disorder.

Per-protocol analysis of primary outcomes at assessment 2

The PP population is a subset of the ITT population and excludes from the analysis participants who were ineligible or had significant non-compliance.

The CCBT arm PP population contained 58 children, the CCBT + MCBT arm contained 60 children and the CCBT + MCI arm contained 64 children. This is a total of 182 children in the PP population, whereas the ITT population contains 211 children.

Table 26 shows for each treatment group the proportion of children who had recovered from their primary diagnosis by assessment 2; in both the CCBT + MCBT and CCBT + MCI arms this was 59% and in the CCBT arm it was 49%.

As shown in *Table 27*, the adjusted RR for the effect of CCBT + MCBT versus CCBT on recovery from primary ADIS-IV diagnosis by assessment 2 was 1.17 (95% CI 0.85 to 1.62; $p = 0.328$). This was very similar to the adjusted estimate of the effect of CCBT + MCI versus CCBT, RR 1.19 (95% CI 0.86 to 1.64; $p = 0.288$).

The proportion of patients where the CGI-I rating improved by assessment 2 is shown in *Table 28*; in the CCBT arm this was 64%, in the CCBT + MCBT arm it was 80% and in the CCBT + MCI arm it was 75%.

As shown in *Table 29*, the adjusted RR for the effect of CCBT + MCBT versus CCBT on improvement in CGI-I by assessment 2 was 1.26 (95% CI 0.99 to 1.59); $p = 0.056$. The adjusted estimate of the effect of CCBT + MCI versus CCBT was RR 1.18 (95% CI 0.93 to 1.52; $p = 0.170$).

TABLE 26 Presence of pre-treatment ADIS-C/P primary anxiety diagnosis at assessment 2: child

Treatment allocation	No diagnosis, *n* (%)	Diagnosis, *n* (%)	Total, *n* (%)
CCBT	27 (49.09)	28 (50.91)	55
CCBT + MCBT	33 (58.93)	23 (41.07)	56
CCBT + MCI	36 (59.02)	25 (40.98)	61
Total	96	76	172

TABLE 27 Analysis of pre-treatment ADIS-C/P primary anxiety diagnosis at assessment 2: child

Parameter		Adjusted RR[a]	95% CI	*p*-value[b]
Treatment	CCBT	Ref.		
	CCBT + MCBT	1.17	0.85 to 1.62	0.328
	CCBT + MCI	1.19	0.86 to 1.64	0.288

Ref., reference category.

a Adjusted for child age, child gender, type of child anxiety disorder (GAD, social phobia, SAD, other), baseline severity (ADIS-C/P CSR) of the child's primary anxiety disorder and baseline severity (ADIS-IV mother self-report) of the mother's primary anxiety disorder.

b Analysis conducted using the modified Poisson regression framework with robust error variance.

TABLE 28 Clinical Global Impression: child – Improvement at assessment 2

Treatment allocation	Much/very much improved, *n* (%)	Not much/very much improved, *n* (%)	Total, *n* (%)
CCBT	35 (63.64)	20 (36.36)	55
CCBT + MCBT	45 (80.36)	11 (19.64)	56
CCBT + MCI	46 (75.41)	15 (24.59)	61
Total	126	46	172

TABLE 29 Analysis of CGI-I at assessment 2

Parameter		Adjusted RR[a]	95% CI	*p*-value[b]
Treatment	CCBT	Ref.		
	CCBT + MCBT	1.26	0.99 to 1.59	0.056
	CCBT + MCI	1.18	0.93 to 1.52	0.170

Ref., reference category.
a Adjusted for child age, child gender, type of child anxiety disorder (GAD, social phobia, SAD, other), baseline severity (ADIS-C/P CSR) of the child's primary anxiety disorder and baseline severity (ADIS-IV mother self-report) of the mother's primary anxiety disorder.
b Analysis conducted using the modified Poisson regression framework with robust error variance.

Secondary outcomes

Severity of child's primary Anxiety Disorder Interview Schedule diagnosis at assessment 2

By assessment 2, 59% of the CCBT arm, 73% of the CCBT + MCBT arm and 73% of the CCBT + MCI arm children had seen an improvement of at least 2 points (*Figure 5* and *Tables 30* and *31*).

There were no significant differences between CCBT + MCBT and CCBT or between CCBT + MCI and CCBT ($p = 0.101$ and 0.118, respectively).

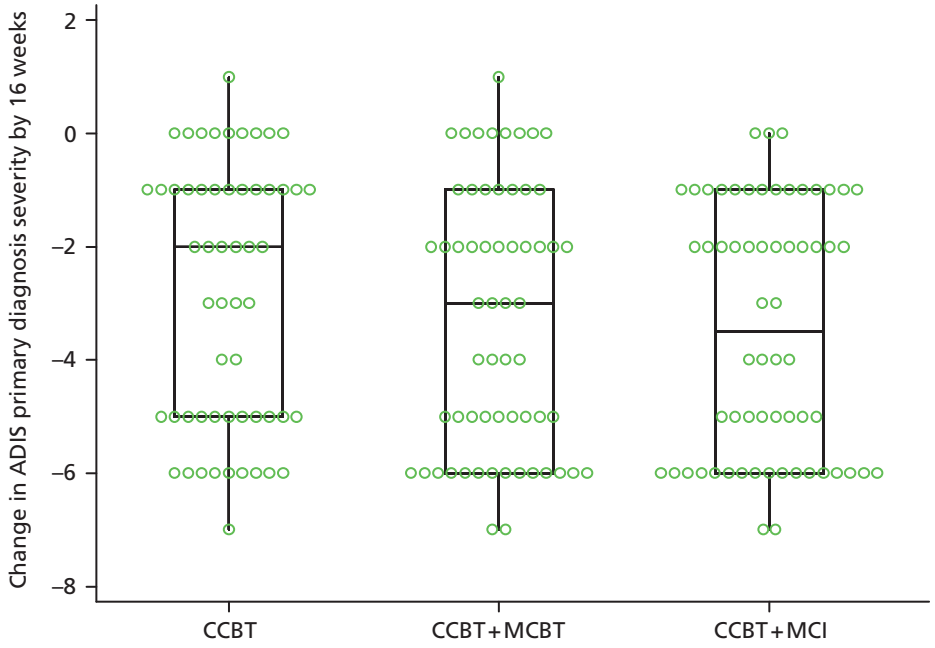


FIGURE 5 Box plot of change in severity of child's primary ADIS-C/P diagnosis at assessment 2 by treatment group.

TABLE 30 Change in severity of child's pre-treatment ADIS-C/P primary diagnosis at assessment 2, frequency (%)

Treatment	–7	–6	–5	–4	–3	–2	–1	0	1	Total
CCBT	1 (1.8)	9 (16.1)	11 (19.6)	2 (3.6)	4 (7.1)	6 (10.7)	13 (23.2)	9 (16.1)	1 (1.8)	56
CCBT + MCBT	2 (3.3)	14 (23.3)	9 (15.0)	4 (6.7)	4 (6.7)	11 (18.3)	7 (11.7)	8 (13.3)	1 (1.7)	60
CCBT + MCI	2 (3.2)	17 (27.4)	8 (12.9)	4 (6.5)	2 (3.2)	12 (19.4)	14 (22.6)	3 (4.8)	0 (0.0)	62
Total	5	40	28	10	10	29	34	20	2	178

TABLE 31 Proportion of children with at least a 2-point reduction in severity of their pre-treatment ADIS-C/P primary diagnosis at assessment 2

Treatment	*n*	*n* (%) with a 2 or more point reduction	*p*-value[a]
CCBT	56	33 (58.9)	
CCBT + MCBT	60	44 (73.3)	0.101
CCBT + MCI	62	45 (72.6)	0.118

a Chi-squared test, comparison with control group.

Presence of any Anxiety Disorder Interview Schedule anxiety diagnosis in children at assessment 2

As shown in *Table 32*, the proportion of children with missing data was higher in the CCBT arm (21%); the CCBT + MCBT arm (13%) and the CCBT + MCI arms (13%) were fairly similar.

As can be seen in *Table 33*, in the CCBT + MCBT and CCBT + MCI arms 18 and 25 children (30% and 40%), respectively, had recovered from all ADIS-C/P anxiety diagnoses at assessment 2. From the CCBT arm, 16 participants (29%) had fully recovered.

Table 34 shows the results from log-binomial regression of the children's recovery from all ADIS-C/P anxiety diagnoses at assessment 2 adjusted for minimisation factors.

The estimated effect of CCBT + MCBT on ADIS-C/P anxiety diagnoses at assessment 2 compared with the CCBT arm was RR 1.06 (0.63 to 1.78; $p = 0.816$). For those children receiving CCBT + MCI the adjusted RR was 1.48 (95% CI 0.92 to 2.37; $p = 0.102$).

TABLE 32 Presence of any ADIS-C/P anxiety diagnosis in children at assessment 2 (including missing data)

Treatment allocation	Missing, *n* (%)	No diagnosis, *n* (%)	Diagnosis, *n* (%)	Total, *n* (%)
CCBT	15 (21.1)	16 (22.5)	40 (56.3)	71
CCBT + MCBT	9 (13.0)	18 (26.1)	42 (60.9)	69
CCBT + MCI	9 (12.7)	25 (35.2)	37 (52.1)	71
Total	33	59	119	211

TABLE 33 Presence of any ADIS-C/P anxiety diagnosis in children at assessment 2

Treatment allocation	No diagnosis, *n* (%)	Diagnosis, *n* (%)	Total, *n* (%)
CCBT	16 (28.6)	40 (71.4)	56
CCBT + MCBT	18 (30.0)	42 (70.0)	60
CCBT + MCI	25 (40.3)	37 (59.7)	62
Total	59	119	178

TABLE 34 Analysis of recovery from any ADIS-C/P anxiety diagnosis in children at assessment 2

Parameter		Adjusted RR[a]	95% CI	*p*-value[b]
Treatment	CCBT	Ref.		
	CCBT + MCBT	1.06	0.63 to 1.78	0.816
	CCBT + MCI	1.48	0.92 to 2.37	0.102

Ref., reference category.
a Adjusted for child age, child gender, type of child anxiety disorder (GAD, social phobia, SAD, other), baseline severity (ADIS-C/P CSR) of the child's primary anxiety disorder and baseline severity (ADIS-IV mother self-report) of the mother's primary anxiety disorder.
b Analysis conducted using the modified Poisson regression framework with robust error variance.

Analysis of change in child-reported questionnaire scores at assessment 2

Analyses of questionnaire results were conducted on the change scores from baseline to assessment 2 owing to the skewed distribution of the raw scores at assessment 2. The change scores were more normally distributed.

The change scores were modelled using linear regression, adjusted for baseline scores and minimisation factors. There were some outliers in the regression models, but these were not thought to be due to incorrect completion of the questionnaires. Furthermore, their removal did not change the conclusions from the regression.

Table 35 shows the adjusted means of the children's responses in each treatment arm along with the adjusted mean difference for CCBT + MCBT and CCBT + MCI in comparison with CCBT. For the SCAS-c a significant difference was seen between CCBT + MCBT and CCBT ($p = 0.031$), with the CCBT arm seeing a bigger reduction in total score on average. For the SMFQ-c a significant difference was seen between CCBT + MCBT and CCBT ($p = 0.004$) and also CCBT + MCI and CCBT ($p = 0.012$); in both cases the difference was in the opposite direction to what was expected, with the CCBT arm seeing a greater reduction in the children's scores than the treatment arms.

Appendix 5, *Table 126*, presents the summary statistics for questionnaire scores at baseline and assessment 2, along with the difference between baseline and assessment 2, for only those participants with data at both time points who are included in *Table 35*.

TABLE 35 Adjusted analyses of change in child-reported questionnaires at assessment 2 (ITT analysis)

Questionnaire	Treatment	*n*	Adjusted[a] mean change (95% CI)	Adjusted[a] mean difference (95% CI)	*p*-value
SCAS-c total score	CCBT	45	–19.68 (–23.48 to –15.89)	Ref.	
	CCBT + MCBT	46	–13.71 (–17.49 to –9.92)	5.97 (0.54 to 11.41)	0.031
	CCBT + MCI	52	–15.73 (–19.27 to –12.19)	3.96 (–1.28 to 9.19)	0.137
CAIS-c total score	CCBT	44	–8.19 (–12.10 to –4.28)	Ref.	
	CCBT + MCBT	45	–6.28 (–10.20 to –2.37)	1.91 (–3.73 to 7.55)	0.505
	CCBT + MCI	53	–6.49 (–10.05 to –2.93)	1.70 (–3.63 to 7.03)	0.530
SMFQ-c total score	CCBT	46	–5.03 (–6.35 to –3.71)	Ref.	
	CCBT + MCBT	47	–2.25 (–3.57 to –0.93)	2.78 (0.88 to 4.68)	0.004
	CCBT + MCI	54	–2.70 (–3.92 to –1.48)	2.33 (0.52 to 4.14)	0.012
SDQ-c conduct subscale	CCBT	47	–0.61 (–1.08 to –0.14)	Ref.	
	CCBT + MCBT	47	–0.52 (–1.00 to –0.05)	0.09 (–0.59 to 0.76)	0.803
	CCBT + MCI	55	–0.50 (–0.94 to –0.07)	0.10 (–0.54 to 0.75)	0.748

Ref., reference category.

a Adjusted for child age, child gender, type of child anxiety disorder (GAD, social phobia, SAD, other), baseline severity (ADIS-C/P CSR) of the child's primary anxiety disorder, baseline severity (ADIS-IV mother self-report) of the mother's primary anxiety disorder and baseline questionnaire score.

Analysis of change in mother-reported child symptoms at assessment 2

The results from the regression of the mothers' questionnaires for child symptoms/impact are shown in *Table 36*. There were no significant differences seen between the CCBT + MCBT and CCBT or between CCBT + MCI and CCBT. *Appendix 5*, *Table 127*, presents a summary of the descriptive statistics.

Analysis of change in teacher-reported questionnaire scores at assessment 2

The analysis results of the change scores from the teachers' questionnaires are shown in *Table 37*. The numbers of respondents were small and there were no significant differences in any of the comparisons. *Appendix 5*, *Table 128*, presents a summary of the descriptive statistics.

TABLE 36 Adjusted analyses of change in mother-reported questionnaires at assessment 2

Questionnaire	Treatment	*n*	Adjusted[a] mean change (95% CI)	Adjusted[a] mean difference (95% CI)	*p*-value
SCAS-c total score	CCBT	36	–18.00 (–21.09 to –14.88)	Ref.	
	CCBT + MCBT	39	–16.77 (–19.75 to –13.78)	1.22 (–3.15 to 5.59)	0.581
	CCBT + MCI	38	–18.30 (–21.35 to –15.25)	–0.32 (–4.77 to 4.14)	0.888
CAIS-c total score	CCBT	33	–10.19 (–12.37 to –8.01)	Ref.	
	CCBT + MCBT	35	–12.95 (–15.09 to –10.80)	–2.76 (–5.86 to 0.34)	0.080
	CCBT + MCI	31	–10.15 (–12.45 to –7.84)	0.04 (–3.20 to 3.28)	0.980
SMFQ-c total score	CCBT	34	–4.60 (–6.03 to –3.18)	Ref.	
	CCBT + MCBT	38	–5.66 (–7.03 to –4.29)	–1.06 (–3.07 to 0.96)	0.301
	CCBT + MCI	35	–5.64 (–7.07 to –4.22)	–1.04 (–3.08 to 1.00)	0.314
SDQ-c conduct subscale	CCBT	37	–0.65 (–1.06 to –0.24)	Ref.	
	CCBT + MCBT	41	–0.74 (–1.12 to –0.35)	–0.09 (–0.66 to 0.49)	0.763
	CCBT + MCI	40	–0.84 (–1.23 to –0.45)	–0.19 (–0.77 to 0.39)	0.515

Ref., reference category.
a Adjusted for child age, child gender, type of child anxiety disorder (GAD, social phobia, SAD, other), baseline severity (ADIS-C/P CSR) of the child's primary anxiety disorder, baseline severity (ADIS-IV mother self-report) of the mother's primary anxiety disorder and baseline questionnaire score.

TABLE 37 Adjusted analysis of change in teacher-reported questionnaires at assessment 2

Questionnaire	Treatment	*n*	Adjusted[a] mean change (95% CI)	Adjusted[a] mean difference (95% CI)	*p*-value
SCAS-t total score	CCBT	7	–4.02 (–11.27 to 3.23)	Ref.	
	CCBT + MCBT	14	–4.94 (–9.90 to 0.03)	–0.92 (–10.69 to 8.85)	0.847
	CCBT + MCI	12	–5.31 (–10.53 to –0.10)	–1.29 (–10.86 to 8.27)	0.782
CAS-t total score	CCBT	18	–0.86 (–2.32 to 0.60)	Ref.	
	CCBT + MCBT	24	–1.96 (–3.22 to –0.70)	–1.10 (–3.11 to 0.90)	0.275
	CCBT + MCI	25	–1.26 (–2.48 to –0.04)	–0.40 (–2.37 to 1.57)	0.684
SDQ-t conduct subscale	CCBT	18	0.35 (–0.21 to 0.91)	Ref.	
	CCBT + MCBT	22	–0.17 (–0.68 to 0.35)	–0.52 (–1.30 to 0.27)	0.190
	CCBT + MCI	23	–0.11 (–0.62 to 0.39)	–0.46 (–1.24 to 0.31)	0.236

Ref., reference category.
a Adjusted for child age, child gender, type of child anxiety disorder (GAD, social phobia, SAD, other), baseline severity (ADIS-C/P CSR) of the child's primary anxiety disorder, baseline severity (ADIS-IV mother self-report) of the mother's primary anxiety disorder and baseline questionnaire score.

Post-treatment follow-up

Child outcomes at 6-month follow-up

Presence of child's Anxiety Disorder Interview Schedule primary diagnosis at 6-month follow-up

Table 38 shows the proportion of missing data within each treatment arm for the assessment of the child's primary diagnosis at 6 months post treatment. The CCBT arm has the highest proportion of missing data (31%).

Table 39 shows the proportion of children who recovered from their primary ADIS-C/P anxiety diagnosis by 6 months. The CCBT + MCI arm had the highest proportion of recovered children (75%). The CCBT arm had the lowest proportion of recovered children (59%).

Table 40 shows the results of the adjusted linear regression of the child's primary diagnosis. The results show no statistically significant difference between CCBT + MCBT or CCBT + MCI treatment arms in comparison with CCBT.

TABLE 38 Presence of pre-treatment ADIS-C/P primary diagnosis at 6 months post treatment (including missing data)

Treatment allocation	Missing, *n* (%)	No diagnosis, *n* (%)	Diagnosis, *n* (%)	Total, *n* (%)
CCBT	22 (30.99)	29 (40.85)	20 (28.17)	71
CCBT + MCBT	16 (23.19)	34 (49.28)	19 (27.54)	69
CCBT + MCI	20 (28.17)	38 (53.52)	13 (18.31)	71
Total	58	101	52	211

TABLE 39 Presence of pre-treatment ADIS-C/P primary diagnosis at 6 months

Treatment allocation	No diagnosis, *n* (%)	Diagnosis, *n* (%)	Total, *n* (%)
CCBT	29 (59.18)	20 (40.82)	49
CCBT + MCBT	34 (64.15)	19 (35.85)	53
CCBT + MCI	38 (74.51)	13 (25.49)	51
Total	101	52	153

TABLE 40 Analysis of pre-treatment ADIS-C/P primary anxiety diagnosis at 6 months

Parameter		Adjusted RR[a]	95% CI	*p*-value[b]
Treatment	CCBT	Ref.		
	CCBT + MCBT	1.09	0.81 to 1.46	0.566
	CCBT + MCI	1.26	0.97 to 1.64	0.077

Ref., reference category.
a Adjusted for child age, child gender, type of child anxiety disorder (GAD, social phobia, SAD, other), baseline severity (ADIS-C/P CSR) of the child's primary anxiety disorder and baseline severity (ADIS-IV mother self-report) of the mother's primary anxiety disorder.
b Analysis conducted using the modified Poisson regression framework with robust error variance.

As in all of the analyses reporting RRs in this report, a value > 1 implies a better outcome for the index treatment arm compared with the control (CCBT) arm, if the value is < 1, the outcome is better for the CCBT arm.

Child's Clinical Global Impression – Improvement at 6 months

The proportion of missing data for child's CGI-I assessment at 6 months was lower in the CCBT + MCBT arm (23%) and similar in the CCBT (31%) and CCBT + MCI arms (28%) (*Table 41*).

The proportion of children who were 'much/very much improved' at 6 months is shown in *Table 42*. The CCBT + MCI arm had the highest proportion (88%). CCBT and CCBT + MCBT were similar (80% and 77%, respectively).

The linear regression results in *Table 43* show that there are no statistically significant differences between treatment arms.

TABLE 41 Clinical Global Impression: child – Improvement at 6 months (including missing data)

Treatment allocation	Missing, *n* (%)	Much/very much improved, *n* (%)	Not much/very much improved, *n* (%)	Total, *n* (%)
CCBT	22 (30.99)	39 (54.93)	10 (14.08)	71
CCBT + MCBT	16 (23.19)	41 (59.42)	12 (17.39)	69
CCBT + MCI	20 (28.17)	45 (63.38)	6 (8.45)	71
Total	58	125	28	211

TABLE 42 Clinical Global Impression: child – Improvement at 6 months

Treatment allocation	Much/very much improved, *n* (%)	Not much/very much improved, *n* (%)	Total, *n* (%)
CCBT	39 (79.59)	10 (20.41)	49
CCBT + MCBT	41 (77.36)	12 (22.64)	53
CCBT + MCI	45 (88.24)	6 (11.76)	51
Total	125	28	153

TABLE 43 Analysis of CGI-I at 6 months

Parameter		Adjusted RR[a]	95% CI	*p*-value[b]
Treatment	CCBT	Ref.		
	CCBT + MCBT	0.97	0.79 to 1.19	0.771
	CCBT + MCI	1.16	0.94 to 1.33	0.216

Ref., reference category.

a Adjusted for child age, child gender, type of child anxiety disorder (GAD, social phobia, SAD, other), baseline severity (ADIS-C/P CSR) of the child's primary anxiety disorder and baseline severity (ADIS-IV mother self-report) of the mother's primary anxiety disorder.

b Analysis conducted using the modified Poisson regression framework with robust error variance.

Presence of any Anxiety Disorder Interview Schedule anxiety diagnosis in children at 6 months

As shown in *Table 44*, the proportion of missing data for any ADIS-C/P anxiety diagnosis was similar in CCBT (31%) and CCBT + MCI (28%), but lower in MCBT (23%) children.

Table 45 shows the proportion of children recovering from all anxiety diagnoses by 6 months; and this is the same in each group (47%).

The results of the linear regression of recovery from all ADIS-C/P anxiety diagnoses by 6 months are shown in *Table 46*; there are no statistically significant differences between treatment groups.

TABLE 44 Presence of any ADIS-C/P anxiety diagnosis at 6 months (including missing data)

Treatment allocation	Missing, *n* (%)	No diagnosis, *n* (%)	Diagnosis, *n* (%)	Total, *n* (%)
CCBT	22 (30.99)	23 (32.39)	26 (36.62)	71
MCBT	16 (23.19)	25 (36.23)	28 (40.58)	69
CCBT + MCI	20 (28.17)	24 (33.80)	27 (38.03)	71
Total	58	72	81	211

TABLE 45 Presence of any ADIS-C/P anxiety diagnosis at 6 months

Treatment allocation	No diagnosis, *n* (%)	Diagnosis, *n* (%)	Total, *n* (%)
CCBT	23 (46.94)	26 (53.06)	49
CCBT + MCBT	25 (47.17)	28 (52.83)	53
CCBT + MCI	24 (47.06)	27 (52.94)	51
Total	72	81	153

TABLE 46 Analysis of recovery from any ADIS-C/P anxiety diagnosis at 6 months

Parameter		Adjusted RR[a]	95% CI	*p*-value[b]
Treatment	CCBT	Ref.		
	CCBT + MCBT	1.04	0.70 to 1.53	0.860
	CCBT + MCI	1.04	0.71 to 1.55	0.814

Ref., reference category.

a Adjusted for child age, child gender, type of child anxiety disorder (GAD, social phobia, SAD, other), baseline severity (ADIS-C/P CSR) of the child's primary anxiety disorder and baseline severity (ADIS-IV mother self-report) of the mother's primary anxiety disorder.

b Analysis conducted using the modified Poisson regression framework with robust error variance.

Severity of child's primary Anxiety Disorder Interview Schedule diagnosis at 6 months

Figure 6 and *Table 47* show the distribution of the change scores from baseline to 6 months for the severity rating of the child's primary diagnosis. As shown in *Table 48*, the proportion of children with a reduction of 2 or more points is 74% in the CCBT arm, 70% in the CCBT + MCBT arm and 92% in the CCBT + MCI arm. When comparing the CCBT + MCBT arm with CCBT there is no significant difference. However, there is a significant difference between CCBT + MCI and CCBT ($p = 0.013$).

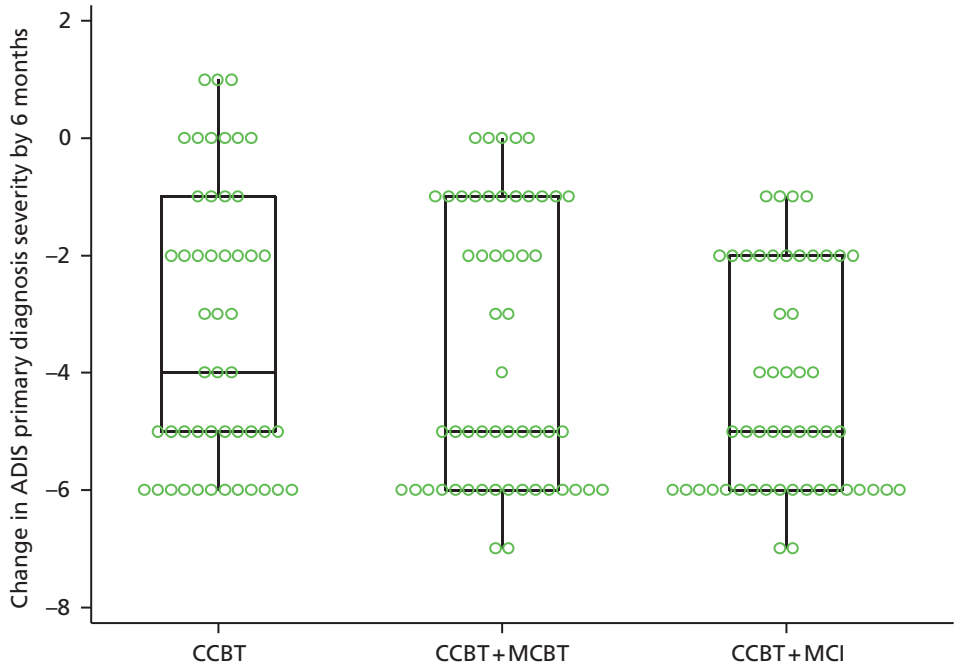


FIGURE 6 Box plot of change in severity of child's pre-treatment ADIS-C/P primary anxiety diagnosis at 6 months.

TABLE 47 Change in severity of child's pre-treatment ADIS-C/P primary anxiety diagnosis at 6 months, frequency (%)

Treatment allocation	–7	–6	–5	–4	–3	–2	–1	0	1	Total
CCBT	0 (0.0)	12 (24.5)	10 (20.4)	3 (6.1)	3 (6.1)	8 (16.3)	4 (8.2)	6 (12.2)	3 (6.1)	49
CCBT + MCBT	2 (3.8)	16 (30.2)	10 (18.9)	1 (1.9)	2 (3.8)	6 (11.3)	11 (20.8)	5 (9.4)	0 (0.0)	53
CCBT + MCI	2 (3.9)	18 (35.3)	9 (17.7)	5 (9.8)	2 (3.9)	11 (21.6)	4 (7.8)	0 (0.0)	0 (0.0)	51
Total	4	46	29	9	7	25	19	11	3	153

TABLE 48 Proportion of children with at least a 2-point reduction in severity of their pre-treatment ADIS-C/P primary anxiety diagnosis at 6 months

Treatment	*n*	*n* (%) with a 2 or more point reduction	*p*-value[a]
CCBT	49	36 (73.5)	
CCBT + MCBT	53	37 (69.8)	0.682
CCBT + MCI	51	47 (92.2)	0.013

a Chi-squared test, comparison with control group.

Analysis of questionnaire data at 6 month follow-up assessments

Analyses of questionnaire results were conducted on the change scores from baseline to the relevant time point. The change scores were more normally distributed. The change scores were modelled using linear regression, adjusted for baseline scores and minimisation factors.

In this section, only patients who are included in the analysis are included in the summary tables.

Adjusted analysis of change in child-reported questionnaire scores at 6 months (intention-to-treat analysis)

Table 49 shows the results for the analysis of the child-reported questionnaire scores, and the change in scores from baseline to 6 months. For all four of the questionnaires there were no significant differences between CCBT + MCBT and CCBT or between CCBT + MCI and CCBT. The adjusted mean scores for each treatment group and every questionnaire are negative, which shows that all groups improved. A summary of the descriptive statistics is given in *Appendix 5*, *Table 136*.

Adjusted analysis of change in mother-reported questionnaire scores at 6 months (intention-to-treat analysis)

Table 50 shows results of linear regression looking at mother-reported questionnaires about child symptoms/impact. For the SDQ-p conduct subscale a significant difference was seen between the CCBT + MCI and the CCBT arms ($p = 0.022$), with the CCBT + MCI arm seeing a bigger reduction in score on average. A summary of the descriptive statistics is given in *Appendix 5*, *Table 137*.

Adjusted analysis of change in teacher-reported questionnaire scores at 6 months (intention-to-treat analysis)

The number of respondents was low. As shown in *Table 51*, no significant differences were seen. A summary of descriptive statistics are given in *Appendix 5*, *Table 138*.

TABLE 49 Adjusted analysis of change in child-reported questionnaire scores at 6 months

Variable name	Treatment	*n*	Adjusted[a] mean change (95% CI)	Adjusted[a] mean difference (95% CI)	*p*-value
CAIS-c total score	CCBT	38	–12.45 (–15.06 to –9.84)	Ref.	–
	CCBT + MCBT	43	–11.02 (–13.50 to –8.54)	1.43 (–2.21 to 5.07)	0.4374
		41	–10.75 (–13.29 to –8.21)	1.70 (–1.97 to 5.37)	0.3614
SCAS-c total score	CCBT	41	–17.85 (–22.73 to –12.98)	Ref.	–
	CCBT + MCBT	43	–16.59 (–21.35 to –11.83)	1.26 (–5.56 to 8.08)	0.7146
	CCBT + MCI	41	–17.60 (–22.52 to –12.67)	0.26 (–6.77 to 7.28)	0.9427
SDQ-c conduct subscale	CCBT	42	–0.88 (–1.35 to –0.42)	Ref.	–
	CCBT + MCBT	44	–0.91 (–1.37 to –0.46)	–0.03 (–0.68 to 0.62)	0.9245
	CCBT + MCI	42	–0.81 (–1.28 to –0.34)	0.07 (–0.60 to 0.74)	0.8317
SMFQ-c total score	CCBT	40	–3.81 (–5.33 to –2.29)	Ref.	–
	CCBT + MCBT	44	–3.52 (–4.97 to –2.06)	0.30 (–1.82 to 2.42)	0.7828
	CCBT + MCI	39	–3.97 (–5.52 to –2.41)	–0.16 (–2.36 to 2.04)	0.8872

Ref., reference category.

a Adjusted for child age, child gender, type of child anxiety disorder (GAD, social phobia, SAD, other), baseline severity (ADIS-C/P CSR) of the child's primary anxiety disorder, baseline severity (ADIS-IV mother self-report) of the mother's primary anxiety disorder and baseline questionnaire score.

TABLE 50 Adjusted analysis of change in mother-reported child symptoms questionnaire scores at 6 months

Variable name	Treatment	*n*	Adjusted[a] mean change (95% CI)	Adjusted[a] mean difference (95% CI)	*p*-value
CAIS-p total score	CCBT	35	–9.25 (–12.12 to –6.37)	Ref.	–
	CCBT + MCBT	37	–12.13 (–14.95 to –9.31)	–2.88 (–6.92 to 1.16)	0.1599
	CCBT + MCI	34	–9.69 (–12.68 to –6.70)	–0.44 (–4.61 to 3.73)	0.8348
SCAS-p total score	CCBT	36	–17.44 (–21.03 to –13.84)	Ref.	–
	CCBT + MCBT	41	–16.62 (–20.00 to –13.25)	0.82 (–4.11 to 5.74)	0.7432
	CCBT + MCI	38	–19.17 (–22.72 to –15.61)	–1.73 (–6.86 to 3.40)	0.5050
SDQ-p conduct subscale	CCBT	39	–0.47 (–0.86 to –0.09)	Ref.	–
	CCBT + MCBT	42	–0.99 (–1.36 to –0.62)	–0.51 (–1.05 to 0.02)	0.0600
	CCBT + MCI	41	–1.11 (–1.49 to –0.73)	–0.64 (–1.19 to -0.09)	0.0224
SMFQ-p total score	CCBT	36	–4.25 (–5.82 to –2.67)	Ref.	–
	CCBT + MCBT	38	–5.86 (–7.40 to –4.32)	–1.61 (–3.83 to 0.61)	0.1542
	CCBT + MCI	36	–4.90 (–6.49 to –3.30)	–0.65 (–2.91 to 1.61)	0.5701

Ref., reference category.
a Adjusted for child age, child gender, type of child anxiety disorder (GAD, social phobia, SAD, other), baseline severity (ADIS-C/P CSR) of the child's primary anxiety disorder, baseline severity (ADIS-IV mother self-report) of the mother's primary anxiety disorder and baseline questionnaire score.

TABLE 51 Adjusted analysis of change in teacher-reported questionnaire scores at 6 months

Variable name	Treatment	*n*	Adjusted[a] mean change (95% CI)	Adjusted[a] mean difference (95% CI)	*p*-value
CAS-t total score	CCBT	11	–1.43 (–3.85 to 0.99)	Ref.	–
	CCBT + MCBT	17	–2.92 (–4.91 to –0.94)	–1.50 (–4.65 to 1.66)	0.3432
	CCBT + MCI	23	–1.40 (–3.02 to 0.23)	0.03 (–2.92 to 2.98)	0.9845
SCAS-t total score	CCBT	4	–1.88 (–15.75 to 12.00)	Ref.	–
	CCBT + MCBT	9	–15.07 (–22.85 to –7.29)	–13.19 (–30.33 to 3.94)	0.1227
	CCBT + MCI	15	–10.26 (–15.89 to –4.64)	–8.39 (–24.79 to 8.01)	0.2955
SDQ-t conduct subscale	CCBT	12	0.57 (–0.36 to 1.50)	Ref.	–
	CCBT + MCBT	18	–0.21 (–0.98 to 0.57)	–0.78 (–1.98 to 0.42)	0.1961
	CCBT + MCI	22	0.31 (–0.37 to 1.00)	–0.26 (–1.42 to 0.90)	0.6540

Ref., reference category.
a Adjusted for child age, child gender, type of child anxiety disorder (GAD, social phobia, SAD, other), baseline severity (ADIS-C/P CSR) of the child's primary anxiety disorder, baseline severity (ADIS-IV mother self-report) of the mother's primary anxiety disorder and baseline questionnaire score.

Child outcomes at 12-month follow-up

Presence of child's Anxiety Disorder Interview Schedule primary diagnosis at 12 months

Table 52 shows that the proportion of missing data for the assessment of the child's primary diagnosis at 12 months is very similar in the CCBT (39%) and CCBT + MCI (35%) arms, but lower in the CCBT + MCBT arm (28%).

Table 53 shows that recovery from primary diagnosis is very similar in the CCBT (72%) and CCBT + MCI arms (74%), whereas in the CCBT + MCBT group it is lower (60%).

The results of the linear regression are shown in *Table 54*. The results show no statistically significant difference between the CCBT + MCBT or CCBT + MCI treatment arms in comparison with CCBT.

TABLE 52 Presence of pre-treatment ADIS-C/P primary diagnosis at 12 months (including missing data)

Treatment allocation	Missing, *n* (%)	No diagnosis, *n* (%)	Diagnosis, *n* (%)	Total, *n* (%)
CCBT	28 (39.44)	31 (43.66)	12 (16.90)	71
CCBT + MCBT	19 (27.54)	30 (43.48)	20 (28.99)	69
CCBT + MCI	25 (35.21)	34 (47.89)	12 (16.90)	71
Total	72	95	44	211

TABLE 53 Presence of pre-treatment ADIS-C/P primary diagnosis at 12 months

Treatment allocation	No diagnosis, *n* (%)	Diagnosis, *n* (%)	Total, *n* (%)
CCBT	31 (72.09)	12 (27.91)	43
CCBT + MCBT	30 (60.00)	20 (40.00)	50
CCBT + MCI	34 (73.91)	12 (26.09)	46
Total	95	44	139

TABLE 54 Analysis of pre-treatment ADIS-C/P primary anxiety diagnosis at 12 months

Parameter		Adjusted RR[a]	95% CI	*p*-value[b]
Treatment	CCBT	Ref.		
	CCBT + MCBT	0.85	0.65 to 1.12	0.257
	CCBT + MCI	1.04	0.82 to 1.30	0.766

Ref., reference category.
a Adjusted for child age, child gender, type of child anxiety disorder (GAD, social phobia, SAD, other), baseline severity (ADIS-C/P CSR) of the child's primary anxiety disorder and baseline severity (ADIS-IV mother self-report) of the mother's primary anxiety disorder.
b Analysis conducted using the modified Poisson regression framework with robust error variance.

Child's Clinical Global Impression – Improvement at 12 months

The proportion of 12-month CGI-I assessments that were missing is shown in *Table 55*. The CCBT arm had 39% missing, CCBT + MCI had 35% missing and CCBT + MCBT had 28% missing.

As shown in *Table 56*, the proportion of children who were 'much/very much improved' was similar between treatment groups; between 77% and 80%.

The results of the linear regression of CGI-I at 12 months are shown in *Table 57*; there are no statistically significant differences between treatment groups.

TABLE 55 Clinical Global Impression: child – Improvement at 12 months (including missing data)

Treatment allocation	Missing, *n* (%)	Much/very much improved, *n* (%)	Not much/very much improved, *n* (%)	Total, *n* (%)
CCBT	28 (39.44)	33 (46.48)	10 (14.08)	71
CCBT + MCBT	19 (27.54)	39 (56.52)	11 (15.94)	69
CCBT + MCI	25 (35.21)	37 (52.11)	9 (12.68)	71
Total	72	109	30	211

TABLE 56 Clinical Global Impression: child – Improvement at 12 months

Treatment allocation	Much/very much improved, *n* (%)	Not much/very much improved, *n* (%)	Total, *n* (%)
CCBT	33 (76.74)	10 (23.26)	43
CCBT + MCBT	39 (78.00)	11 (22.00)	50
CCBT + MCI	37 (80.43)	9 (19.57)	46
Total	109	30	139

TABLE 57 Analysis of CGI-I at 12 months

Parameter		Adjusted RR[a]	95% CI	*p*-value[b]
Treatment	CCBT	Ref.		
	CCBT + MCBT	1.02	0.82 to 1.27	0.834
	CCBT + MCI	1.05	0.85 to 1.30	0.628

Ref., reference category.
a Adjusted for child age, child gender, type of child anxiety disorder (GAD, social phobia, SAD, other), baseline severity (ADIS-C/P CSR) of the child's primary anxiety disorder and baseline severity (ADIS-IV mother self-report) of the mother's primary anxiety disorder.
b Analysis conducted using the modified Poisson regression framework with robust error variance.

Presence of any Anxiety Disorder Interview Schedule anxiety diagnosis in children at 12 months

As shown in *Table 58*, the proportion of missing data for all anxiety diagnoses at 12 months was lowest in the CCBT + MCBT arm (28%). In the CCBT + MCI arm it is 35% and in the CCBT arm 39%.

The proportion of recovered children was similar in the CCBT arm (53%) and the CCBT + MCI arm (52%). In the CCBT + MCBT arm the proportion was slightly lower at 46% (*Table 59*).

The results of the linear regression of recovery from all ADIS-C/P anxiety diagnoses by 12 months are shown in *Table 60*. There are no statistically significant differences between treatment groups.

TABLE 58 Presence of any ADIS-C/P anxiety diagnosis at 12 months (including missing data)

Treatment allocation	Missing, *n* (%)	No diagnosis, *n* (%)	Diagnosis, *n* (%)	Total, *n* (%)
CCBT	28 (39.44)	23 (32.39)	20 (28.17)	71
CCBT + MCBT	19 (27.54)	23 (33.33)	27 (39.13)	69
CCBT + MCI	25 (35.21)	24 (33.80)	22 (30.99)	71
Total	72	70	69	211

TABLE 59 Presence of any ADIS-C/P anxiety diagnosis at 12 months

Treatment allocation	No diagnosis, *n* (%)	Diagnosis, *n* (%)	Total, *n* (%)
CCBT	23 (53.49)	20 (46.51)	43
CCBT + MCBT	23 (46.00)	27 (54.00)	50
CCBT + MCI	24 (52.17)	22 (47.83)	46
Total	70	69	139

TABLE 60 Analysis of recovery from any ADIS-C/P anxiety diagnosis at 12 months

Parameter		Adjusted RR[a]	95% CI	*p*-value[b]
Treatment	CCBT	Ref.		
	CCBT + MCBT	0.89	0.61 to 1.31	0.569
	CCBT + MCI	1.01	0.70 to 1.45	0.972

Ref., reference category.
a Adjusted for child age, child gender, type of child anxiety disorder (GAD, social phobia, SAD, other), baseline severity (ADIS-C/P CSR) of the child's primary anxiety disorder and baseline severity (ADIS-IV mother self-report) of the mother's primary anxiety disorder.
b Analysis conducted using the modified Poisson regression framework with robust error variance.

Severity of child's pre-treatment Anxiety Disorder Interview Schedule primary diagnosis at 12 months

By 12 months 77% of the control group, 74% of the CCBT + MCBT group and 87% of the CCBT + MCI group children had seen an improvement of at least 2 points (*Figure 7* and *Tables 61* and *62*).

There were no significant differences between the CCBT + MCBT and CCBT arms or between the CCBT + MCI and CCBT arms ($p = 0.760$ and $p = 0.210$, respectively).

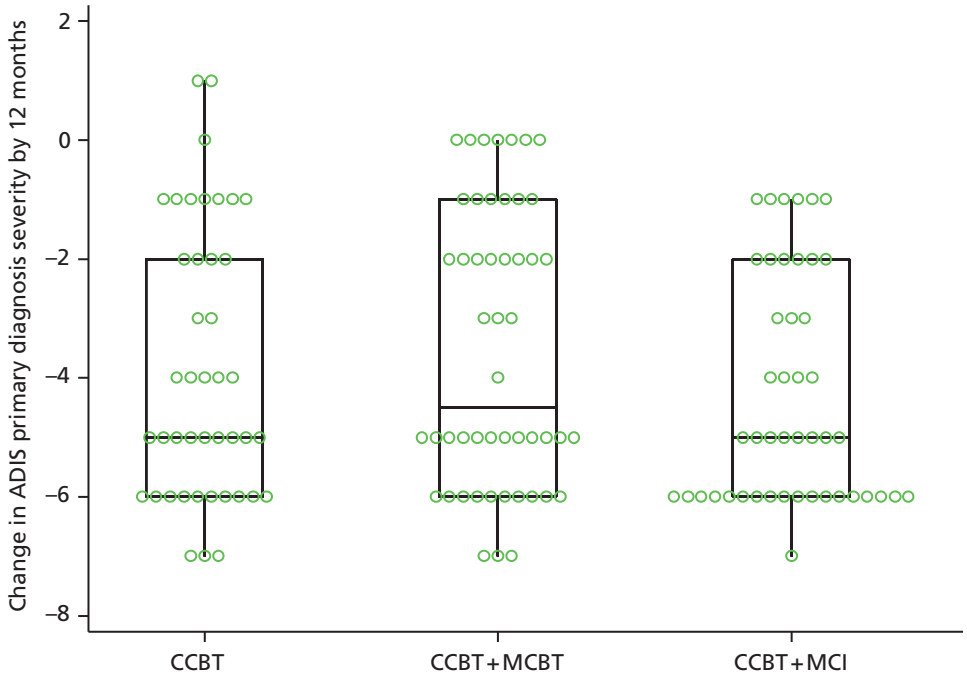


FIGURE 7 Box plot of change in severity of child's primary ADIS-C/P anxiety diagnosis at 12 months.

TABLE 61 Change in severity of child's pre-treatment ADIS-C/P primary anxiety diagnosis at 12 months, frequency (%)

Treatment allocation	–7	–6	–5	–4	–3	–2	–1	0	1	Total
CCBT	3 (6.98)	10 (23.26)	9 (20.93)	5 (11.63)	2 (4.65)	4 (9.30)	7 (16.28)	1 (2.33)	2 (4.65)	43
CCBT + MCBT	3 (6.00)	10 (20.00)	12 (24.00)	1 (2.00)	3 (6.00)	8 (16.00)	6 (12.00)	7 (14.00)	0 (0.00)	50
CCBT + MCI	1 (2.17)	18 (39.1)	8 (17.39)	4 (8.70)	3 (6.52)	6 (13.04)	6 (13.04)	0 (0.00)	0 (0.00)	46
Total	7	38	29	10	8	18	19	8	2	139

TABLE 62 Proportion of children with at least a 2-point reduction in severity of their pre-treatment ADIS-C/P primary anxiety diagnosis at 12 months

Treatment	*n*	*n* (%) with 2 or more point reduction	*p*-value[a]
CCBT	43	33 (76.7)	
CCBT + MCBT	50	37 (74.0)	0.760
CCBT + MCI	46	40 (87.0)	0.210

a Chi-squared test, comparison with control group.

Analysis of questionnaire data at 12-month follow-up assessments

Analyses of questionnaire results were conducted on the change scores from baseline to the relevant time point owing to the skewed distribution of the raw scores at each time point. The change scores were more normally distributed. The change scores were modelled using linear regression, adjusted for baseline scores and minimisation factors.

In this section, only patients who are included in the analysis are included in the summary tables.

Adjusted analysis of change in child-reported questionnaire scores at 12 months (intention-to-treat analysis)

As shown in *Table 63*, no significant differences were seen. A summary of the descriptive statistics is given in *Appendix 5*, *Table 139*.

Adjusted analysis of change in mother-reported questionnaire scores at 12 months (intention-to-treat analysis)

As shown in *Table 64*, no significant differences were seen. A summary of descriptive statistics is given in *Appendix 5*, *Table 140*.

Adjusted analysis of change in teacher-reported questionnaire scores at 12 months (intention-to-treat analysis)

As shown in *Table 65*, no significant differences were seen. A summary of descriptive statistics is given in *Appendix 5*, *Table 141*.

Note the small number of observations when looking at these results.

TABLE 63 Adjusted analysis of change in child-reported questionnaire scores at 12 months

Variable name	Treatment	*n*	Adjusted[a] mean change (95% CI)	Adjusted[a] mean difference (95% CI)	*p*-value
CAIS-c total score	CCBT	29	–12.83 (–17.14 to –8.51)	Ref.	–
	CCBT + MCBT	33	–9.25 (–13.41 to –5.09)	3.57 (–2.59 to 9.74)	0.2525
	CCBT + MCI	37	–11.71 (–15.48 to –7.93)	1.12 (–4.59 to 6.83)	0.6978
SCAS-c total score	CCBT	31	–18.11 (–23.18 to –13.03)	Ref.	–
	CCBT + MCBT	34	–18.92 (–23.82 to –14.01)	–0.81 (–7.96 to 6.34)	0.8225
	CCBT + MCI	37	–17.98 (–22.59 to –13.38)	0.12 (–6.73 to 6.97)	0.9718
SDQ-c conduct subscale	CCBT	31	–1.21 (–1.87 to –0.55)	Ref.	–
	CCBT + MCBT	34	–0.94 (–1.58 to –0.30)	0.27 (–0.65 to 1.18)	0.5622
	CCBT + MCI	38	–1.00 (–1.59 to –0.40)	0.21 (–0.68 to 1.10)	0.6373
SMFQ-c total score	CCBT	28	–4.08 (–5.95 to –2.21)	Ref.	–
	CCBT + MCBT	35	–4.20 (–5.91 to –2.49)	–0.12 (–2.71 to 2.48)	0.9284
	CCBT + MCI	37	–2.09 (–3.72 to –0.47)	1.99 (–0.48 to 4.46)	0.1132

Ref., reference category.
a Adjusted for child age, child gender, type of child anxiety disorder (GAD, social phobia, SAD, other), baseline severity (ADIS-C/P CSR) of the child's primary anxiety disorder, baseline severity (ADIS-IV mother self-report) of the mother's primary anxiety disorder and baseline questionnaire score.

TABLE 64 Adjusted analysis of change in mother-reported questionnaire scores at 12 months

Variable name	Treatment	*n*	Adjusted[a] mean change (95% CI)	Adjusted[a] mean difference (95% CI)	*p*-value
CAIS-p total score	CCBT	28	–9.50 (–12.44 to –6.56)	Ref.	–
	CCBT + MCBT	27	–12.11 (–15.19 to –9.04)	–2.61 (–6.88 to 1.66)	0.2270
	CCBT + MCI	31	–12.15 (–14.99 to –9.32)	–2.65 (–6.72 to 1.42)	0.1985
SCAS-p total score	CCBT	30	–22.37 (–26.62 to –18.12)	Ref.	–
	CCBT + MCBT	31	–16.36 (–20.58 to –12.15)	6.01 (–0.01 to 12.02)	0.0502
	CCBT + MCI	33	–20.74 (–24.78 to –16.71)	1.62 (–4.27 to 7.51)	0.5850
SDQ-p conduct subscale	CCBT	32	–1.04 (–1.56 to –0.53)	Ref.	–
	CCBT + MCBT	32	–0.89 (–1.40 to –0.38)	0.16 (–0.57 to 0.89)	0.6685
	CCBT + MCI	38	–0.85 (–1.31 to –0.38)	0.20 (–0.50 to 0.89)	0.5755
SMFQ-p total score	CCBT	30	–5.14 (–6.81 to –3.48)	Ref.	–
	CCBT + MCBT	29	–4.54 (–6.25 to –2.82)	0.61 (–1.82 to 3.04)	0.6194
	CCBT + MCI	33	–5.97 (–7.55 to –4.39)	–0.83 (–3.11 to 1.46)	0.4739

Ref., reference category.
a Adjusted for child age, child gender, type of child anxiety disorder (GAD, social phobia, SAD, other), baseline severity (ADIS-C/P CSR) of the child's primary anxiety disorder, baseline severity (ADIS-IV mother self-report) of the mother's primary anxiety disorder and baseline questionnaire score.

TABLE 65 Adjusted analysis of change in teacher-reported questionnaire scores at 12 months

Variable name	Treatment	*n*	Adjusted[a] mean change (95% CI)	Adjusted[a] mean difference (95% CI)	*p*-value
CAS-t total score	CCBT	9	–2.56 (–4.76 to –0.37)	Ref.	–
	CCBT + MCBT	10	–0.04 (–2.23 to 2.14)	2.52 (–0.62 to 5.66)	0.1099
	CCBT + MCI	12	–0.40 (–2.29 to 1.48)	2.16 (–0.77 to 5.09)	0.1391
SCAS-t total score	CCBT	4	–7.90 (–17.17 to 1.37)	Ref.	–
	CCBT + MCBT	4	–0.04 (–18.30 to 18.22)	7.86 (–12.83 to 28.55)	0.2437
	CCBT + MCI	5	–11.90 (–23.14 to –0.66)	–4.00 (–18.25 to 10.25)	0.3510
SDQ-t conduct subscale	CCBT	9	–0.09 (–1.21 to 1.03)	Ref.	–
	CCBT + MCBT	11	–0.27 (–1.30 to 0.75)	–0.18 (–1.71 to 1.34)	0.8051
	CCBT + MCI	12	0.41 (–0.54 to 1.36)	0.50 (–0.99 to 2.00)	0.4903

Ref., reference category.
a Adjusted for child age, child gender, type of child anxiety disorder (GAD, social phobia, SAD, other), baseline severity (ADIS-C/P CSR) of the child's primary anxiety disorder, baseline severity (ADIS-IV mother self-report) of the mother's primary anxiety disorder and baseline questionnaire score.

Secondary research questions

The extent to which improvement in child anxiety was associated with changes in maternal anxiety and parenting responses is shown in the following tables of correlations (see *Tables 66–75*). In each case Pearson's correlation coefficient (*r*), the *p*-value and the number of observations are shown. For each of the three child anxiety variables that are used to correlate with other variables, a higher score implies a worse outcome for the child (as we are looking at the change from baseline).

Associations between change in maternal anxiety and child anxiety outcomes immediately post treatment (assessment 2)

Table 66 (assessment 1B) and *Table 67* (assessment 2) show the correlations between child anxiety (change in SCAS-c total score, change in CSR of primary diagnosis and CGI-I) and maternal anxiety (change in CSR of primary diagnosis). In these tables none of the correlations are statistically different from zero.

Similarly to before, the following table (*Table 68*) shows the correlations between the change in child anxiety scores from baseline to assessment 2 (SCAS-c, CSR and CGI-I) and mother anxiety questionnaire change scores (DASS-21).

TABLE 66 Correlation between child and mother anxiety scores at assessment 1B

Mother anxiety change scores (baseline to assessment 1B)		Child anxiety change scores (baseline to assessment 1B)		
		SCAS-c	CSR of primary diagnosis	CGI-I
Change in CSR	*r*	0.03295	0.06790	0.05102
	p-value	0.6642	0.3419	0.4753
	n	176	198	198

TABLE 67 Correlation between child and mother anxiety scores at assessment 2

Mother anxiety change scores (baseline to assessment 2)		Child anxiety change scores (baseline to assessment 2)		
		SCAS-c	CSR of primary diagnosis	CGI-I
Change in CSR	*r*	0.01689	0.03667	0.09354
	p-value	0.8447	0.6339	0.2237
	n	137	171	171

TABLE 68 Correlations between child and mother anxiety questionnaire change scores at assessment 2

Mother anxiety change scores (baseline to assessment 2)		Change in child anxiety (baseline to assessment 2)		
		SCAS-c	CSR of primary diagnosis	CGI-I
DASS-21 anxiety	*r*	–0.06825	–0.0036	0.05363
	p-value	0.5227	0.9710	0.5943
	n	90	101	101

Associations between change in maternal parenting responses and child anxiety outcomes

Table 69 shows the correlations between the same child anxiety ratings and each of the behavioural change scores at assessment 2. There are significant correlations between change in CSR and change in overprotection ($r = -0.1956$; $p = 0.0225$), CGI-I and change in overprotection ($r = -0.3123$; $p = 0.0002$), CGI-I and change in quality of relationship ($r = -0.1097$; $p = 0.0450$).

Similarly, *Table 70* shows the correlations between the same child anxiety change scores and each of the cognition change scores at assessment 2. None of the correlations are statistically different from zero.

TABLE 69 Correlation between change in child anxiety scores and change in mother behavioural change scores (baseline to assessment 2)

Mother–child behavioural change scores (baseline to assessment 2)		Child anxiety change scores (baseline to assessment 2)		
		SCAS-c	CSR of primary diagnosis	CGI-I
Positive behaviour	*r*	0.00914	–0.01251	–0.06857
	p-value	0.9220	0.8851	0.4294
	n	117	136	135
Overprotection	*r*	0.03525	–0.19558	–0.31226
	p-value	0.7059	0.0225	0.0002
	n	117	136	135
Promotion of avoidance	*r*	0.02498	–0.04638	0.07694
	p-value	0.7892	0.5918	0.3751
	n	117	136	135
Intrusiveness	*r*	0.14039	–0.01128	–0.02442
	p-value	0.1311	0.8963	0.7786
	n	117	136	135
Anxiety	*r*	–0.06341	–0.00024	–0.10791
	p-value	0.4970	0.9978	0.2129
	n	117	136	135
Quality of relationship	*r*	–0.03089	–0.15215	–0.17282
	p-value	0.7409	0.0770	0.0450
	n	117	136	135
POI	*r*	0.17777	–0.00642	0.07565
	p-value	0.0848	0.9479	0.4409
	n	95	106	106

POI, Parent Over-Involvement Questionnaire.

TABLE 70 Correlation between change in child anxiety scores and change in mother cognition change scores (baseline to assessment 2)

Mother–child cognition change scores (baseline to assessment 2)		Child anxiety change scores (baseline to assessment 2)		
		SCAS-c	CSR of primary diagnosis	CGI-I
Pre-task 'scared'	*r*	0.15092	0.00701	0.16665
	p-value	0.1122	0.9367	0.0581
	n	112	131	130
Pre-task 'anxious'	*r*	–0.02832	0.01928	0.07960
	p-value	0.7669	0.8270	0.3680
	n	112	131	130
Pre-task 'child in control'	*r*	–0.03400	–0.04478	–0.08487
	p-value	0.7219	0.6115	0.3370
	n	112	131	130
Pre-task 'mother in control'	*r*	0.17628	0.04862	0.04707
	p-value	0.0630	0.5813	0.5949
	n	112	131	130

Associations between change in maternal anxiety and child anxiety outcomes 6 and 12 months post treatment (assessments 3 and 4)

Tables 71 and *72* show correlations between change in child anxiety scores and change in mother anxiety questionnaire scores from baseline to the 6- and 12-month post-treatment follow-up assessment.
At the 6-month time point none of the correlations were statistically significant. At 12 months, maternal general anxiety (DASS-21) was significantly associated with change in the CSR of the child's primary diagnosis ($p = 0.0195$).

TABLE 71 Correlations between change in child anxiety scores and change in mother anxiety questionnaire score at 6 months (assessment 3)

Mother change scores (baseline to 6 months)		Child change scores (baseline to 6 months)		
		SCAS-c	CSR of primary diagnosis	CGI-I
DASS-21 anxiety	*r*	0.08825	–0.06079	0.06979
	p-value	0.3875	0.5359	0.4772
	n	98	106	106

TABLE 72 Correlations between change in child anxiety scores and change in mother anxiety questionnaire score at 12 months

Mother change scores (baseline to 12 months)		Child change scores (baseline to 12 months)		
		SCAS-c	CSR of primary diagnosis	CGI-I
DASS-21 anxiety	*r*	–0.05089	–0.25755	–0.05375
	p-value	0.6624	0.0195	0.6315
	n	76	82	82

Observations of parental behaviours and cognitions were not made at the 6- and 12-month follow-up assessments, so associations between change in these variables and longer-term outcomes were assessed on the basis of maternal behavioural and cognition change scores at assessment 2 and child anxiety outcomes at 6 and 12 months (*Tables 73* and *74*). Change in maternal overprotection at assessment 2 was associated with CGI-I at 6 months ($p = 0.044$) and change in child anxiety symptoms (SCAS-c) at 12 months ($p = 0.004$). Change in maternal intrusiveness was significantly associated with child CGI-I at 12 months ($p = 0.009$). In relation to maternal cognitions, change in pre-task expectations of how much the mother would be in control of her child's response was significantly associated with change in child anxiety symptoms at 6 months (SCAS-c) ($p = 0.022$).

Parent-reported overinvolvement was assessed at all assessments so concurrent change in this variable could be correlated with child outcomes at the 6- and-12 month assessments, as shown in *Table 75*. There were no significant correlations.

TABLE 73 Correlation between change in child anxiety scores at 6 and 12 months and change in mother behavioural change scores (baseline to assessment 2)

Mother–child behavioural change scores (baseline to assessment 2)		Child anxiety change scores (baseline to 6 months)			Child anxiety change scores (baseline to 12 months)		
		SCAS-c	CSR of primary diagnosis	CGI-I	SCAS-c	CSR of primary diagnosis	CGI-I
Positive behaviour	*r*	0.14050	–0.02741	0.02782	–0.00056	0.00176	0.03081
	p-value	0.1489	0.7615	0.7581	0.9958	0.9850	0.7416
	n	107	125	125	90	117	117
Overprotection	*r*	0.12875	0.05708	–0.18019	0.30408	0.03819	–0.09012
	p-value	0.1863	0.5272	0.0443	0.0036	0.6827	0.3339
	n	107	125	125	90	117	117
Promotion of avoidance	*r*	0.01996	–0.05951	0.03262	–0.02830	0.03669	0.05961
	p-value	0.8383	0.5098	0.7180	0.7912	0.6945	0.5232
	n	107	125	125	90	117	117
Intrusiveness	*r*	0.03897	0.11560	–0.05094	–0.05594	–0.07602	–0.24017
	p-value	0.6902	0.1992	0.5726	0.6005	0.4153	0.0091
	n	107	125	125	90	117	117
Expressed anxiety	*r*	–0.09444	–0.10867	–0.11103	–0.14463	–0.02053	–0.16905
	p-value	0.3333	0.2277	0.2177	0.1738	0.8261	0.0685
	n	107	125	125	90	117	117
Quality of relationship	*r*	–0.03542	–0.09344	–0.06767	0.00020	–0.10428	–0.11616
	p-value	0.7172	0.3000	0.4534	0.9985	0.2632	0.2123
	n	107	125	125	90	117	117

TABLE 74 Correlation between change in child anxiety scores at 6 and 12 months and change in mother cognition change scores (baseline to assessment 2)

Mother–child cognition change scores (baseline to assessment 2)		Child anxiety change scores (baseline to 6 months)			Child anxiety change scores (baseline to 12 months)		
		SCAS-c	CSR of primary diagnosis	CGI-I	SCAS-c	CSR of primary diagnosis	CGI-I
Pre-task 'scared'	*r*	0.05618	0.13760	0.06005	0.14249	–0.05847	–0.02565
	p-value	0.5711	0.1323	0.5129	0.1906	0.5384	0.7874
	n	104	121	121	86	113	113
Pre-task 'anxious'	*r*	0.00674	0.07552	–0.00865	–0.04708	–0.02433	–0.06011
	p-value	0.9458	0.4103	0.9249	0.6669	0.7981	0.5271
	n	104	121	121	86	113	113
Pre-task 'child in control'	*r*	0.06490	–0.16300	–0.05574	0.12284	0.00607	–0.01974
	p-value	0.5127	0.0740	0.5437	0.2598	0.9492	0.8356
	n	104	121	121	86	113	113
Pre-task 'mother control'	*r*	0.22508	0.06698	0.03040	0.20293	–0.05837	0.01778
	p-value	0.0216	0.4654	0.7406	0.0609	0.5391	0.8517
	n	104	121	121	86	113	113

TABLE 75 Correlation between change in child anxiety scores and change in maternal-reported overprotection at 6 and 12 months

POI change scores		SCAS-c	CSR of primary diagnosis	CGI-I
Baseline to 6-month follow-up	*r*	0.11522	–0.05258	0.07649
	p-value	0.2488	0.5854	0.4270
	n	102	110	110
Baseline to 12-month follow-up	*r*	0.09522	–0.06828	0.04747
	p-value	0.3860	0.5201	0.6568
	n	85	91	90

POI, Parent Over-Involvement Questionnaire.

Adverse events

Adverse events were defined as follows:

> *Adverse or unexpected events resulting in physical or psychological injury that arise from the administration of research procedures or the provision of treatment within the trial. This will include events such as breach of confidentiality, adverse therapeutic interventions, diagnostic error, improper staff behaviour, falls and injury.*

There were no adverse events.

Chapter 4 Economic evaluation: cost–utility analysis of treatment of childhood anxiety disorder in the context of maternal anxiety disorder

Introduction

The aim of the economic evaluation was to assess the cost-effectiveness of the CCBT + MCBT and CCBT + MCI treatment arms compared with the CCBT treatment arm. This design mirrored the study research questions, and hence was equivalent to conducting two separate economic evaluations, that is CCBT + MCBT versus CCBT, and CCBT + MCI versus CCBT. An incremental comparison between CCBT + MCBT and CCBT + MCI was not a research question and the statistical and economic analyses were not powered for this comparison. The primary economic analyses followed an ITT approach and adopted a health service provider perspective. The economic analyses aligned with the primary aim of the trial, namely to evaluate whether or not the CCBT treatment arm could be improved by the addition of (i) treatment of maternal anxiety disorders (MCBT), or (ii) treatment focused on maternal responses (MCI). Secondary economic analyses complemented the results of the primary analyses by measuring additional mother and child resource use of health and personal social services beyond the main costs of the treatment. Broader impacts on other sectors, including education and employment, were also measured. Data were collected on time off school for children and time off work and usual activities for mothers/carers.

Methods

The primary economic analyses for both comparisons consisted of a cost–utility analysis (CUA) conducted from a health service provider perspective. Secondary economic analyses supplemented the primary results by identifying, measuring and valuing resource use impacts from a wider social and personal social service perspective in addition to measuring the impact on the education and employment sectors. Recent methods guidance on the conduct, reporting and presentation of economic evaluations were adhered.[75–77] Costs and outcomes were combined within a CUA framework and presented using incremental cost-effectiveness ratios (ICERs) with uncertainty represented using the cost-effectiveness plane. The results were also reported using net monetary benefit (NMB). Prices were reported in 2011/12 as the base year, adjusted for inflation using Retail Price Index (RPI) 2012[78] or Hospital and Community Health Service (HCHS) index 2011/12[79] as appropriate. All statistical analyses were performed using Stata version 12.1. Statistical significance was set at p-values < 0.05.

Identification and measurement of health and social care resource use

Patient-level resource use data, including all associated treatment costs, additional health and personal social service costs, were identified and measured as an integral part of the trial data collection process. Resource use data were collected via a 'bottom up' approach where detail on the intervention and control resources used to deliver the CCBT + MCBT, CCBT + MCI and CCBT treatment arms were identified and measured via the use of a specially designed 'therapist resource use log'. This log was designed for trial therapists to complete every time a contact was made. Details for all types of visit (e.g. client face-to-face visit, phone contact, school visit) were collected by recording all resources used, duration of any contact with the patient as well as other resources such as travel mileage, rail fares or other expenses incurred during the contact. See *Appendix 3*, *Health economic logs*, for a copy of the therapist resource use log.

A patient-held 'resource use' diary was developed to capture any additional health and social care resources used by the mother and child beyond the therapy sessions (see *Appendix 3*, *Health economics diary/patient-held resource use diary*). The aim of the diary was to aid recall, that is for the use of mothers as a means of recording relevant resource use information for them and their children during the time between assessments (baseline to assessment 1B for mid-intervention; assessment 1B to assessment 2 for post intervention; assessment 2 to 6 months for the 6-month follow-up; 6 months to 12 months for the 12-month follow-up), so that they might be able to complete the mid- and post-intervention questionnaires more efficiently. The resource use diaries comprised three sections. The first section included questions on use of primary and secondary care health services (*except* the main anxiety intervention), of other social services (e.g. social worker contacts) and of services provided by government bodies other than the NHS (e.g. education department). The second section aimed to collect information on drug treatment by asking mothers whether or not they and/or their children made use of medications and if the latter were GP prescribed or purchased 'over-the-counter'. Finally, in a bid to capture broader societal impacts on employment and education, the third section asked mothers to report how much time they had to take off work and/or usual activities owing to ill health and how many days off school their children had taken owing to ill health.

Valuation of health and social care resource use

For each trial participant (mother and child), all components of treatment costs stratified by category of resource use were computed by multiplying units of resource use by their unit costs. These were then summed over all resource use categories to obtain a total annual cost for each participant. Unit cost sources included NHS reference costs and unit costs of community care.[79–86] Unit costs can be found in *Appendix 3*, *Table 89*. Primary economic analyses focused only on the NHS cost of the alternative anxiety treatments; preliminary secondary analyses included also wider societal and further health and social care costs and will be developed further to include cost of medications and time off work. Prescription cost analysis[87] and published literature will be used to identify unit costs of prescribed and 'over-the-counter' drugs, respectively, whereas time off work will be valued using the human capital approach, using the median gross weekly earnings by age and sex.[88] Values are expressed in 2011/12 UK pounds sterling (£). Values available only in 2010/11 or earlier prices were adjusted for inflation using RPI 2012[78] or the HCHS pay and price inflation index 2011/12.[79] As the duration of the study was 12 months, discounting of future costs and benefits was not required.

Identifying and measuring outcomes: quality-adjusted life-years

In line with National Institute for Health and Care Excellence (NICE) recommendations, outcomes in the economic analyses were identified and measured using quality-adjusted life-years (QALYs). Data to estimate QALYs for mothers were collected through the European Quality of Life-5 Dimensions (EQ-5D) self-completion questionnaire,[89] which was administered to mothers at baseline, assessment 1B (mid-treatment), assessment 2 (post treatment), and at 6- and 12-month follow-ups. For children the EQ-5D child-friendly version was used.[90] The EQ-5D is a generic measure of health-related quality of life, designed to estimate QALYs and widely used across disease areas. It contains five questions each concerned with a different area or 'domain' of everyday life: mobility; self-care; usual activities such as work, study, housework and leisure activities; pain/discomfort; and anxiety/depression. The answers to these questions provide a description or profile of the respondent's quality of life and a value is then attached to each profile using the results of a large UK general population survey.[91] The tariff was used to estimate health-related quality of life (EQ-5D scores) for each child and mother at baseline, assessment 1B (mid-treatment), assessment 2 (post treatment), and at 6- and 12-month follow-ups. These EQ-5D utilities were then combined with duration spent in each health state to estimate QALY gain over the 12-month period of the study, assuming linear changes of utility between measurements and linear interpolation to identify the area under the curve for the 12-month period.[92] QALYs were computed using the area under the curve approach, weighting the 12-month period by utility measured on a scale from 0 to 1.[92]

Reporting and presenting results

Within the primary economic analyses the mean volume of health-care resources associated with each arm were estimated and reported together with their standard errors (CCBT + MCBT, CCBT + MCI and CCBT). Mean differences were calculated using ordinary least squares (OLS) regression to reflect the trial comparisons: first the incremental resources used by the CCBT + MCBT arm versus the CCBT arm, and second the incremental resources used by the CCBT + MCI arm versus the CCBT arm. Differences in resource use are reported alongside 95% CIs.

Within the secondary economic analyses, health-care services other than those associated with the intervention, other personal social services, non-NHS resources and medication use, were investigated both for the mother and the child in each arm using descriptive statistics on the available data. More specifically, mean resource use volumes were reported with their SDs for mother and child separately over the following periods: baseline to assessment 1B (mid-treatment); assessment 1B to assessment 2 (post treatment); assessment 2 to 6 months follow-up; and from 6 months to 12 months follow-up.

In the primary analyses the total intervention cost per participant (mother and child) was estimated by multiplying the volume of each item of resource used by the unit cost of that item, then summing each item cost for each participant. Mean costs were estimated and reported together with their standard errors for each trial arm. Statistical differences in mean cost estimates across trial arms (CCBT + MCBT vs. CCBT; and CCBT + MCI vs. CCBT) were evaluated using OLS regression. Robustness checks were conducted using generalized linear modelling estimates to account for skewedness of cost data. Similar analyses were conducted in relation to wider health and social care costs in the preliminary secondary analyses. In those cases, however, total cost per patient was first calculated over each period between measurements, namely from baseline to assessment 1B (mid-treatment); from assessment 1B to assessment 2 weeks (post treatment); from assessment 2 to 6 months follow-up; and from 6 months to 12 months follow-up, and then summed for each patient in order to obtain a total cost over the 12-month period. Cost estimates were calculated for mother and child separately and then combined into one variable.

In order to inform whether or not either intervention is cost-effective, current methods recommended by NICE technology assessment guidance have been adopted to report and present the results of the incremental costs and QALYs for each comparison (CCBT + MCBT vs. CCBT; CCBT + MCI vs. CCBT). The methods recommended by NICE are to combine incremental costs and outcomes within an ICER and to report the joint distribution of the bootstrapped ICERs on a cost-effectiveness plane to provide information on the associated uncertainty around this point estimate. Currently NICE uses a threshold range of £20,000–30,000 per QALY gained (i.e. any ICER within or below this range would be deemed a cost-effective use of resources). Mean incremental cost of the intervention and mean child QALYs were combined within an ICER for CCBT + MCBT versus CCBT and CCBT + MCI versus CCBT, respectively. Uncertainty around matched costs and QALY dyads were explored using both a parametric (Fieller's theorem[93,94]) and non-parametric (bootstrap method[95,96]) approach. Within the bootstrap approach, uncertainty was investigated using 1000 bootstrapped samples to generate multiple cost–effect pairs, and displayed and analysed using cost-effectiveness acceptability curves (CEACs).[97] CEACs show the probability of a treatment being cost-effective given a wide range of willingness-to-pay threshold values for health gains. In addition, a linear representation of the CEAC, incorporating values for societal willingness to pay, NMB, was calculated for CCBT + MCBT and CCBT + MCI versus CCBT, respectively, as:

$$\mathrm{NMB}_i(\lambda) = \lambda E_i - C_i, \quad (1)$$

where E_i and C_i are the observed differences in effects (E) and costs (C), respectively, for patient 'i' and λ is the societal willingness to pay for a health gain. Where NMB is positive, this suggests the intervention is a worthwhile use of resources. The NMB framework can be seen as an alternative way of representing the ICER.

In the secondary analyses, days off school for the child and days off work and/or usual activities for the mother due to ill health were investigated using descriptive statistics. Further analyses will be developed to explore mean differences statistically and to include a valuation of lost productivity using the human capital approach with standard valuations to avoid bias.[98]

Sensitivity analysis

Sensitivity analysis around key variables is performed in a bid to determine the key factors influencing cost-effectiveness. A key question is uncertainty in the cost-effectiveness analysis related to the impact of reducing the treatment costs of non-specific interventions. Hence, sensitivity analysis was conducted by setting the treatment costs related to non-specific interventions to zero. Treatment costs related to non-specific interventions included NDC and the FH control delivered to balance groups for therapist contact. Exploring the impact of reducing these costs was intended to reflect what would happen in reality if the interventions were adopted in current practice. Further sensitivity analysis will be developed by altering other key assumptions to explore their consequences for the results at the 12-month follow-up. In particular, an exploration of the incorporation of broader societal impacts on the cost-effectiveness results will be carried out, as well as further exploration of the results of the cost-effectiveness analysis to include combined child and maternal QALYs in the full CUA. The latter were not included in the primary analyses (only the child QALYs) in order to mirror the main trial outcomes.

Handling missing data

The primary economic evaluation adopted an ITT approach and missing data on resource use and health outcomes were imputed using two different methods. For face-to-face therapist contacts, where missing data values were highly deterministic (i.e. readily identifiable and standardised given observed practice), a conditional imputation method was conducted whereby missing data were estimated as an average of know durations for that client and session type. For the other resource use (mainly supervision time), costs (i.e. reward costs) and health outcomes (EQ-5D), where missing data were presented in higher percentages, multiple imputation was performed using a chained equation procedure[99] and 20 imputed data sets were generated using the Stata command 'mi impute chained'. Prediction equations for each imputation variable were customised and allowed to differ. Conditional models for imputed variables are specified in *Appendix 3*, *Health economic supplementary material section 1*.

Results

Data completeness

Data were missing because questionnaires were not fully completed at all time points. However, a high percentage of complete data were obtained from the likely key drivers, the therapist log for the intervention and control service costs (e.g. 76.8% complete for MCBT contact time). Complete EQ-5D data from mothers and child-friendly EQ-5D data for children ranged from 47.9% to 91.3% for mother and from 46.5% to 98.6% for children. Detailed percentages of missing data are presented in *Appendix 3*, *Tables 90* and *91* to maximise transparency and aid interpretation of results. A complete case analysis was not possible owing to the high percentage of missing data across resource use and health outcomes. Restricting the sample to those children who had the EQ-5D measured at each assessment reduced the sample size to just above one-third of the initial sample (77 vs. 211). These results were underpowered and are therefore unreliable hence not reported, but they are available from the authors on request.

Resource use: therapy time

Utilising data obtained from the therapists' log, *Table 76* provides a detailed descriptive breakdown of the specific components of health-care resources used across each trial's arm (face-to-face contact with patients, supervision time, preparation time, travel time and mileage). The principal resource used for the intervention was the staff time that the therapists spent directly with the patient, preparation time and travelling time.

Table 77 reports the incremental mean time differences in minutes between CCBT + MCBT and CCBT. Although the total time difference between the groups is not statistically significant, individual items including duration of treatment for maternal anxiety, travel time and mileage are all significantly higher in the CCBT + MCBT arm.

Table 78 reports incremental differences between the CCBT + MCI and CCBT treatment arms. Total time differences between the arms are not statistically significant; however, there are statistically significant differences among individual items including time spent providing CCBT, MCBT/NDC, MCI/FH; treatment and supervision time for MCBT/NDC; and treatment and supervision time for MCI/FH.

TABLE 76 Detailed treatment resource use volumes

Resource use item	CCBT + MCBT ($n = 69$), mean (SD) (minutes)	CCBT + MCI ($n = 71$), mean (SD) (minutes)	CCBT ($n = 71$), mean (SD) (minutes)
CCBT	423.95 (143.26)	454.31 (147.13)	391.74 (183.95)
MCBT	380.79 (106.30)	NA	NA
Maternal counselling (NDC)	NA	108.77 (20.27)	329.73 (110.05)
MCI treatment (MCI; mother only)[a]	NA	399.79 (132.24)	NA
MCI treatment (MCI; mother and child)[a]	NA	58.94 (37.56)	NA
FH	143.41 (65.11)	NA	138.61 (70.85)
Supervision time for CCBT (therapist time)	26.22 (3.42)[b]	30.43 (3.77)[b]	26.22 (3.55)[b]
Supervision time for CCBT (supervisor time)	26.22 (3.42)[b]	30.43 (3.77)[b]	26.22 (3.55)[b]
Supervision time for MCBT/NDC (therapist time)	46.03 (4.59)[b]	35.50 (5.09)[b]	52.21 (6.62)[b]
Supervision time for MCBT/NDC (supervisor time)	46.03 (4.59)[b]	35.50 (5.09)[b]	52.21 (6.62)[b]
Supervision time for MCI/FH (therapist time)	8.77 (2.36)[b]	24.99 (2.55)[b]	9.09 (2.06)[b]
Supervision time for MCI/FH (supervisor time)	8.77 (2.36)[b]	24.99 (2.55)[b]	9.09 (2.06)[b]
Travel (duration)	317.13 (437.18)	221.48 (379.50)	191.08 (298.52)
Travel (mileage)	181.31 (260.03)	127.73 (231.39)	105.69 (180.75)
Other	33.04 (48.06)	20.61 (49.35)	30.26 (86.41)
Extra time associated to 'not attended' sessions (e.g. waiting time, phone call, etc.)	0.80 (4.67)	3.52 (17.14)	0.42 (3.56)
Reward (monetary only)	£0.97 (2.14)	£1.07 (2.34)	£0.86 (2.14)
Parking (monetary only)	£0.10 (0.84)	£0.03 (0.24)	£0

NA, not applicable.
a One child/mother belonging to the MCBT treatment arm also received MCI 'mother only' (minutes = 420) and 'child and mother' treatment (minutes = 35) (see *Chapter 2, Statistical analysis*).
b Standard error in parentheses, as variable is multiply imputed or is derived from other multiply imputed variables.

TABLE 77 Treatment resource use mean differences: CCBT + MCBT vs. CCBT

Resource use item	CCBT + MCBT ($n = 69$), mean (SD) (minutes)	CCBT ($n = 71$), mean (SD) (minutes)	Mean differences (minutes): CCBT + MCBT – CCBT (95% CI)	*p*-value
CCBT	423.95 (143.26)	391.74 (183.95)	32.21 (–22.99 to 87.41)	0.251
MCBT/NDC	380.79 (106.30)	329.73 (110.05)	51.06 (14.89 to 87.24)	0.006
MCI/FH	150.00 (72.94)	138.61 (70.85)	11.39 (–12.63 to 35.43)	0.350
Supervision time for CCBT (therapist time)	26.22 (3.42)[a]	26.22 (3.55)[a]	0.0019596 (–9.10 to 9.10)	1.000
Supervision time for CCBT (supervisor time)	26.22 (3.42)[a]	26.22 (3.55)[a]	0.0019596 (–9.10 to 9.10)	1.000
Supervision time for MCBT/NDC (therapist time)	46.03 (4.59)[a]	52.21 (6.62)[a]	–6.18 (–22.77 to 10.42)	0.456
Supervision time for MCBT/NDC (supervisor time)	46.03 (4.59)[a]	52.21 (6.62)[a]	–6.18 (–22.77 to 10.42)	0.456
Supervision time for MCI/FH (therapist time)	8.77 (2.36)[a]	9.09 (2.06)[a]	–0.32 (–5.88 to 5.24)	0.905
Supervision time for MCI/FH (supervisor time)	8.77 (2.36)[a]	9.09 (2.06)[a]	–0.32 (–5.88 to 5.24)	0.905
Preparation time and record keeping	376.22 (192.47)	404.28 (191.75)	–28.06 (–92.27 to 36.15)	0.39
Travel (duration)	317.13 (437.18)	191.08 (298.52)	126.05 (1.25 to 250.84)	0.048
Travel (mileage)	181.31 (260.03)	105.69 (180.75)	75.63 (0.97 to 150.29)	0.047
Other	33.04 (48.06)	30.26 (86.41)	2.78 (–20.68 to 26.24)	0.815
Extra time associated to 'not attended' sessions (e.g. waiting time, phone call, etc.)	0.80 (4.67)	0.42 (3.56)	0.37 (–1.01 to 1.76)	0.594
Total therapy resource use[b] (minutes)	1843.98 (81.78)[a]	1661.18 (78.67)[a]	182.79 (–40.92 to 406.51)	0.108

a Standard error in parentheses, as variable is multiply imputed or is derived from other multiply imputed variables.
b Excluding travel mileage, which is not expressed in minutes.

TABLE 78 Treatment resource use mean differences: CCBT + MCI vs. CCBT

Resource use item	CCBT + MCI ($n = 71$), mean (SD) (minutes)	CCBT ($n = 71$), mean (SD) (minutes)	Mean differences (minutes): CCBT + MCI – CCBT (95% CI)	*p*-value
CCBT	454.31 (147.13)	391.74 (183.95)	62.57 (7.30 to 117.84)	0.027
MCBT/NDC	108.77 (20.27)	329.73 (110.05)	–220.97 (–247.22 to –194.71)	0.000
MCI/FH	458.73 (148.85)	138.61 (70.85)	320.12 (281.45 to 358.80)	0.000
Supervision time for CCBT (therapist time)	30.43 (3.77)[a]	26.22 (3.55)[a]	4.21 (–6.52 to 14.94)	0.436
Supervision time for CCBT (supervision time)	30.43 (3.77)[a]	26.22 (3.55)[a]	4.21 (–6.52 to 14.94)	0.436
Supervision time for MCBT/NDC (therapist time)	35.50 (5.09)[a]	52.21 (6.62)[a]	–16.72 (–32.21 to –1.22)	0.035
Supervision time for MCBT/NDC (supervision time)	35.50 (5.09)[a]	52.21 (6.62)[a]	–16.72 (–32.21 to –1.22)	0.035
Supervision time for MCI/FH (therapist time)	24.99 (2.55)[a]	9.09 (2.06)[a]	15.90 (9.30 to 22.49)	0.000
Supervision time for MCI/FH (supervision time)	24.99 (2.55)[a]	9.09 (2.06)[a]	15.90 (9.30 to 22.49)	0.000
Preparation time and record keeping	346.93 (157.95)	404.28 (191.75)	–57.36 (–115.64 to 0.93)	0.054
Travel (duration)	221.48 (379.50)	191.08 (298.52)	30.39 (–82.89 to 143.68)	0.597
Travel (mileage)	127.73 (231.39)	105.69 (180.75)	22.05 (–46.85 to 90.94)	0.528
Other	20.61 (49.35)	30.26 (86.41)	–9.65 (–32.99 to 13.70)	0.415
Extra time associated to 'not attended' sessions (e.g. waiting time, phone call, etc.)	3.52 (17.14)	0.42 (3.56)	3.10 (–1.01 to 7.21)	0.138
Total therapy resource use[b] (minutes)	1796.18 (75.27)[a]	1661.18 (78.67)[a]	134.99 (–79.71 to 349.69)	0.216

a Standard error in parentheses, as variable is multiply imputed or is derived from other multiply imputed variables.
b Excluding travel mileage, which is not expressed in minutes.

Cost of therapy

Resource differences in time for CCBT + MCBT versus CCBT are translated into cost differences in *Table 79* below and reveal a borderline statistically significant difference in total cost between the groups, with CCBT + MCBT being £233.55 more expensive than the CCBT arm.

Resource differences in time for CCBT + MCI versus CCBT are translated into cost differences in *Table 80* and reveal a borderline statistically significant difference in total cost between the groups, with the CCBT + MCI arm being £233.16 more expensive that the CCBT arm.

TABLE 79 Treatment cost mean differences: CCBT + MCBT vs. CCBT

Cost[a]	CCBT + MCBT ($n = 69$), mean (SD)	CCBT ($n = 71$), mean (SD)	Mean differences: CCBT + MCBT – CCBT (95% CI)	*p*-value
CCBT	£621.65 (210.07)	£574.42 (269.72)	£47.23 (–£33.72 to £128.17)	0.251
MCBT/NDC	£558.37 (155.87)	£483.50 (161.38)	£74.87 (£21.83 to £127.91)	0.006
MCI/FH	£219.96 (106.96)	£203.24 (103.88)	£16.71 (–£18.52 to £51.95)	0.350
Supervision time for CCBT (therapist time)	£17.11 (2.23)[b]	£17.11 (2.32)[b]	£0.001 (–£5.94 to £5.94)	1.000
Supervision time for CCBT (supervision time)	£30.93 (4.03)[b]	£30.92 (4.19)[b]	£0.002 (–£10.73 to £10.74)	1.000
Supervision time for MCBT/NDC (therapist time)	£30.04 (2.99)[b]	£34.07 (4.32)[b]	–£4.03 (–£14.87 to £6.80)	0.456
Supervision time for MCBT/NDC (supervision time)	£54.29 (5.41)[b]	£61.59 (7.80)[b]	–£7.29 (–£26.88 to £12.29)	0.456
Supervision time for MCI/FH (therapist time)	£5.72 (1.54)[b]	£5.93 (1.35)[b]	–£0.21 (–£3.84 to £3.42)	0.905
Supervision time for MCI/FH (supervision time)	£10.34 (2.79)[b]	£10.72 (2.43)[b]	–£0.38 (–£6.94 to £6.18)	0.905
Preparation time and record keeping	£245.49 (125.58)	£263.80 (125.11)	–£18.31 (–£60.21 to £23.59)	0.389
Travel (duration)	£206.93 (285.26)	£124.68 (194.78	£82.24 (£0.82 to £163.67)	0.048
Travel (mileage)	£97.91 (140.42)	£57.07 (97.60)	£40.84 (£0.52 to £81.16)	0.047
Other	£21.56 (31.36)	£19.75 (56.39)	£1.81 (–£13.50 to £17.12)	0.815
Extra time associated to 'not attended' sessions (e.g. waiting time, phone call, etc.)	£0.52 (3.05)	£0.28 (2.32)	£0.24 (–£0.66 to £1.15)	0.594
Rewards	£3.95 (0.46)[b]	£4.22 (0.48)[b]	–£0.27 (–£1.72 to £1.18)	0.763
Parking	£0.10 (0.84)	£0 NA	£0.10 (–£0.10 to £0.30)	0.312
Treatment total cost	£2124.85 (84.98)[b]	£1891.30 (87.14)[b]	£233.55 (–£6.81 to £473.92)	0.057

NA, not applicable.

a Time delivering treatments (CCBT, MCBT/NDC, MCI/FH) was cost at the therapist–client contact hourly rate, whereas the other therapist's time was cost at the therapist standard hourly rate.

b Standard error in parentheses, as variable is multiply imputed or is derived from other multiply imputed variables.

TABLE 80 Treatment cost mean differences: CCBT + MCI vs. CCBT

Cost[a]	CCBT + MCI ($n = 71$), mean (SD)	CCBT ($n = 71$), mean (SD)	Mean differences: CCBT + MCI – CCBT + MCBT (95% CI)	*p*-value
CCBT	£666.18 (215.74)	£574.42 (269.72)	£91.75 (£10.71 to £172.80)	0.027
MCBT/NDC	£159.49 (29.72)	£483.50 (161.38)	–£324.01 (–£362.51 to –£285.51)	0.000
MCI/FH	£672.65 (218.26)	£203.24 (103.88)	£469.41 (£412.69 to £526.13)	0.000
Supervision time for CCBT (therapist time)	£19.85 (2.46)[b]	£17.11 (2.32)[b]	£2.75 (–£4.25 to £9.75)	0.436
Supervision time for CCBT (supervision time)	£35.89 (4.44)[b]	£30.92 (4.19)[b]	£4.96 (–£7.69 to £17.62)	0.436
Supervision time for MCBT/NDC (therapist time)	£23.16 (3.32)[b]	£34.07 (4.32)[b]	–£10.91 (–£21.02 to –£0.80)	0.035
Supervision time for MCBT/NDC (supervision time)	£41.87 (6.00)[b]	£61.59 (7.80)[b]	–£19.72 (–£37.99 to–£1.44)	0.035
Supervision time for MCI/FH (therapist time)	£16.31 (1.66)[b]	£5.93 (1.35)[b]	£10.37 (£6.07 to £14.68)	0.000
Supervision time for MCI/FH (supervision time)	£29.48 (3.01)[b]	£10.72 (2.43)[b]	£18.75 (£10.97 to £26.53)	0.000
Preparation time and record keeping	£226.37 (103.06)	£263.80 (125.11)	–£37.42 (–£75.46 to £0.61)	0.054
Travel (duration)	£144.52 (247.62)	£124.68 (194.78)	£19.83 (–£54.09 to £93.75)	0.597
Travel (mileage)	£68.97 (124.95)	£57.07 (97.60)	£11.90 (–£25.30 to £49.11)	0.528
Other	£13.45 (32.20)	£19.75 (56.39)	–£6.30 (–£21.53 to £8.94)	0.415
Extra time associated to 'not attended' sessions (e.g. waiting time, phone call, etc.)	£2.30 (11.19)	£0.28 (2.32)	£2.02 (–£0.66 to £4.70)	0.138
Reward	£3.96 (0.49)[b]	£4.22 (0.48)[b]	–£0.26 (–£1.77 to £1.25)	0.727
Parking	£0.03 (0.24)	£0	£0.03 (–£0.03 to £0.08)	0.319
Treatment total cost	£2124.46 (83.06)[b]	£1891.30 (87.14)[b]	£233.16 (–£6.81 to £473.92)	0.054

a Time delivering treatments (CCBT, MCBT/NDC, MCI/FH) was cost at the therapist client contact hourly rate, while the other therapist's time was cost at the therapist standard hourly rate.
b Standard error in parentheses, as variable is multiply imputed or is derived from other multiply imputed variables.

Cost of additional health, personal social and non-NHS services

The total cost variable for use in the CUA comparing CCBT + MCBT with CCBT and CCBT + MCI with CCBT was derived using the treatment costs only. Limited data were available from the additional health and social service use patient diaries and three monthly resource use questionnaires (see *Appendix 3*, *Tables 92–115*) owing to small numbers completed (reported in *Appendix 3*, *Table 91*). The results from these analyses provide an indication of the broad health and social care resources used by this group. *Tables 81* and *82* report a summary of these results for CCBT + MCBT versus CCBT and for CCBT + MCI versus CCBT. Further, detailed sensitivity analyses using chained equations to impute missing data will consider this wider societal perspective. The analyses will include these health and social care resources and costs beyond the resources/cost of the treatment, as well as resource use/cost from other sectors of the economy (e.g. education). Furthermore, additional information on productivity loss (i.e. days off school for children, and days off work and usual activities for mothers) will be included in these sensitivity analyses (see *Appendix 3*, *Tables 112–115*).

TABLE 81 Cost of other health and social care resources and other non-NHS services: child, mother and overall (available data only) – CCBT + MCBT vs. CCBT

Cost	*n*	CCBT + MCBT, mean (SD)	*n*	CCBT, mean (SD)	Mean differences: CCBT + MCBT – CCBT (95% CI)	*p*-value
Child						
Baseline to assessment 1B	35	£191.10 (281.97)	32	£148.01 (302.32)	£43.10 (–£99.46 to £185.66)	0.548
Assessment 1B to assessment 2	17	£202.02 (648.96)	20	£121.76 (369.93)	£80.25 (–£265.66 to £426.18)	0.641
Assessment 2 to assessment 3	32	£161.53 (267.83)	30	£385.78 (1043.20)	–£224.25 (–£605.70 to £157.19)	0.244
Assessment 3 to assessment 4	23	£103.47 (158.66)	30	£327.45 (1178.54)	–£223.98 (–£721.84 to £273.88)	0.371
Total over 12 months (child)	54	£327.26 (546.50)	51	£560.16 (1803.80)	–£232.90 (–£742.72 to £276.90)	0.367
Mother						
Baseline to assessment 1B	35	£145.32 (189.04)	32	£223.66 (429.56)	–£78.33 (–£237.89 to £81.22)	0.330
Assessment 1B to assessment 2	17	£202.95 (272.91)	20	£382.62 (867.47)	–£179.66 (–£625.18 to £265.85)	0.418
Assessment 2 to assessment 3	32	£194.44 (323.03)	30	£313.20 (886.12)	–£118.76 (–£453.43 to £215.91)	0.481
Assessment 3 to assessment 4	23	£299.35 (537.12)	30	£206.27 (614.93)	£93.09 (–231.09 to 417.27)	0.567
Total over 12 months (mother)	54	£400.81 (622.99)	51	£595.95 (1987.14)	–£195.13 (–£758.53 to £368.25)	0.494
Child and mother						
Total over 12 months (child and mother)	54	£728.07 (860.19)	51	£1156.11 (281.97)	–£428.048 (–£1453.25 to £597.16)	0.410

TABLE 82 Cost of other health and social care resources and other non-NHS services: child, mother and overall (available data only) – CCBT + MCI vs. CCBT

Cost	*n*	CCBT + MCI, mean (SD)	*n*	CCBT, mean (SD)	Mean differences: CCBT + MCI – CCBT (95% CI)	*p*-value
Child						
Baseline to assessment 1B	47	£172.17 (390.05)	32	£148.01 (302.32)	£24.16 (–£138.91 to £187.24)	0.769
Assessment 1B to assessment 2	25	£120.25 (330.03)	20	£121.76 (369.93)	–£1.51 (–£212.19 to £209.17)	0.989
Assessment 2 to assessment 3	31	£89.51 (169.73)	30	£385.78 (1043.20)	–£296.28 (–£676.18 to £83.63)	0.124
Assessment 3 to assessment 4	23	£132.54 (258.41)	30	£327.45 (1178.54)	–£194.90 (–£698.31 to £308.51)	0.441
Total over 12 months (child)	60	£282.03 (586.32)	51	£560.16 (1803.80)	–£278.139 (–£767.21 to £210.93)	0.262
Mother						
Baseline to assessment 1B	47	£122.15 (232.82)	32	£223.66 (429.56)	–£101.512 (–£250.56 to £47.54)	0.179
Assessment 1B to assessment 2	25	£129.19 (259.35)	20	£382.62 (867.47)	–£253.42 (–£621.46 to £114.61)	0.172
Assessment 2 to assessment 3	31	£82.67 (127.86)	30	£313.20 (886.12)	–£230.53 (–£552.31 to £91.25)	0.157
Assessment 3 to assessment 4	23	£151.26 (213.60)	30	£206.27 (614.93)	–£55.01 (–£324.56 to £214.55)	0.684
Total over 12 months (mother)	60	£250.21 (311.15)	51	£595.95 (1987.14)	–£345.74 (–£861.08 to £169.59)	0.186
Child and mother						
Total over 12 months (child and mother)	60	£311.15 (814.58)	51	£1156.11 (281.97)	–£623.88 (–£1595.28 to £347.52)	0.206

Quality-adjusted life-years

Table 83 reports the results of the child EQ-5D utility values and QALYs for CCBT + MCBT versus CCBT. There are no statistically significant differences in QALYs at 12 months.

Table 84 reports the results of the child EQ-5D utility values and QALYs for CCBT + MCI versus CCBT. There are no statistically significant differences in QALYs at 12 months.

Table 85 reports the results of the mother EQ-5D utility values and QALYs for CCBT + MCBT versus CCBT. There are no statistically significant differences in QALYs at 12 months.

Table 86 reports the results of the mother EQ-5D utility values and QALYs for CCBT + MCI versus CCBT. There are no statistically significant differences in QALYs at 12 months.

TABLE 83 Child EQ-5D utility values and QALYs gained: CCBT + MCBT vs. CCBT

Time of assessment	CCBT + MCBT ($n = 69$), mean (SE)	CCBT ($n = 71$), mean (SE)	Mean differences: CCBT + MCBT – CCBT (95% CI)	*p*-value
EQ-5D utility values				
Baseline	0.706 (0.028)	0.684 (0.036)	0.022 (–0.070 to 0.113)	0.641
Assessment 1B	0.727 (0.030)	0.773 (0.034)	–0.046 (–0.135 to 0.042)	0.300
Assessment 2	0.798 (0.028)	0.862 (0.028)	–0.065 (–0.144 to 0.015)	0.108
6-month follow-up	0.823 (0.033)	0.840 (0.034)	–0.018 (–0.116 to 0.081)	0.723
12-month follow-up	0.821 (0.038)	0.862 (0.034)	–0.042 (–0.150 to 0.067)	0.440
QALYs gained				
Baseline to assessment 1B	0.110 (0.004)	0.112 (0.004)	–0.002 (–0.013 to 0.009)	0.741
Assessment 1B to assessment 2	0.117 (0.004)	0.126 (0.004)	–0.009 (–0.019 to 0.002)	0.097
Assessment 2 to 6 months	0.156 (0.005)	0.164 (0.005)	–0.008 (–0.023 to 0.007)	0.291
6–12 months	0.411 (0.015)	0.426 (0.015)	–0.015 (–0.059 to 0.030)	0.508
Total over 12 months	0.794 (0.022)	0.827 (0.024)	–0.033 (–0.101 to 0.035)	0.332

SE, standard error.

TABLE 84 Child EQ-5D utility values and QALYs gained: CCBT + MCI vs. CCBT

Time of assessment	CCBT + MCI ($n = 71$), mean (SE)	CCBT ($n = 71$), mean (SE)	Mean differences: CCBT + MCI – CCBT (95% CI)	*p*-value
EQ-5D utility values				
Baseline	0.729 (0.036)	0.684 (0.036)	0.045 (–0.058 to 0.147)	0.393
Assessment 1B	0.798 (0.026)	0.773 (0.034)	0.025 (–0.059 to 0.109)	0.559
Assessment 2	0.867 (0.023)	0.862 (0.028)	0.004 (–0.068 to 0.076)	0.904
6-month follow-up	0.897 (0.023)	0.840 (0.034)	0.057 (–0.026 to 0.139)	0.175
12-month follow-up	0.864 (0.031)	0.862 (0.034)	0.001 (–0.083 to 0.086)	0.973
QALYs gained				
Baseline to assessment 1B	0.118 (0.004)	0.112 (0.004)	0.005 (–0.006 to 0.017)	0.370
Assessment 1B to assessment 2	0.128 (0.003)	0.126 (0.004)	0.002 (–0.007 to 0.012)	0.637
Assessment 2 to 6 months	0.170 (0.004)	0.164 (0.005)	0.006 (–0.007 to 0.018)	0.358
6–12 months	0.440 (0.012)	0.426 (0.015)	0.015 (–0.021 to 0.050)	0.424
Total over 12 months	0.855 (0.018)	0.827 (0.024)	0.028 (–0.030 to 0.086)	0.342

SE, standard error.

TABLE 85 Mother EQ-5D utility values and QALYs gained: CCBT + MCBT vs. CCBT

Time of assessment	CCBT + MCBT ($n = 69$), mean (SE)	CCBT ($n = 71$), mean (SE)	Mean differences: CCBT + MCBT – CCBT (95% CI)	p-value
EQ-5D utility values				
Baseline	0.833 (0.022)	0.816 (0.025)	0.017 (–0.050 to 0.084)	0.613
Assessment 1B	0.848 (0.022)	0.810 (0.036)	0.038 (–0.044 to 0.120)	0.358
Assessment 2	0.865 (0.026)	0.842 (0.030)	0.022 (–0.060 to 0.103)	0.597
6-month follow-up	0.861 (0.026)	0.855 (0.026)	0.007 (–0.069 to 0.082)	0.860
12-month follow-up	0.824 (0.030)	0.841 (0.034)	–0.017 (–0.101 to 0.067)	0.689
QALYs gained				
Baseline to assessment 1B	0.129 (0.003)	0.125 (0.004)	0.004 (–0.005 to 0.014)	0.384
Assessment 1B to assessment 2	0.132 (0.003)	0.127 (0.004)	0.005 (–0.006 to 0.015)	0.381
Assessment 2 to 6 months	0.166 (0.004)	0.163 (0.004)	0.003 (–0.011 to 0.016)	0.690
6–12 months	0.421 (0.011)	0.424 (0.013)	–0.003 (–0.036 to 0.031)	0.878
Total over 12 months	0.848 (0.019)	0.839 (0.023)	0.009 (–0.050 to 0.068)	0.763

SE, standard error.

TABLE 86 Mother EQ-5D utility values and QALYs gained: CCBT + MCI vs. CCBT

Time of assessment	CCBT + MCI ($n = 71$), mean (SE)	CCBT ($n = 71$), mean (SE)	Mean differences: CCBT + MCI – CCBT (95% CI)	p-value
EQ-5D utility values				
Baseline	0.799 (0.028)	0.816 (0.025)	–0.017 (–0.091 to 0.058)	0.655
Assessment 1B	0.822 (0.027)	0.810 (0.036)	0.012 (–0.079 to 0.104)	0.789
Assessment 2	0.843 (0.027)	0.842 (0.030)	0.0003 (–0.082 to 0.083)	0.995
6-month follow-up	0.829 (0.026)	0.855 (0.026)	–0.026 (–0.097 to 0.045)	0.474
12-month follow-up	0.857 (0.029)	0.841 (0.034)	0.016 (–0.067 to 0.100)	0.696
QALYs gained				
Baseline to assessment 1B	0.125 (0.004)	0.125 (0.004)	–0.0003 (–0.011 to 0.010)	0.950
Assessment 1B to assessment 2	0.128 (0.004)	0.127 (0.004)	0.001 (–0.011 to 0.013)	0.869
Assessment 2 to 6 months	0.161 (0.004)	0.163 (0.004)	–0.002 (–0.015 to 0.010)	0.705
6–12 months	0.422 (0.012)	0.424 (0.013)	–0.002 (–0.036 to 0.032)	0.893
Total over 12 months	0.835 (0.021)	0.839 (0.023)	–0.004 (–0.065 to 0.057)	0.894

Cost–utility analysis

Table 87 and *Figures 8–10* report the results of the CUA from a health-care perspective for CCBT + MCBT compared with CCBT. The bootstrapped ICERs for this comparison are shown in the cost-effectiveness plane in *Figure 8*. With higher mean costs (albeit statistically insignificant) and lower mean utility (albeit statistically insignificant) differences between the groups, *Figure 8* reveals that, given current thresholds for commonly accepted levels of cost-effectiveness (£20,000–30,000), CCBT + MCBT is not likely to be a cost-effective alternative to CCBT. The CEAC shown in *Figure 9* reveals that the probability that CCBT + MCBT will be cost-effective in comparison with CCBT is < 10%. The NMB curve (see *Figure 10*) confirms that CCBT + MCBT confers no monetary benefit over CCBT for a broad range of societal willingness-to-pay thresholds and would not be deemed cost-effective given commonly accepted threshold values representing value for money.

TABLE 87 Cost–utility analysis (health service perspective): ITT approach – CCBT + MCBT vs. CCBT

CUA results	CCBT + MCBT ($n = 69$), mean (SE)	CCBT ($n = 71$), mean (SE)
Cost of intervention	£2124.85 (84.98)	£1891.30 (87.14)
QALY gain	0.794 (0.022)	0.827 (0.024)
Incremental cost (95% CI)	£233.55 (–£6.81 to £473.92)	
Incremental QALY gain (95% CI)	–0.033 (–0.101 to 0.035)	
ICER, incremental cost per QALY gain	–£7077	
(95% CI) bootstrap method	Lower limit, £12,373; upper limit, –£91	
(95% CI) Fieller's method	Lower limit, £10,000; upper limit, £187	
NMB for WTP = £20,000	–0.033 × £20,000 – £233.55 = –£893.55	
NMB for WTP = £30,000	–0.033 × £30,000 – £233.55 = –£1223.55	

SE, standard error; WTP, willingness to pay.

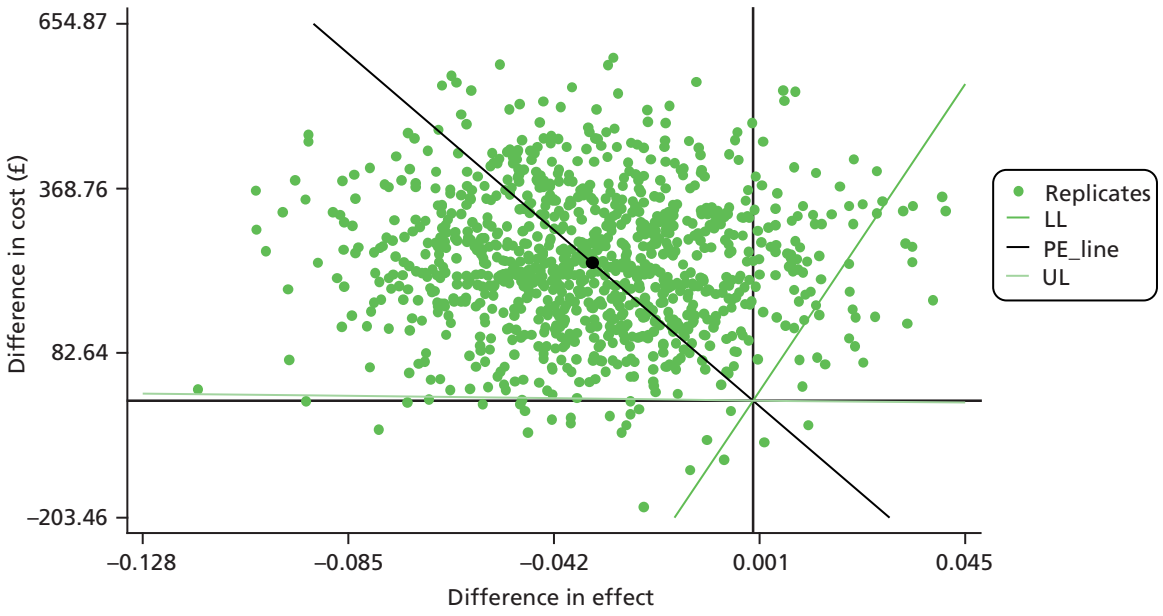


FIGURE 8 Cost-effectiveness plane showing bootstrapped replicates of the ICER: CCBT + MCBT vs. CCBT. LL, lower limit; PE, point estimate; UL, upper limit.

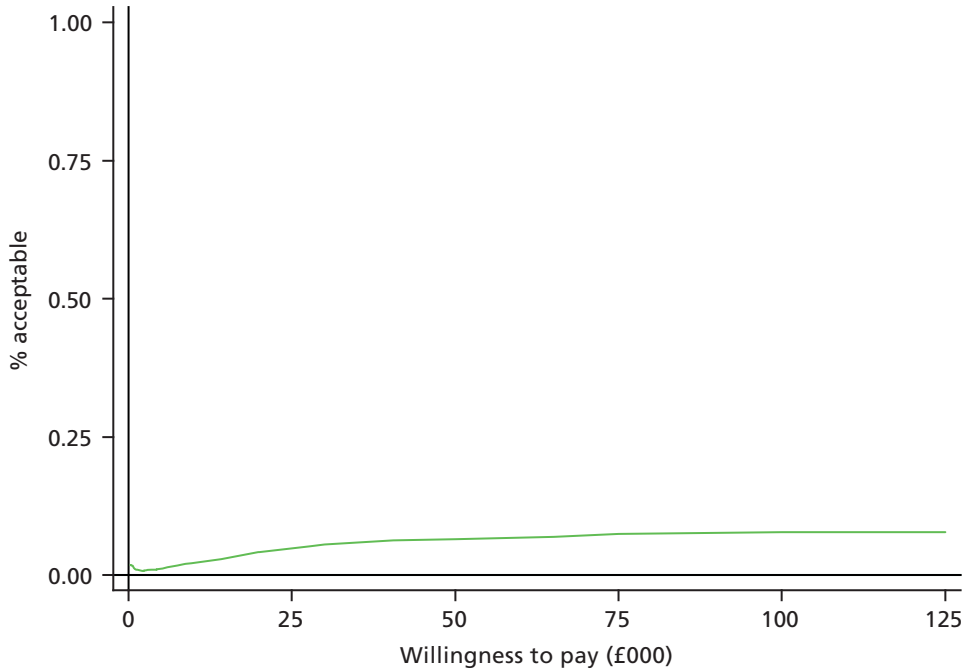


FIGURE 9 Cost-effectiveness acceptability curve showing the probability that the intervention is cost-effective at different willingness-to-pay thresholds: CCBT + MCBT vs. CCBT.

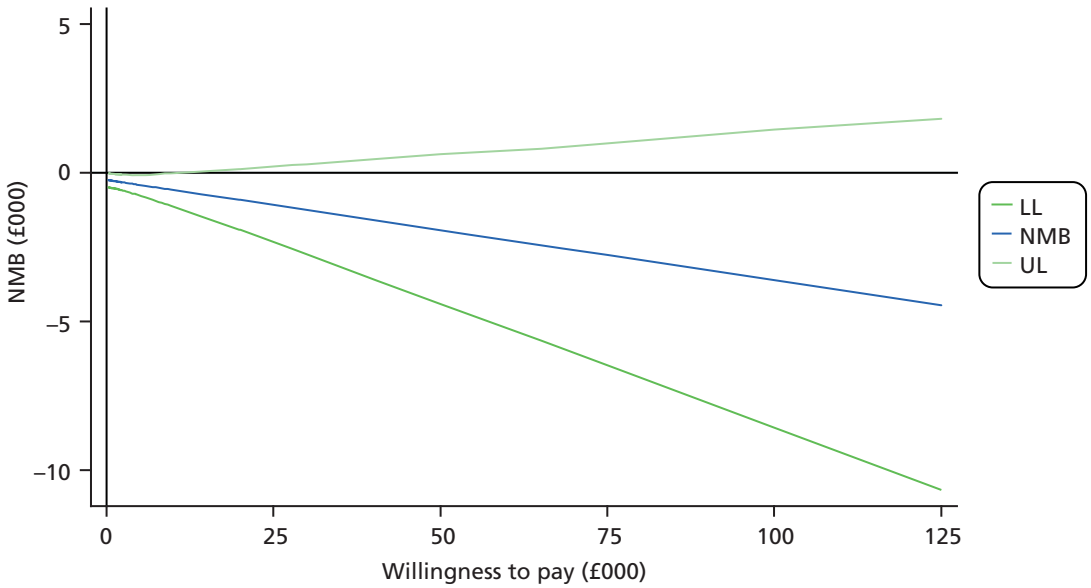


FIGURE 10 Net monetary benefit curve and limit curves: CCBT + MCBT vs. CCBT. LL, lower limit; UL, upper limit.

Table 88 and *Figures 11–13* present the results of the CUA from a health-care perspective for CCBT + MCI compared with CCBT. The bootstrapped ICERS for this comparison are shown in the cost-effectiveness plane in *Figure 11*. With higher mean costs (albeit statistically insignificant) and higher mean utility (albeit statistically insignificant) differences between the groups, *Figure 11* reveals that, given the distribution of the ICERS, CCBT + MCI is highly likely to be a cost-effective alternative to CCBT. The CEAC shown in *Figure 12* reveals that, given current NICE thresholds for accepted levels of willingness to pay for an extra QALY (£20,000–30,000), the probability that CCBT + MCI will be cost-effective in comparison with CCBT is around 75%. The NMB curve (see *Figure 13*) confirms that CCBT + MCI confers additional monetary benefit over CCBT alone and would be deemed a cost-effective alternative given commonly accepted threshold values representing value for money.

TABLE 88 Cost–utility analysis (health service perspective): ITT approach – CCBT + MCI vs. CCBT

CUA results	CCBT + MCI ($n = 71$), mean (SE)	CCBT ($n = 71$), mean (SE)
Cost of intervention	£2124.46 (83.06)	£1891.30 (87.14)
QALYs	0.855 (0.018)	0.827 (0.024)
Incremental cost (95% CI)	£233.16 (–£6.81 to £473.92)	
Incremental benefit, QALY gain (95% CI)	0.028 (–0.030 to 0.086)	
ICER, incremental cost per QALY gain	£8327	
(95% CI) bootstrap method	Lower limit, –£173; upper limit, –£11,021	
(95% CI) Fieller's method	Lower limit, –£95; upper limit, –£8881	
NMB for WTP = £20,000	0.028 × £20,000 – £233.16 = £326.84	
NMB for WTP = £30,000	0.028 × £30,000 – £233.16 = £606.84	

SE, standard error; WTP, willingness to pay.

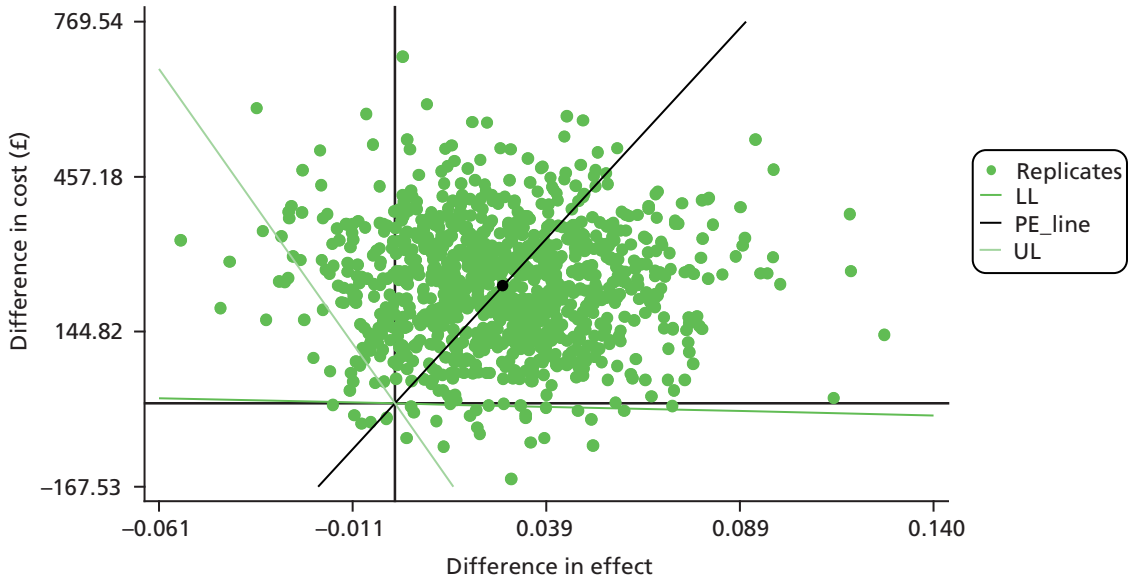


FIGURE 11 Cost-effectiveness plane showing bootstrapped replicates of the ICER: CCBT + MCI vs. CCBT. LL, lower limit; PE, point estimate; UL, upper limit.

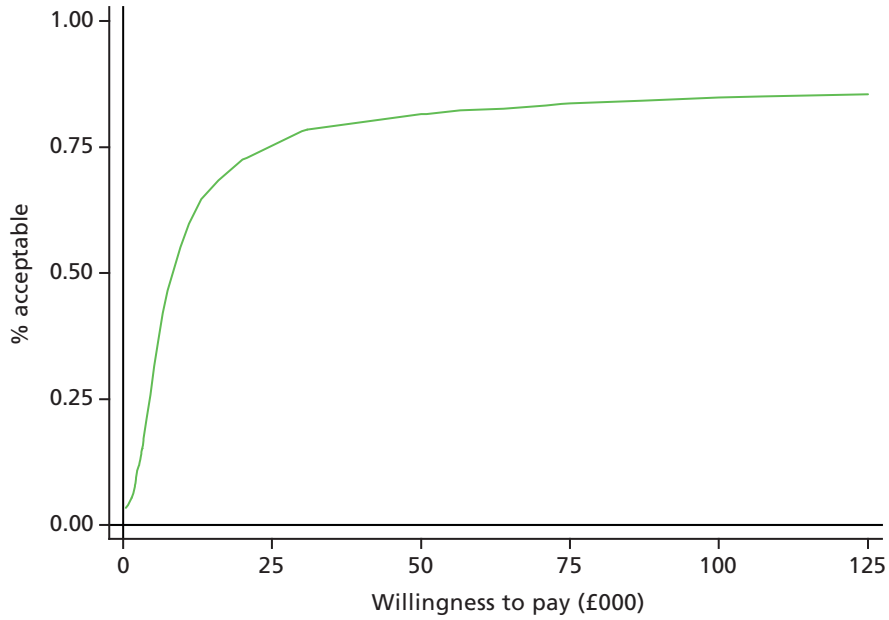


FIGURE 12 Cost-effectiveness acceptability curve showing the probability that the intervention is cost-effective at different willingness-to-pay thresholds: CCBT + MCI vs. CCBT.

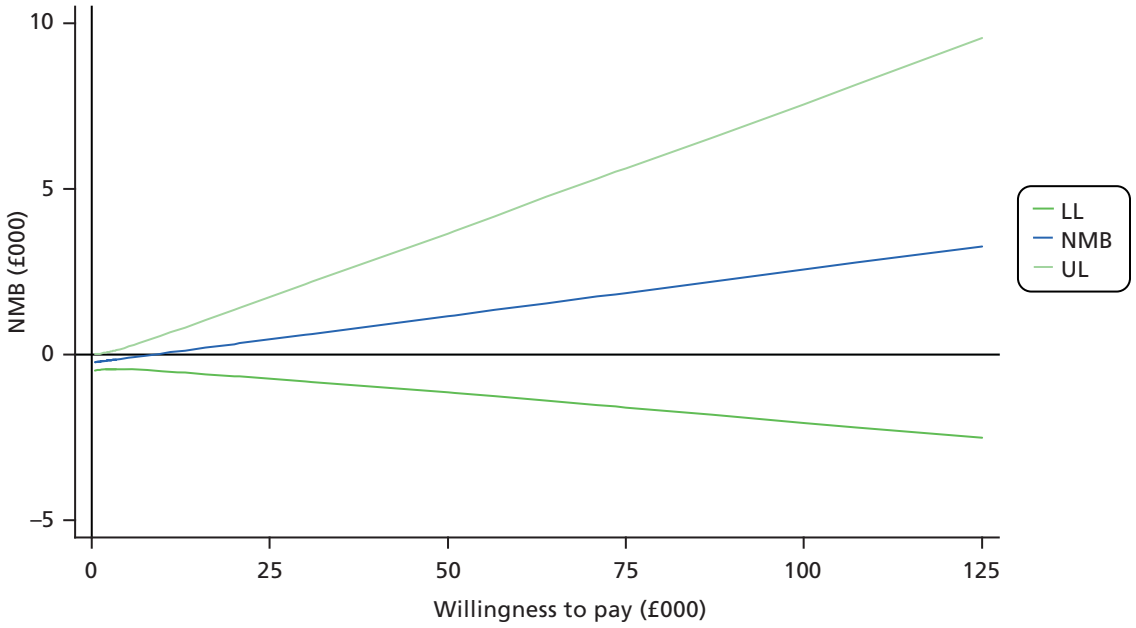


FIGURE 13 Net monetary benefit curve and limit curves: CCBT + MCI vs. CCBT. LL, lower limit; UL, upper limit.

Sensitivity analysis

A key question of uncertainty in the cost-effectiveness analysis related to the impact of reducing the treatment costs of non-specific interventions. Hence, sensitivity analysis was conducted by setting the treatment costs related to non-specific interventions to zero. Treatment costs related to non-specific interventions included NDC and a generic FH control intervention delivered to balance groups for therapist contact. Although this analysis was conducted with the intention to reflect what would happen in reality if the interventions were adopted in current practice, it relied on the strong assumption that the non-specific interventions had no impact at all on the child anxiety outcomes. By increasing the cost difference between interventions and control, but maintaining the difference in effects invariant (as counterfactual outcomes in absence of non-specific interventions could not be measured), no evidence was found that either CCBT + MCBT or CCBT + MCI would offer any added value for money in improving child anxiety outcomes beyond what was already suggested in the primary analyses. Detailed results are reported in *Appendix 3*, *Tables 116* and *117*, and *Figures 14–19*.

Further sensitivity analysis will be developed by altering other key assumption to explore their consequences for the results at 12 months follow-up. In particular, an exploration of the incorporation of broader societal impacts and of the combined child and maternal QALYs on the cost-effectiveness results will be carried out.

Limitations of the data

The high level of missing data in the follow-up health and social care resource use beyond the treatment costs is a limitation for this economic evaluation. If the health and personal social service costs reported for the CCBT + MCBT versus CCBT comparison were representative of this population and included in the ICER, as they typically would be, the costs in the CCBT arm would increase by £428, thereby placing CCBT + MCBT into the lower cost/lower effectiveness zone of the cost-effectiveness plane (south west) and a different scenario to the cost-ineffective scenario arising when treatment only costs were included in the ICER. If the health and social care resources reported for the CCBT + MCI versus CCBT comparison were representative of this population and included in this analysis, the costs in the control arm would increase by £624. This would have placed the CCBT + MCI arm in the realms of being highly cost-effective (south-east quadrant of the cost-effectiveness place), that is dominating the CCBT arm and being both less costly and more effective, a clear win–win scenario. Another limitation of the data was the high percentage of missing data. This was dealt with using appropriate data imputation techniques; however, imputation cannot account for potentially non-random reasons for missing data.

Discussion

The aim of the economic evaluation was to assess the cost-effectiveness of the CCBT + MCBT and CCBT + MCI treatment arms in relation to the CCBT treatment arm from a health service perspective. The economic analyses aligned with the primary aim of the trial, namely to evaluate whether or not CCBT could be improved by the addition of (i) treatment of maternal anxiety disorders (MCBT), or (ii) treatment focused on maternal responses (MCI). Combining the total treatment costs with maternal and child QALYs revealed that, within commonly accepted levels of value for money (i.e. £20,000–30,000 per extra QALY gained), CCBT + MCBT was not likely to be a cost-effective alternative to CCBT. However, combining the total treatment costs with child QALYs revealed that in the comparison of the CCBT + MCI with CCBT treatment arms, the CCBT + MCI treatment arm was highly likely to be a cost-effective alternative to the CCBT arm. A limitation of these analyses, however, was that the resource use and costs of additional health and personal social services, beyond the current treatment costs, were not included in the primary analyses owing to very small sample sizes for these data components. Insufficient statistical power meant that conclusions could not be drawn about the impact of these additional costs on the overall cost-effectiveness. These additional data, however, do provide insights about the type and range of services this group of children and mothers use. Children undergoing treatment for anxiety disorders can be seen to be accessing a broad range of services beyond treatment from GPs, including social workers, psychologists, psychiatrists,

education welfare officers, family liaison officers, teachers, paediatricians, audiologists, ophthalmology, accident and emergency (A&E), dieticians, physiotherapists, mental health workers and 'other services'. Notwithstanding the limited evidence these small sample sizes convey, comparisons of CCBT + MCBT and CCBT + MCI with the CCBT treatment arm reveal increasing costs prevalent in the CCBT arm in the majority of the assessment periods. Furthermore, counting the number of services accessed by each group it can be seen that overall participants in the CCBT arm were accessing approximately one-third more services than those in the CCBT + MCBT and CCBT + MCI arms. In addition, the total costs are always higher in the CCBT arm for both comparisons. If these differences translated into actual differences then this would only increase the likelihood of the CCBT + MCBT and CCBT + MCI arms being more cost-effective than the CCBT arm. It is only by replicating these data collection exercises with larger samples that these results can be confirmed or refuted. On a cautionary note, however, it is important to outline that increased use of services may not represent an inferior quality-of-life outcome owing to the benefits of increased awareness about the health and well-being advantages of accessing additional services.

Broader impacts on other sectors, including impacts on education, employment and impacts on leisure time including time off school for children and time off work and usual activities for their mothers, were also presented but not included in the primary analyses. Further analyses will explore the impact of these effects on a broader societal perspective.

Conclusions

These CUAs have shown that when adopting a health service perspective, only the addition of MCI to standard CCBT is highly likely to represent a cost-effective use of resources for these mother/child pairs within commonly accepted thresholds of cost-effectiveness. Further, analyses reveal that when adopting a health service perspective only the addition of MCBT to standard CCBT is unlikely to be a cost-effective use of resources for these mother/child pairs. However, the latter result should be interpreted with caution because of the high percentage of missing data in some variables which, despite being dealt with using appropriate imputation techniques, may still be viewed as a shortcoming. However, further analysis incorporating the additional health and social care costs has indicated that, depending on the representativeness of these data, there are possible improvements in the cost-effectiveness of both CCBT + MCBT and CCBT + MCI depending on the assumptions made about these costs. Further analysis of the data exploring inclusion of the additional health and personal social service costs and employment and educational impacts using multiple imputations within sensitivity analyses may provide further insight to the cost-effectiveness of these interventions. This economic evaluation provides insight to the broad range of services accessed by this client group, hence it is recommended that future economic evaluations in this area incorporate data collection on this full range of services to fully capture the impact of new interventions.

Chapter 5 Discussion and conclusions

Summary of findings

Children with anxiety disorders whose mothers are also highly anxious have been shown to have a poorer response to treatment than those whose mothers are not anxious,[9,100] yet the impact on children of treating the maternal anxiety has been unclear. Further, the clinical impact on children with anxiety disorders of targeting potentially anxiogenic maternal behaviours has not previously been evaluated systematically. The current study set out to address both these issues in a large RCT.

There was some evidence that the MCBT and MCI treatments were successful in altering the maternal factors which they were designed to address. Specifically, MCBT conferred short-term benefits in maternal recovery from primary diagnoses. However, by the post-treatment assessment, when children in all treatment arms had received CCBT, mothers in all arms had experienced a good level of recovery from their primary disorder and differences between treatment arms were no longer apparent. It is important to note that there were no significant differences between treatment arms on maternal-reported symptoms of anxiety at any time point. For the CCBT + MCI treatment arm there was evidence of change in maternal overprotection and expectations relating to a lack of child coping with challenge. There were no differences between treatment arms in change in other potentially anxiogenic parenting responses (such as expressed anxiety and positive behaviours).

Despite the success in changing some aspects of maternal anxiety and parenting responses, adding neither treatment of maternal anxiety (MCBT) nor treatment of maternal responses (MCI) conferred a significant benefit on children on the basis of the primary child treatment outcomes. Although both adjunct treatments achieved higher child recovery and global improvement rates post treatment than the group in which neither maternal anxiety nor potentially anxiogenic parenting received specific therapeutic attention, the advantages were neither statistically significant nor consistent across treatment arms and outcome measures.

There was some evidence of an advantage for the CCBT + MCI treatment arm on the primary outcomes at the 6-and 12-month follow-up assessments, but this did not reach statistical significance. There was a significant advantage of CCBT + MCI over CCBT on change in child anxiety severity at the 6-month follow-up, and a similar pattern existed at the 12-month follow-up (although it was no longer statistically significant). There was a general lack of significant differences between treatment arms on child-, mother- and teacher-reported anxiety symptom questionnaires. Where statistically significant differences did exist, these were contrary to expectations, with children in the CCBT group reporting a greater reduction in symptoms of anxiety and low mood than children in the CCBT + MCI arm at the post-treatment assessment. In contrast, mothers in the CCBT + MCI arm reported a greater reduction in child conduct problems at the 12-month follow-up assessment than mothers in the CCBT arm.

The secondary research questions considered whether or not improvement in child anxiety was significantly associated with change in (i) maternal anxiety, and (ii) maternal parenting responses. No significant associations were found between change in maternal anxiety and change in child anxiety symptoms, severity or improvement at the mid-treatment, post-treatment and 6-month follow-up assessments. Contrary to expectations, greater change in maternal anxiety symptoms was associated with less change in the severity of the child's primary anxiety diagnosis. It is important to note that a large number of correlations were conducted to examine this research question and the lack of a consistent pattern of results highlights the fact that no clear conclusions can be drawn. In relation to maternal parenting responses, significant associations were found between change in maternal behaviours and change in child anxiety, most commonly for maternal overprotection. Specifically, and contrary to expectations, a greater increase in overprotection was associated with a greater reduction in the severity of the child's primary

anxiety diagnosis post treatment and global improvement at both the post-treatment and the 6-month follow-up assessments. These indices are both assessor rater; when child symptom ratings were used the opposite pattern was found, with a greater reduction in maternal overprotection being associated with greater reduction in child anxiety symptoms. The difference in the pattern of findings according to who is reporting on child anxiety is interesting and warrants further investigation, but for now clear conclusions about mechanisms of change cannot be drawn.

Economic evaluation

The CUAs demonstrated that, when adopting a health service perspective, the addition of MCI to standard CCBT is highly likely to represent a cost-effective use of resources for these mother/child pairs within commonly accepted thresholds of cost-effectiveness. Further, analyses reveal that when adopting a health service perspective the addition of MCBT to standard CCBT is unlikely to be a cost-effective use of resources for these mother/child pairs. Those cost-effectiveness results should be interpreted with caution owing to the high percentage of missing data on some variables which, despite being dealt with using appropriate imputation techniques, may still be viewed as a shortcoming. Furthermore, analysis incorporating the additional health and social care costs has indicated that, depending on the representativeness of these data, there are possible improvements in the cost-effectiveness of both CCBT + MCBT and CCBT + MCI depending on the assumptions made about these costs. Further analysis of the data exploring inclusion of the additional health and personal social service costs and employment and educational impacts using multiple imputations within sensitivity analyses may provide further insight to the cost-effectiveness of these interventions. The economic evaluation provides insight into the broad range of services accessed by this client group; hence, it is recommended that future economic evaluations in this area incorporate data collection on this full range of services when evaluating new interventions.

Strengths and limitations

The study had several notable strengths, including the referred clinical sample, the use of reliable, blind raters to make assessments of child and maternal anxiety and maternal behaviours before and after treatment, and a design which allowed for isolating the effects of specifically targeting maternal anxiety and parenting responses. A further strength of the study was the inclusion of non-specific interventions designed to balance therapist contact. However, the data collected for health economic analyses indicated that therapist contact did not end up entirely balanced within each phase of treatment. Most notably, more therapist time was spent delivering the eight sessions of MCBT treatment than the eight sessions of NDC that were delivered in the CCBT arm. Similarly, the MCI treatment took more time to deliver than the FH-oriented control. In both cases this may have resulted from the more directive treatment manuals in the MCBT and MCI treatments requiring longer sessions, or from therapist difficulties in maintaining engagement in the NDC and FH treatments so moving through the material more quickly. This suggestion is consistent with the fact that the highest rate of dropout was found during the eight-session NDC phase of treatment. Despite these differences, the overall time and cost of interventions across the entire treatment period was not significantly different across arms, supporting a good balance overall in therapist contact across treatment arms.

The strengths of the study need to be considered in the light of various other limitations. Although we allowed for 20% loss to follow-up, by the 1-year post-treatment assessment retention was down to 61% in the CCBT condition. This limits the conclusions that can be drawn about differences between treatment conditions in the longer term. Although there were no clear baseline differences between completers and those who dropped out, it is of concern that the greatest amount of dropout occurred during the eight-session maternal counselling phase. Therefore, this form of intervention appears not to have been an acceptable treatment approach for some families. This finding presents a challenge for future research; the inclusion of non-specific interventions presents a conservative test of the specific effects of particular

interventions but requires the delivery of credible, alternative interventions. Whether longer-term dropouts over-represented those with good or bad treatment outcomes cannot be determined, although the sensitivity analyses that were conducted suggest that this was not the case. Our impression was that, in some cases, those that dropped out from follow-up assessments did so because they felt that their child had made a good recovery and had 'moved on' (and so did not want them to have to take part in a long diagnostic assessment). Future studies might benefit from an abridged follow-up assessment which places a minimal burden on participants. The degree to which long-term outcome was also influenced by involvement with help seeking elsewhere is also unclear. Although families agreed not to initiate any other treatment during the course of the intervention, they may have sought help elsewhere during the follow-up period. However, as indicated in the economic analyses (see *Appendix 3*, *Tables 91–111*), use of other resources was low across all treatment arms.

The lack of additional health and social care resource use beyond the treatment costs is a limitation for the economic evaluation presented here. Unfortunately there was a large amount of missing data on this measure which precluded its inclusion in these analyses. However, preliminary analysis incorporating the limited data available on the additional health and social care costs has indicated that, depending on the representativeness of these data, there are possible improvements in the cost-effectiveness of both CCBT + MCBT and CCBT + MCI depending on the assumptions made about these costs. Further analysis of the data exploring inclusion of the additional health and personal social service costs and employment and educational impacts using multiple imputations within sensitivity analyses may provide further insight to the cost-effectiveness of these interventions.

Other limitations include the relatively restricted demographic characteristics of the participating group, who were predominantly of non-minority ethnicity and relatively high socioeconomic status (SES), although this was lower than in a comparable trial on the basis of parent education.[19] Our study population also had somewhat higher rates of child- and parent-rated anxiety levels than in similar studies.[19] In terms of marital status, the population was representative of the wider population.[101] We elected to focus on middle childhood (ages 7–12 years) and intervening with mothers as a methodological expediency as it is likely that the nature of parental influences on child anxiety varies with child age[102,103] and parent gender;[34] however, as a result, the findings cannot be generalised to young children or adolescents or to interventions with fathers or other caregivers. The extent to which characteristics of other parental figures (e.g. paternal anxiety and parenting responses) moderate treatment outcomes warrants further examination. In our trial each phase of treatment was delivered by a different therapist, this meant that there was a very large number of different combinations of therapists (116 combinations) which precluded us from examining therapist effects.

The study also included children and mothers with a broad range of anxiety disorders. There is emerging evidence that generic treatment approaches, of the sort provided in the study, may be more beneficial for some child anxiety disorders than others[104] and that particular potentially anxiogenic parental responses may be disorder specific.[64,105] Both of these sets of findings suggest that further work needs to be done which takes account of the precise form of parental and child anxiety, as well as particular forms of parenting responses. The inclusion of mothers with a broad range of disorders also meant that it was most appropriate for a transdiagnostic anxiety treatment to be delivered. Although there is evidence for the effectiveness of this approach (both here and in previous studies),[38] it is unclear if disorder-specific treatments would have conferred greater benefits in terms of maternal anxiety. Furthermore, anxiety disorders are commonly comorbid with depression;[32] the extent to which maternal depression moderates treatment outcomes in the context of maternal anxiety disorders warrants further attention. Finally, although we recruited a referred clinical population, their experience of treatment will have been very different from routine child mental health services because of the intensive research assessments and the adjunct interventions that were essential for our research purposes. Further insights in to the experiences of patients and therapists participating in this trial would be of value.

Interpretation of results

The findings suggest that adding specific interventions targeting maternal anxiety or the MCIs to individual CBT for children with anxiety disorders in the context of maternal anxiety disorder do not confer significant benefits in terms of child outcomes when compared with individual CBT (supplemented with non-specific therapist support); although some cost–benefit may obtain from the addition of an intervention to target the MCI.

Our findings, in relation to the treatment of parental anxiety disorder, are consistent with those obtained in a recent study by Hudson and colleagues.[19] Their study also specifically focused on children with anxiety disorders who had a parent with an anxiety disorder, and they also failed to find a significant benefit of the addition of parental anxiety management to CCBT. The findings also run contrary to the idea that changing parental responses is necessary for successful treatment of child anxiety disorder in the context of parental anxiety disorder.[23] Notably, however, the CCBT treatment arm in the current study performed considerably better than expected: immediately post treatment, 48% of children were free of their primary anxiety disorder, and 64% were 'much' or 'very much' improved; a year after treatment, 72% were free of their primary diagnosis and 77% were 'much'/'very much' improved. These outcomes are particularly notable given the relatively brief nature of the CCBT intervention.[106] They are also higher than the 33% of children (with a parent with an anxiety disorder) who were free of their primary anxiety disorder in the study reported by Hudson and colleagues.[19] Indeed, the success rates reported here are similar to those found from more intensive (14-session) CBT for children with anxiety disorders, regardless of parental anxiety disorder status, where 60% and 72% were 'much'/'very much' improved at post treatment[55] and 6-month follow-up,[107] respectively. The lack of consistent differences between groups on clinical outcomes and the failure to find consistent, significant associations between the hypothesised mechanisms of change and child outcomes, may suggest that the association that has been commonly found between maternal anxiety disorder and child treatment outcomes may be the result of some third factor, for example other stressors experienced by the family, or shared associations with particular child or maternal comorbidities. The fact that we obtained higher child outcomes than expected following CCBT suggests that it is possible that this third factor variable was addressed to some extent by the generic support received by all mothers in this trial.

One consideration in making sense of the lack of main effects of the two active adjunct interventions (MCI/MCBT) is statistical power, given the higher than anticipated success rate on the CCBT arm. However, the extent of differences found between our treatment arms was below our a priori criteria for clinical significance (30% more children free of their anxiety diagnoses). The unexpectedly high rate of recovery within the CCBT group in the current study is unlikely to be a function of particular features of our sample, as our study population was a referred sample with systematically confirmed anxiety diagnoses, comparable to other clinic samples in the literature. One possible explanation may lie in the potential added value of the non-specific interventions. These both provided some level of parental support. Although the design used for the current study was appropriate for determining whether or not the MCBT and MCI interventions conferred specific benefits, controlling for therapist contact time using non-specific interventions is a conservative approach and the effects of the non-specific treatments are unclear. The absence of a significant main effect of either CCBT + MCBT or CCBT + MCI also needs to be considered in the light of the degree to which the adjunctive interventions were successful in altering their respective targets. In the one previous study that assessed the impact of adding CBT for parental anxiety disorders to CBT for child anxiety disorders,[12] the failure to find differences in child outcomes was attributed to the fact that the parental CBT did not confer a benefit in terms of reducing parental anxiety compared with when only the children received CBT (i.e. 35.5% vs. 32.7% of mothers were free of their primary anxiety disorder, respectively). In the current study, a more intensive CBT intervention was delivered to the mothers and, as predicted, CCBT + MCBT was associated with a significant reduction in the frequency of maternal anxiety disorder compared with when mothers received NDC (58.5% vs. 36.5% diagnosis free). However, by the end of the CCBT treatment phase there were no group differences in maternal anxiety disorder, with all groups showing high rates of recovery from maternal anxiety disorder (52–66%). The fact that a marked reduction in anxiety disorders across all groups was found following CCBT is consistent with recent findings indicating that reduction in child anxiety promotes reduction in parental anxiety.[25]

This study is the first of which we are aware to report on observational assessments of parental responses before-and-after treatment for child anxiety disorders. We were able to rigorously evaluate the extent to which the MCI intervention successfully altered maternal responses to her child when confronted with a challenge. These assessments provided evidence that, in terms of a reduction in overprotective behaviours, the MCI treatment was indeed successful. It is notable that this observation-based finding was confirmed by maternal self-report data. The MCI intervention was also associated with change in maternal cognitions associated with confidence in child coping (i.e. reduced predictions regarding child fear and increased predictions regarding child control). Despite these positive benefits of the MCI intervention, no significant benefit to child outcomes was conferred on primary outcome measures (although MCI added to CCBT seemed to represent good value for money). One possible reason for this may be that the changes were not of sufficient magnitude to be of benefit in terms of the clinical outcomes. Another possibility is that the factors that did change are not central to the maintenance of child anxiety. Indeed, although scores on the self-report maternal overprotection scale used have been found to be associated with the development of child anxiety,[108] others have found that they do not discriminate clinically anxious children from their non-anxious peers.[66] It will be important to evaluate whether the association between maternal anxiety disorder and child treatment outcomes is in fact mediated by other shared factors, for example other stressors experienced by the family, which might have been addressed to some extent by the generic support received by all mothers in this trial. It is of interest that no specific benefit was apparent for the MCI intervention on the measures of maternal expressed anxiety, intrusiveness or positive behaviours. Although it is, of course, possible that the intervention was ineffective with respect to these dimensions, it is also possible that these findings reflect a lack of sensitivity of the laboratory-based observational tasks. It is also possible that these parental behaviours changed equally across groups in response to improvements in child anxiety.[13]

Although there were no significant differences between treatment arms on the primary outcome measures at the post-treatment assessment, an advantage for CCBT + MCI was found on indices of change in anxiety disorders severity and an advantage which approached significance in terms of being free of the primary anxiety diagnosis at the 6-month follow-up assessment. There was also a trend for an advantage of CCBT + MCI over the CCBT arm in terms of the proportion of children who were free of all their anxiety diagnoses. These findings are consistent with the health economic outcomes which suggest that the CCBT + MCI is a cost-effective use of resources in comparison with the CCBT intervention. As the inclusion of two non-specific interventions within the CCBT arm would be expected to reduce its cost-effectiveness, sensitivity analyses were conducted in which zero costs were attributed to the non-specific interventions. This is a conservative test given that the non-specific interventions might be expected to confer some benefit to children and mothers, yet there was still evidence to support the cost-effectiveness of the CCBT + MCI intervention in this context. As noted above, the mechanisms by which CCBT + MCI conferred a cost–benefit advantage remain unclear.

It is notable that there was also a trend for CCBT + MCBT to have an advantage over CCBT in terms of general improvement post treatment. However, differences between arms were not consistent across time points or measures. Thus, although there is a possibility that MCBT helped support the generalisation of benefits in the short term, this speculation received only weak support.

Some unexpected findings should also be noted. In particular, on the basis of child self-reported anxiety symptoms, the CCBT + MCBT group did less well than the CCBT group at the post-treatment assessment. Both the CCBT + MCI and CCBT + MCBT groups also reported less of a reduction in low mood than the CCBT groups. None of these findings were maintained at the later assessment (although CCBT + MCBT had the poorest overall outcomes by the 12-month assessment); however, they are surprising given the content of the child treatment was the same across groups. Whether or not the full course of NDC (eight sessions) received by the mothers in the CCBT group led to some short-term benefit in terms of children's perceptions of their symptoms remains unclear. There were also some unexpected findings in relation to the secondary research questions, which addressed the extent to which change in maternal anxiety and parenting responses was associated with change in child anxiety. However, as the pattern of findings was not consistent across measures and assessment time points no clear conclusions can be drawn.

It is important to note that the sample size for this study was based on providing enough power to assess the primary outcomes. Other outcomes are secondary and, owing to the large number of tests, the results must be interpreted with caution.

Implications for health care

- The novel intervention that focused on modifying maternal parenting responses was associated with some benefit to children and mothers with anxiety disorders, and is likely to be cost-effective (although the latter result needs to be considered with caution because of the high percentage of missing data in the economic analyses). Incorporating effective measures to address maternal cognitions and behaviours when interacting with her child may improve health outcomes for children with anxiety disorders in the context of maternal anxiety disorder.
- We can be confident that supplementing individual CCBT with CBT to target the maternal anxiety disorder is unlikely to confer substantial health benefits and is unlikely to be cost-effective (although the latter result needs to be considered with caution owing to the high percentage of missing data in the economic analyses). Given the intensity of this intervention and its general lack of effectiveness we think it is unlikely that supplementing CCBT with this intervention will improve child outcomes.

Implications for future research

- Given that CCBT alone was sufficient for a good number of patients, it is possible that a benefit of the CCBT + MCI and CCBT + MCBT interventions may be enhanced in particular contexts, for example in the context of particular maternal or child anxiety disorders or high levels of severity. Future research that directly addresses these possibilities is warranted.
- The relatively low level of association between change in parental anxiety and responses and child anxiety may suggest that other factors may account for the modest treatment outcomes typically found among children with anxiety disorders who have mothers with anxiety disorders (such as genetic or broader social/environmental factors). Future research is warranted to address these issues.
- The economic evaluation provides insight as to the broad range of services accessed by this client group, hence it is recommended that future economic evaluations in this area incorporate data collection on this full range of services when evaluating new interventions.

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Contribution of authors

Cathy Creswell and **Peter J Cooper** had overall responsibility for the study.

Cathy Creswell was responsible for the day-to-day operationalisation and of the study and drafting the final report.

Susan Cruddace and **Rachel Gitau** were responsible for day-to-day management of the research and **Lucy Willetts** was responsible for clinical management.

Stephen Gerry was responsible for the final statistical analysis of the clinical outcomes, under supervision of **Merryn Voysey** and **Ly-Mee Yu**.

Emma McIntosh led on the design of the economic analysis.

The initial statistical analyses were designed by **Jill Mollison**.

Lynne Murray and **Alan Stein** were involved in the design, monitoring the trial and interpretation of results.

Rosamund Shafran was responsible for developing and overseeing the MCBT intervention.

Mara Violato led on the analysis and drafting of the economic results in collaboration with **Emma McIntosh**.

Lucy Willetts and **Cathy Creswell** were responsible for developing the MCI intervention.

Nicola Williams was responsible for monitoring of randomisation and interim data monitoring.

All authors contributed to drafting the final report.

Ethical approval

The study was approved by the Berkshire Research Ethics Committee (07/H0505/156) and the University of Reading Research Ethics Committee (07/48).

Publications

Data from initial assessments of subgroups of participants included in this trial were included in the following papers:

Creswell C, Apetroaia A, Murray L, Cooper P. Cognitive, affective, and behavioural characteristics of mothers with anxiety disorders in the context of child anxiety disorder. *J Abnorm Psychol* 2013;**122**:26.

Clarke K, Cooper P, Creswell C. The Parental Over-protection Scale: associations with child and parental anxiety. *J Affect Disord* 2013;**151**:618–24.

Orchard F, Cooper PJ, Creswell C. Interpretation and expectations among mothers of children with anxiety disorders: associations with maternal anxiety disorder. *Depress Anxiety* 2015;**32**:99–107.

Publication reporting on trial outcomes

Creswell C, Cruddace S, Gerry S, Murray L, Stein A, Willetts L, *et al.* Treatment of childhood anxiety disorder in the context of maternal anxiety disorder: A randomised controlled trial. In preparation.

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Appendix 1 Patient and public involvement

Public involvement in the conduct of the research

A member of the public was a full member of the TSC from initiation to completion of the trial. This lay member was identified by contacting parents of children that had received treatment for anxiety disorders at the University of Reading/Berkshire Healthcare NHS Foundation Trust/Berkshire Child Anxiety Clinic. The individual appointed was the only parent to express an interest who was available to commit to ongoing participation and so no selection process was needed. The lay member's contributions to the conduct of the trial included reviewing information sheets for children and parents, providing feedback on the study protocol and providing guidance on strategies for successful recruitment. This proved invaluable, particularly in providing advice on how to best inform potential participants about the trial and recruitment strategies.

Lessons learned

We benefited from the commitment of our one lay representative; however, we were unable to secure a commitment from other potential lay members, and two general practitioners who gave agreement to join the TSC were ultimately unable to attend meetings. We clearly recognise the value of patient and public involvement at all stages of the research process so will include more comprehensive costings to cover the expenses/lost earnings associated with patient and public involvement and will be more explicit in forming patient and public involvement relationships (e.g. through honorary appointments) in future grants.

Appendix 2 Mother and child anxiety trial study protocol

Treatment of Child Anxiety Disorder in the Context of Maternal Anxiety: A Randomised Controlled Trial

Trial Acronym: MACh (i.e. mother and child anxiety treatment study)

RATIONALE: The outcome from CBT for children with anxiety disorders is highly variable. A major factor contributing to this is likely to be the presence of maternal anxiety and the associated disturbances in mother-child interactions and maternal behaviours. Where parental anxiety has been addressed in treatment research it has been difficult to assess its contribution to child outcome. Similarly, where therapeutic measures to address parent-child interactions have been included, it has not been possible to determine the specific role of such measures in the treatment package employed.

The trial is a three-arm RCT which aims to determine the extent to which treatments of maternal anxiety and mother-child interactions enhance standard cognitive behaviour therapy for children (CCBT) who have anxiety disorders in the context of maternal anxiety disorder (a group who currently show a poor response to treatment). Index children will receive CCBT with either additional treatment for maternal anxiety or specific measures to address features of mother-child interactions; and their outcome will be compared to that of children receiving standard individual CCBT (together with appropriate control conditions)

A. Background

Childhood Anxiety Disorders

Anxiety disorders are the most common form of psychopathology in children. They have a significant adverse impact on children's general socio-emotional functioning and commonly persist into adulthood.

Treatments of childhood anxiety disorders

Following advances in the development of successful cognitive behavioural therapies (CBT) for adult anxiety disorders (e.g. Clark & Fairburn, 1996), CBT for child anxiety disorders has now been developed. Although there is still some uncertainty over the optimal form of such intervention, recent systematic reviews of outcome research indicate that the general CBT approach produces significant therapeutic benefit in this patient group. However, it is clear from these reviews, and from the individual treatment trials, that outcome is highly variable,

with a significant proportion of patients retaining their anxiety diagnoses following treatment (i.e. 16-61%; James, Soler & Wetherall, 2006).

Predictors of Treatment Outcome

There has been little research into the factors that predict response to CBT in anxious children, although, in addition to severity of child anxiety, two factors are likely to be especially significant: anxiety in the mother, and features of mother-child interactions.

i. Anxiety in mothers.

It has been known for some time that the rate of anxiety disorder amongst the parents of anxious children is raised (Last et al, 1987; Last et al, 1991), but the extent of this elevation has been uncertain and the implications for treatment outcome of child anxiety have not been fully considered. Recent research of our own has addressed this issue. In a consecutive series of children referred for treatment of an anxiety disorder, two thirds of the mothers were found to have a current DSM-IV anxiety disorder (with no elevated rate of current disorder amongst the fathers), almost three times the base rate (Cooper et al, 2006). Furthermore, follow up of the children after treatment revealed a significant association between child response and level of maternal anxiety (Cooper et al, in press).

ii. Mother-child interactions

Specific features of mother-child interactions have been implicated in the maintenance of child anxiety, in particular, an over-controlling and over-protective maternal style (see Rapee, 1997; Wood et al, 2003) and associated maternal cognitions and expectations about child competence (Creswell et al, 2006). Notably, strong associations have been found between level of maternal anxiety and both maternal behaviours (e.g. Whaley et al, 1999; Bogels & van Melick, 2004) and maternal expectations of child competence (Wheatcroft & Creswell, 2007). It appears that the disturbances in mother-child interactions which serve to maintain child anxiety are, at least in part, themselves driven by maternal anxiety. These conclusions are supported by the findings of further research by our group. We have been conducting a prospective study of 250 infants born to mothers with anxiety disorders and control mothers to investigate the intergenerational transmission of anxiety disorders. Recent data from both this study (Murray et al, 2007), and from an associated experimental study (DeRosnay et al, 2006), have shown that a lack of both appropriate modelling and support, both features of mothers with anxiety disorders, are associated with the development of anxiety in offspring.

Implications for optimal treatment outcomes

In so far as CBT treatments of child anxiety disorder commonly require the day-to-day prosecution of treatment regimes to be managed by the mother (e.g. mothers are typically required to model positive responses to fear provoking stimuli and to prompt and reinforce their child's positive responses), the mother's own anxiety and the associated disturbances in mother-child interactions are likely to militate against optimal treatment delivery. Although the CBT treatments developed to date for the treatment of child anxiety do acknowledge the importance of both parental anxiety and parenting (e.g. Barrett et al, 1996; Mendlowitz et al, 1999; Nauta et al, 2003; Spence et al, 2000), there has been no systematic evaluation of an intervention in which both maternal anxiety and mother-child interactions are specifically addressed. There is, therefore, a need for the development and evaluation of a CBT treatment for child anxiety disorder in which maternal anxiety and associated disturbances in mother-child interactions are systematically targeted.

Rationale for the trial

The outcome from CBT for children with anxiety disorders is highly variable. Major factors contributing to this are likely to be the presence of maternal anxiety and associated disturbances in mother-child interactions and maternal behaviours. Where parental anxiety has been addressed in treatment research (e.g. Barrett et al, 1996; Mendlowitz et al, 1999; Nauta et al, 2003; Spence et al, 2000), for several methodological reasons, it has been difficult to assess its contribution to child outcome. It is notable, however, that in the single study in which treatment of parental anxiety was systematically varied, child anxiety outcome was better where therapeutic measures to address parental anxiety symptoms were included (Cobham et al, 1998). Whilst this is a finding of critical importance, since the treatment did not significantly alter levels of parental anxiety it remains unclear what aspect of the treatment effected the clinical improvement in the children. Similarly, where therapeutic measures to address parent-child interactions have been included (e.g. Wood et al, 2006), it has not been possible to determine the specific role of such measures in the complex treatment package employed. A controlled trial in which both factors – treatment of maternal anxiety and measures to address mother-child interactions - are systematically varied, would produce data of both clinical utility and scientific importance.

Research Questions

In an RCT for child anxiety occurring in the context of maternal anxiety, the principal questions are:

1. Is the impact of child CBT (CCBT) enhanced by first providing CBT to the mother for her own anxiety?
2. Is the impact of CCBT enhanced by the addition of therapeutic measures designed to improve mother-child interactions?

Secondary questions are:

a. Is sustained improvement in child anxiety significantly associated with a reduction in maternal anxiety?

b. Is sustained improvement in child anxiety significantly associated with improvements in maternal modelling, encouragement, over-controlling/over-protective behaviour, and associated cognitions?

B. Summary

The aim of the trial is to establish the relative effectiveness of treatments of (i) maternal anxiety and (ii) key features of mother-child interactions for children with anxiety disorders who have a mother with current anxiety disorder. All treatments will be in addition to individual Cognitive Behaviour Therapy administered to all children.

Patients who consent to join the trial (participants) will be randomised to one of three conditions: (i) Child Cognitive Behaviour Therapy (CCBT) plus Cognitive Behaviour Therapy for Maternal Anxiety (MCBT); (ii) CCBT plus treatment targeting the Mother-Child Interaction (MCI), (iii) CCBT plus control conditions (see below).

Condition	**CCBT+MCBT**	**CCBT+MCI**	**CCBT**
Standard child treatment	CCBT (child: 8 sessions)	CCBT (child: 8 sessions)	CCBT (child: 8 sessions)
Treatment of maternal anxiety	MCBT (mother: 8 sessions)	Counselling control (mother: 2 sessions)	Counselling control (mother: 8 sessions)
Treatment of mother-child interactions	Family Health Control (child and mother: 2 sessions; mother: 2 sessions)	MCI (child and mother: 2 sessions; mother: 8 sessions)	Family Health Control (child and mother: 2 sessions; mother: 2 sessions)
Total therapist	Child: 8 sessions	Child: 8 sessions	Child: 8 sessions

contact	Mother: 10 sessions Child and mother: 2 sessions	Mother: 10 sessions Child and mother: 2 sessions	Mother: 10 sessions Child and mother: 2 sessions

CCBT: Individual CBT for child anxiety; MCBT: Individual CBT for maternal anxiety; MCI: Mother-child interaction treatment

C. Eligibility

The trial is open to children with a current primary diagnosis of a major anxiety disorder (Generalised Anxiety Disorder, Social Phobia, Separation Anxiety Disorder, Panic Disorder/Agoraphobia, Specific Phobia, as long as co-morbid with another anxiety disorder) whose mother also has a current major anxiety disorder.

1. Inclusion Criteria

Child:

(i) Aged 7 to 12 years;

(ii) Primary diagnosis of DSM-IV generalised anxiety disorder, social phobia, separation anxiety disorder, panic disorder/agoraphobia or specific phobia (if co-morbid with another anxiety disorder).

Mother:

(i) Primary carer;

(ii) Current maternal DSM-IV anxiety disorder.

2. Exclusion Criteria

Participants will not be eligible if the following criteria are met.

Child:

(i) Significant physical[1] or intellectual impairment (including ASD)[2];

(ii) Current prescription of psychotropic medication (or, if psychotropic medication is prescribed, it should have been at a stable dose for at least one month with agreement to maintain that dose throughout the study);

[1] Where physical disability would impede treatment delivery (e.g. significant speech/ hearing impairment).
[2] Significant intellectual impairment will be determined by children being registered within local learning disability services. Children will be excluded if they have a current diagnosis of an Autistic Spectrum Disorder (ASD). In case of undiagnosed ASD, a preliminary assessment will be made at the initial assessment (see Section S).

(iii) Previously received six or more sessions of systematically administered Cognitive-Behaviour Therapy for an anxiety disorder;

Mother:

(i) Significant intellectual impairment[3];

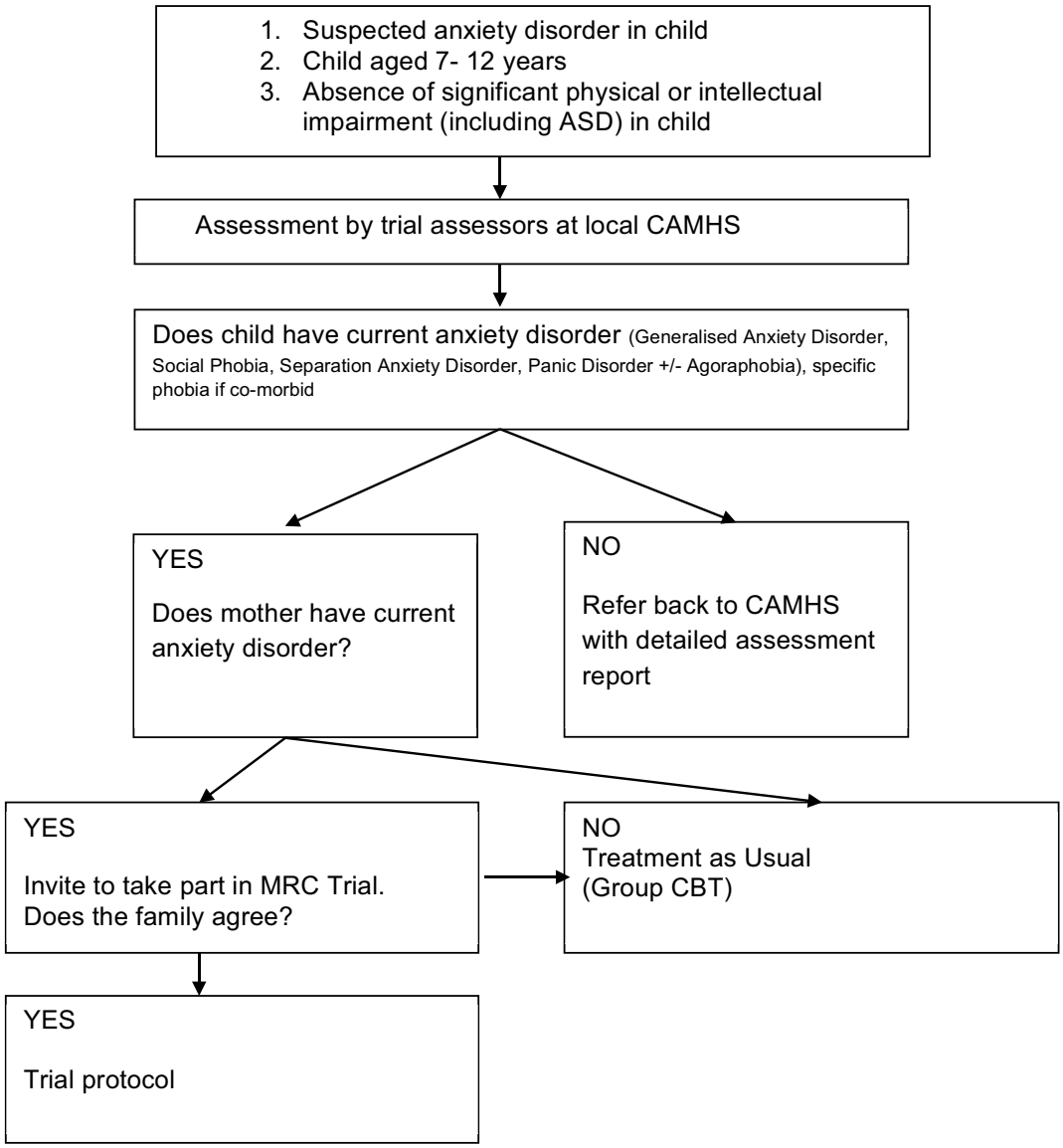
(ii) Severe comorbid disorder (e.g. severe major depressive disorder, psychosis, substance/alcohol dependence);

(ii) Prescription of psychotropic medication (Or, if psychotropic medication is prescribed, it should have been at a stable dose for at least one month with agreement to maintain that dose throughout the study);

[3] Significant intellectual impairment will be determined by the mother being registered within local learning disability services.

D. Trial Procedures

1. ***Recruitment schedule***



2. Treatment Interventions

There will be two stages of treatment intervention in the trial:

(1) Individual Cognitive Behavioural Treatment for maternal anxiety (MCBT), or control

a. Individual CBT for maternal anxiety

This will consist of an eight session (one hour each) intervention for mothers delivered by a clinical psychologist (or equivalent) over eight-weeks. Sessions will take place in the participants' local CAMHS, within their home, or at the University of Reading. The CBT programme will follow a manualised transdiagnostic treatment for adult anxiety disorders (Shafran, unpublished manuscript).

b. Control: Supportive Counselling

This will consist of either two or eight sessions (one hour each) of supportive counselling (see figure 1), delivered by a clinical psychologist (or equivalent) over eight-weeks. Sessions will take place in the participants' local CAMHS, within their home, or at the University of Reading. The supportive counselling programme will follow a manualised treatment (Borkovec & Costello, 1993).

(2) Individual Cognitive Behavioural Treatment for child anxiety (CCBT) with Mother Child Interaction treatment (MCI) or control

Individual CBT for child anxiety

All participating children will receive an eight session (one hour each) intervention based on the Cool Kids programme (Rapee, 2000), delivered by a clinical psychologist (or equivalent) over eight-weeks. Sessions will take place in the participants' local CAMHS, within their home, or at the University of Reading.

a. Mother-Child Interaction Treatment

This intervention consists of 10 sessions: eight with the mother alone and two with the mother and child together. This is a novel intervention which specifically targets anxiogenic features of mother-child interactions. Specifically it aims to enhance maternal cognitions associated with child competence, reduce maternal overcontrol/overprotection, and enhance maternal warmth and encouragement. This is achieved through a combination of specific materials from existing family interventions for childhood anxiety (Rapee & Wignall, 2000; Wood et al, 2006) and video-feedback techniques developed and piloted by the trial investigators (Stein et al, 2006; Creswell et al, in press). This intervention is provided by a clinical psychologist (or equivalent) in parallel with the CCBT sessions. Sessions will generally take place in the participants' local CAMHS, within their home, or at the University of Reading. The two mother and child sessions will be conducted within the laboratory at the

University of Reading, as these involve the mother and child completing structured tasks which are video-recorded for feedback purposes.

b. Control: Family Lifestyle Management

This will consist of four sessions, two with the mother alone and two with the mother and child together. These sessions will focus on promoting a healthy lifestyle with a focus on family diet and exercise, based on existing packages applied within school settings (British Dietetic Association, 2003). This intervention is provided by a clinical psychologist (or equivalent) in parallel with the CCBT sessions. Sessions will generally take place in the participants' local CAMHS, within their home, or at the University of Reading.

For all treatment conditions, therapists will routinely rate the extent to which participants adhere to the intervention (e.g. completion of in-session and homework exercises, session attendance).

How the second stage interventions run in parallel is illustrated in Section R.

E. Randomisation

Following confirmation of eligibility and informed consent, participants will be randomised to treatment condition. Randomisation will be performed centrally by facsimile contact at the Centre for Statistics in Medicine, Oxford (CSM). This will be performed/coordinated by the Trial Statistician. The randomisation programme will include a minimisation algorithm to ensure balanced allocation of participants across the three treatment groups for the following potential prognostic factors: child age, child gender, type of child anxiety disorder (GAD, Social Phobia, SAD, Other) and baseline severity (ADIS Clinician Severity Rating) of child and mother's primary anxiety disorder. To reduce the possibility of outcome measure events occurring after randomisation and before treatment, intervention will start within 2 weeks of randomisation.

F. Routine Care Outside of the Trial

Participants (mothers and children) will be asked not to engage in other psychological interventions during the course of the trial. They will also be asked not to initiate psychotropic medication and if psychotropic medication is prescribed, this should have been at a stable dose for at least one month with agreement to maintain that dose throughout the study. Referrers (Local CAMHS) and General Practitioners will be informed of this requirement.

G. Serious and Unexpected Adverse Events

There are no adverse side-effects of the interventions being delivered. Successful treatment of anxiety may involve some distress, however this will be managed and contained by qualified clinical psychologists, receiving regular expert supervision. Although substantial clinical benefits are anticipated from the interventions, some children and mothers can be expected to not respond to the interventions. Where children continue to meet criteria for a current anxiety disorder at the six month post treatment assessment, they will be invited to participate in a group intervention for anxious children or referred back to their local CAMHS team following clinical review and liaison. If other significant difficulties emerge these will be discussed with referrer from the local CAMHS team.

H. Assessment of Outcome

1. Primary outcomes

The primary outcome is child anxiety (assessed both categorically [i.e. diagnosis] and continuously [i.e. symptoms]). Diagnostic status will be assessed by the ADIS for DSM-IV: C/P administered to both the mother and child. Assessors will be blind to treatment condition. Assessors' beliefs about treatment condition will be formally assessed. Child anxiety symptoms will be assessed using questionnaires (SCAS; Spence, 1998) administered to the child, the mother and the child's teacher. These measures will be administered post-treatment, and at 6 and 12 month follow-up assessments.

2. Secondary outcomes

Maternal anxiety will be assessed categorically using the ADIS (DSM-IV) and continuously using questionnaires (i.e. DASS, Lovibond & Lovibond, 1995; PSWQ, Meyer et al, 1990; SIAS and SPS, Mattick & Clark, 1998). These measures will be administered post-treatment, and at 6 and 12 month follow-up assessments.

Maternal interactive behaviours will be assessed by filming the mother assisting the child perform an anxiety provoking task and applying standardised ratings of anxiogenic behaviours (i.e. modelling, lack of encouragement, overcontrol/overprotection). Interactive behaviours will be coded by independent, trained, reliable raters. Coders will be blind to the purpose and conditions of the trial. Maternal cognitions will be assessed by a standardised interview. These measures will be conducted at the post-treatment assessment.

See Section S for a full assessment schedule.

3. Health Economic Assessment

An economic evaluation will be undertaken integral to the main trial. The evaluation will adhere to guidelines for good economic evaluation practice as outlined in the reference case by Gold et al (1996). The economic analysis will estimate the incremental cost and effectiveness of each of CCBT/MCBT and CCBT/MCI in relation to the control group as well as their relative costs. Patient level resource use data, including all health and social care costs (staff costs for provision of CCBT, MCBT, MCI, and the control interventions, GP costs, referrals, and other relevant services identified) as well as leisure and productivity estimates for the parents will be collected within trial forms and valued using appropriate unit costs. Staff training costs and the costs of staff supervision will also be identified and allocated pro-rata. The outcome measure for the cost-effectiveness analysis will be the ADIS as well as a measure of 'days off school avoided'. In line with recent recommendations from the National Institute for Health and Clinical Excellence (NICE) the economic evaluation will also include generic quality of life instruments, the child friendly EuroQol EQ-5D (EuroQol, 1990; Hennesy & Kind, 2002) and HUI2 outcome measure (Feeny et al, 1995), on which normative data are available. Measures of the impact of anxiety disorders will also be included, using questionnaires administered to the child and mother (CAIS; Langley et al, 2004) and teacher (School Adjustment/ Teacher Report Form; Achenbach, 1986). These instruments will be administered at baseline, following treatment and at 6 and 12 months follow up.

I. Power and Sample Size

A total sample size of 210 pairs of anxious children with anxious mothers will be recruited into the trial. This sample size is based on calculations relating to the primary outcome of child anxiety diagnosis for the principal questions.

i. Efficacy of CCBT/MCBT:

Comparison of Group 1 and the Control Group. To detect an absolute difference of 30% in success (i.e. absence of child anxiety diagnosis) post-treatment for CCBT/MCBT compared with control (40% to 70%), with 90% power at the 5% significance level (two sided) would require 56 patients per treatment group. This difference is based on reported effect of CBT with parental anxiety management in children where at least one parent had high anxiety (Cobham et al, 1998).

ii. Efficacy of CCBT/MCI:

Comparison of Group 2 and the Control Group. Assuming that the response to treatment in the control group is 40% (from Cobham et al, 1998) and the minimum clinical difference in response due to MCI is 30%, 56 patients per group are required to enable us to detect this difference with 90% power at the 5% significance level.

Thus, 56 patients are required in each of the three randomised groups. Accounting for a 20% loss to follow up would require 210 children in total to be recruited to the study. No formal comparison will be made between Groups 1 and 2 (CCBT/MCBT and CCBT/MCI). The sample size has been estimated as if two independent trials were conducted, with no adjustment for multiple testing, as recommended by Machin et al (1997).

A difference of 30% in the proportion of anxiety-free children following completion of the treatment is considered to be the minimum that would be clinically worthwhile taking into account the increased resources required and change to service delivery that would be required if either of these interventions were found to be effective and implemented in practice.

J. Data Management

Data management will be consistent with MRC Guidelines for Good Clinical Practice in Clinical Trials (MRC, 1998) and with the Data Protection Act (1998). Principal investigators will ensure that all personnel are familiar and comply with the MRC guidelines, particularly section 5.9 'Data handling and record keeping' and section 7 'Documentation'.

1. Identifying information

After providing consent, participants will be given a unique, sequential, study identifier. This will be used for randomisation and data entry purposes.

2. Data entry

Data will be entered in to desktop computers, fitted with SPSS for Windows v13 as standard allowing for an immediate interactive message to be displayed if an invalid data entry is made. The Trial Manager will arrange appropriate quality assurance checks.

3. Backing up of data

Immediately after every episode of data entry, data will be backed up onto a portable USB drive, which will be securely stored locally. These files will be backed up on to a password-protected system on a weekly basis. A hard copy will be printed and stored locally compliant with Data Protection Act (1998).

K. Data Analysis

The principal comparisons will be performed on an intention-to-treat basis. The results from the trial will be presented as comparative summary statistics (difference in proportion of anxiety-free children or mean anxiety level) with 95% confidence intervals. The analysis and reporting of results will follow the general principles of Consolidated Standards of Reporting Trials (CONSORT; Moher et al, 2001).

The primary analysis will focus on the effect of the intervention following completion of treatment (post-treatment/16 week assessment). Analysis of the 6 and 12 month outcome data will utilize all outcome assessments (post treatment, 6 and 12 months) using multilevel repeated measures analysis, to establish maintenance of change.

Child anxiety diagnosis (ADIS for DSM-IV C/P): The proportion of anxiety-free children in the two groups following treatment will be compared using the Chi squared test. Testing for a treatment effect after adjustment for minimisation factors will be conducted using multiple logistic regression.

Child anxiety symptoms: Change in anxiety scores following treatment will be analysed using multiple linear regression with baseline score and minimisation factors entered as covariates. We will formally assess the distribution of the change in anxiety scores for evidence of departure from normality. If necessary, data will either be transformed or analysed using a non-parametric equivalent. Change in anxiety scores at 6 and 12 months will be analysed using a multilevel repeated measures analysis, adjusted for baseline anxiety score and minimisation covariates.

The secondary research questions will be explored using univariate tests (e.g. Chi squared test, t-test and correlation) to examine whether the particular factors identified are associated with sustained improvement in child anxiety. Multiple logistic and linear regression will be adopted to investigate the independent factors predictive of sustained improvement in child anxiety.

A comprehensive statistical analysis plan will be produced prior to any data being seen.

L. Management Structure

1. Trial Management

The Trial Management Group (TMG) comprises the five grant holders, the clinical director (LW) and the Trial Manager (RG). The group will meet periodically throughout the trial as requested by the Principal applicant (PJC).

The day to day administration of the trial will be the overall responsibility of the principal applicant (PJC) who will monitor all aspects of recruitment, treatment and assessment, as well as the budget.

The child anxiety clinics will be under the direction of the Clinical Director (LW). She will coordinate all clinical referrals, and, together with her assistant, carry out initial clinical assessments of all referred children. Where both child and mother are found to have a current anxiety disorder, the trial manager (RG) will recruit to the trial and, in liaison with the trial statistician (NA), will ensure randomisation to treatment condition and assign to the appropriate therapists. The Trial Manager will also coordinate and supervise the maternal and child assessments. Assessment and coding of the mother-child interactions will be the under the supervision of Professor Lynne Murray.

Professor Roz Shafran (Reading) will train and supervise the adult therapists providing treatment to mothers. The therapists providing the non-directive counseling (control condition) will be supervised by an experienced counseling practitioner and supervisor to ensure adherence to protocol. The Clinical Director (LW) will supervise the two child therapists delivering CCBT to the children and the mother-child interaction treatment as well as the healthy lifestyle sessions (control). Professor Alan Stein will provide supervision to Dr Willetts on the interaction treatment.

The Trial Manager (RG) will have responsibility for the data file which will be handed over to the Trial statistician for analysis. The Trial Manager will also liaise with Dr McIntosh to ensure that all health economic data are collected appropriately.

2. Trial Steering Committee (TSC)

Overall responsibility for the trial will lie with the Trial Steering Committee comprising: Professor Jonathon Hill (Chair), Dr Gavin Malloch (MRC), Dr Natasha Conner and Vicky Taylor (Berkshire Healthcare NHS Foundation Trust), Dr Pasco Fearon (Reading) and a consumer representative. Their function is to maintain the overall integrity of the trial, to receive and consider reports from both the Trial Management Group and IDMEC and take action if appropriate. The Trial Steering Committee will meet before the trial is initiated and then every 6 months throughout the trial.

3. Independent Data Monitoring and Ethics Committee (IDMEC)

The Independent Data Monitoring and Ethics Committee will be chaired by Professor Jonathon Geddes (Oxford). Other members are Dr Craig Ramsay (Aberdeen) and a representative from Berkshire Healthcare NHS Foundation Trust). The Trial statistician will also attend meetings to present reports. The IDMEC will monitor: recruitment to the trial, protocol adherence and serious adverse events as well as the difference between trial treatments on the primary outcome measures. The IDMEC will consider reports prepared by the Trial Statistician and any other relevant studies published during the timeframe of the trial. Recommendations of IDMEC will be passed on to the Chair of the Steering Committee. The Data Monitoring and Ethics Committee will meet throughout the trial as determined by the Chair.

M. Indemnity

University of Reading indemnity will apply:

i. To meet the potential legal liability of the University of Reading for harm to participants arising from the management and design of the research.

ii. To meet the potential legal liability of the investigators/collaborators arising from harm to participants in the conduct of the research.

iii. For payment of compensation in the event of harm to the research participants where no legal liability arises.

N. Ethics

Berkshire Local Research Ethics Committee has given a favourable opinion of this study (07/H0505/156), as has the University of Reading Research Ethics Committee (07/48). All aspects of the study will be conducted in line with MRC Guidelines for Good Clinical Practice in Clinical Trials (MRC, 1998).

O. Informed Consent

Information about the trial will be provided to both the mother and child in person from the Clinical Director (LW) as well as in written information. A copy will be provided for the participants to keep. Written consent will be obtained from parents by the Clinical Director (LW). Assent will be obtained from children. Following treatment completion, participants will be asked whether they would be happy for video-taped material to be used for teaching and training purposes. Where participants agree, separate written consent will be obtained.

P. Publications and Ancillary Studies

1. Publications

A meeting of the Trial Management Group will be held on completion of the study to allow discussion of the main results among the collaborators. The results will then be presented to a combined meeting of the TSC and IDMEC for comment. Public presentations pertaining to the main trial must not be made without the prior agreement of the Trial Management Group.

2. Ancillary studies

Ancillary studies will be conducted by Dr Cathy Creswell (MRC Clinician Scientist Fellowship, Reading), Mr Ray Percy (PhD student, Reading) and Dr Thalia Eley (Institute of Psychiatry, London), in collaboration with Peter Cooper. The protocols for these studies will be referred to the Trial Steering Committee, whose responsibility is to safeguard the integrity of the trial, for final approval. Any further proposals for ancillary studies should initially be referred to the Trial Management group for consideration. Studies considered appropriate by the TMG will then be submitted to the TSC for final approval. In principle it is preferable for the trial to be kept as simple as possible with few further add-on studies.

Q. Proposed Timetable

Main tasks	Proposed timetable
Finalise protocols	May- November 2007
Submit Ethics & Trust approval	August 2007
Register Trial Receipt of MRC award In post: Cathy Creswell (Trial Manager; MRC) Lucy Willetts (Clinic Manager; NHS/MRC)	1 September 2007
Ethics Outcomes	November 2007
Invite referrals from East and West Berks (establish wait-list for assessments)	September- December 2007

Recruit remaining University & Trust staff Establish satellite clinics Convene Trial Steering Committee and IDMEC	
Training University and Trust staff	January – February 2008
Initiation of assessments	January 2008
Initiation of treatment	March 2008
Recruitment ends	30 August 2010
Treatments end	31 January 2011
Trials end	30 June 2012

Recruitment assessments will be conducted from January 2008 until end of August 2010 (32 month), therefore we aim to recruit 6-7 new cases to the trial every month.

R. Stage 2 Treatment (CCBT/MCI/FH) Outline

Week		CCBT (child 8 sessions)	MCI (mother 8; mother& child 2)	FH (mother 2; mother & child 2)
1	Session 1	Introduction- 1. Getting to know each other 2. Psychoeducation	Mother 1. Introduction-psycho-education and rationale.	Mother 1. Introduction-healthy family lifestyle
2	Session 2	1. Update & review 2. How I feel depends	Mother 1. Update & Review	

		on what I think; Detective Thinking	2. Promoting autonomy (i):Self-help skills: giving choices, allowing struggle, attention (ii) Feedback on video from research assessment: highlight parental positive impact on child through autonomy granting, encouragement, modelling, cognitions re child coping)	
3	Session 3	1. Update & review 2. How I feel depends on what I think; Detective Thinking Practice	Mother 1. Update & Review 2. Promoting autonomy (i) Alternative strategies: managing child's anxious thoughts	
4	Session 4A	1. Update & review 2. Rewards	Mother 1. Update & review 2. Promoting autonomy: encouraging brave behaviour; inc CALM strategy (reflective listening, selective attention , planned	Mother & Child Family diet

			ignoring), positive encouragement (verbal and nonverbal), modelling brave behaviours	
4	Session 4B		Mother & Child Video Task: setting up an exposure hierarchy	
5	Session 5	1.Update &review 2. Problem solving	Mother 1. Update & Review 2. Video feedback (to highlight successful autonomy granting). 3. Promoting autonomy: Family problem-solving	
6	Session 6A	1. Update & review 2. Practice	Mother 1. Update and review 2. Promoting autonomy: New roles	Mother & Child Family exercise
6	Session 6B		Mother & Child Challenging task	
7	Session 7	1. Update & review 2. Practice	Mother 1. Update & Review *2.* Video feedback (to highlight successful autonomy granting, modelling, encouragement (verbal/nonverbal), positive cognitions re	

			child coping).	
8	Session 8	1. Update & review 2. You did it	Mother 1. Update & Review 2. You did it- what helped? Future plans/ Relapse Prevention	Mother Healthy family lifestyle Review and summary

S. Assessment Schedule

l clinical assessment Conducted within local CAMH service	Structured clinical interviews: 1. Anxiety Disorders Interview Schedule-Child/Parent version (ADIS-C/P) 2. Anxiety Disorders Interview Schedule (ADIS) (Mother self-report) Questionnaires: 1. Spence Children's Anxiety Scale –parent/child version (SCAS-c/p) 2. Child Anxiety Impact Scale- parent/child version (CAIS-c/p) 3. Depression Anxiety Stress Scales (DASS) 4. Penn State Worry Inventory 5. Mattick Social Phobia Scale and Social Interaction Assessment Scale (SPS, SIAS) 6. Over-involvement questionnaire (POI) parent self-report 7. Social Communication Questionnaire (SCQ) 8.The Short Moods and Feelings Questionnaire-Child/Parent version (SMFQ-C/P) 9.The Strengths and Difficulties Questionnaire - Child/Parent version (SDQ-C/P)

Research assessment 1. (pre-treatment) Conducted at University of Reading	1. Laboratory assessment of mother-child interaction and associated cognitions 2. Spence Children's Anxiety Scale-teacher report (SCAS-T) 3. Teacher Report Form (TRF) 4. Teacher report- child adjustment to school 5. Health economic assessments (EQ-5D, HUI-2, diaries)
Research assessment 1b. (mid-treatment) Conducted at University of Reading/ Local CAMH service	Structured clinical interviews: 1. Anxiety disorders Interview Schedule-Child/Parent version (ADIS-C/P) 2. Anxiety Disorders Interview Schedule (ADIS) (Mother self-report) Questionnaires: 1. Spence Children's Anxiety Scale –parent/child version (SCAS-c/p) 2. Child Anxiety Impact Scale- parent/child version (CAIS-c/p) 3. Depression Anxiety Stress Scales (DASS) 4. Penn State Worry Inventory 5. Mattick (SPS, SIAS) 6. Over-involvement questionnaire (POI) parent self-report 7. The Short Moods and Feelings Questionnaire-Child/Parent version (SMFQ-C/P) 8. The Strengths and Difficulties Questionnaire - Child/Parent version (SDQ-C/P)

	9. Therapy Questionnaire 10. Health economic assessments (EQ-5D, HUI-2, diaries)
Research assessment 2 (post-treatment) Conducted at University of Reading	Structured clinical interviews: 1. Anxiety Disorders Interview Schedule-Child/Parent version (ADIS-C/P) 2. Anxiety Disorders Interview Schedule (ADIS) (Mother self-report) Questionnaires: 1. Spence Children's Anxiety Scale –parent/child version (SCAS-c/p) 2. Child Anxiety Impact Scale- parent/child version (CAIS-c/p) 3. Depression Anxiety Stress Scales (DASS) 4. Penn State Worry Inventory 5. Mattick (SPS, SIAS) 6. Over-involvement questionnaire (POI) parent self-report 7. The Short Moods and Feelings Questionnaire-Child/Parent version (SMFQ-C/P) 8. The Strengths and Difficulties Questionnaire - Child/Parent version (SDQ-C/P)

	9. Health economic assessments (EQ-5D, HUI-2, diaries) Other 1. Laboratory assessment of mother-child interaction and associated cognitions
Research assessment 3 (6 months post-treatment) Conducted at University Of Reading/ Local CAMH service	Structured clinical interviews: 1. Anxiety Disorders Interview Schedule-Child/Parent version (ADIS-C/P) Questionnaires: 1. Spence Children's Anxiety Scale –parent/child version (SCAS-c/p) 2. Child Anxiety Impact Scale- parent/child version (CAIS-c/p) 3. Depression Anxiety Stress Scales (DASS) 4. Penn State Worry Inventory 5. Mattick (SPS, SIAS) 6. Over-involvement questionnaire (POI) parent self-report 7. The Short Moods and Feelings Questionnaire-Child/Parent version (SMFQ-C/P) 8. The Strengths and Difficulties Questionnaire - Child/Parent version (SDQ-C/P) 9. Spence Children's Anxiety Scale-teacher report (SCAS-T) 10. Teacher Report Form (TRF) 11. Teacher report- child adjustment to school

	12. Health economic assessments (EQ-5D, HUI-2, diaries)
Research assessment 4 (12 months post-treatment) Conducted at University Of Reading/ Local CAMH service	Structured clinical interviews: 1. Anxiety disorders Interview Schedule-Child/Parent version (ADIS-C/P) Questionnaires: 1. Spence Children's Anxiety Scale –parent/child version (SCAS-c/p) 2. Child Anxiety Impact Scale- parent/child version (CAIS-c/p) 3. Depression Anxiety Stress Scales (DASS) 4. Penn State Worry Inventory 5. Mattick (SPS, SIAS) 6. Over-involvement questionnaire (POI) parent self-report 7. The Short Moods and Feelings Questionnaire-Child/Parent version (SMFQ-C/P) 8. The Strengths and Difficulties Questionnaire - Child/Parent version (SDQ-C/P) 9. Spence Children's Anxiety Scale-teacher report (SCAS-T) 10. Teacher Report Form (TRF) 11. Teacher report- child adjustment to school 12. Health economic assessments (EQ-5D, HUI-2, diaries)

Appendix 3 Health economic measures

Health economic logs

MaCh ECONOMIC LOG

Log for recording resources used, and duration of, any clinical contact

Important: Please complete a new log every time a contact is made *(client visit, phone contact, school visit e.t.c.)*

Patient ID:

Date:

Type of contact	Session No.	Duration of contact
Maternal CBT		
Maternal Counselling		
Child CBT		
MCI		
Healthy Living		
Supervision time (time spent discussing this particular patient)		
Preparation time & record keeping		

Other* *(please state)*		

* Please record all phone contact, school visits, home visits and any other types of visit.

Additional Resources used (Staff only)

Please record below any travel mileage, rail fares or other expenses incurred during this contact

_____

_____

_____

_____

Participant number:
Assessment:
Date:

Diary 1

One component of this study is to provide the NHS with information about the costs of different treatments and the overall impact this has on the use of other health and social services, as well as medications, time off work and time off school for children. In order to do this we would like you to use this diary to record you and your child's use of such services, and treatments that you and your child have had.

This is a 'Diary' (or record) of your use of services, medications and time off work and school between now and your next assessment appointment, for any cause. It is for your use only, to fill in each time you come into contact with any of the health professionals or use any of the facilities listed over the page. We would also like you to keep a record of any prescription drugs and medications taken as well as days off work and school.

For example: If you or your child visits the GP surgery we would like you to **tick one of the circles** on the line 'Family Doctor (GP)'. One tick = one visit. If you are prescribed a drug then we would like to know the name of it and whether it is for you or your child.

This Diary covers the period from Study Entry to your next trial assessment. At your next assessment we will ask you about your 'resource use' during this time period. **Please remember to bring your diary along to this appointment so that you may use it to complete this questionnaire.**

We will give you new diaries every time a 'resource use' questionnaire has been completed so that you can use the diary to keep a record of your use of services ready to complete the next questionnaire.

N.B: Please **do not** include any appointments related to the study itself such as the therapy sessions.

Berkshire Child Anxiety Clinic

University of Reading

Berkshire Research Ethics reference number: 07/H0505/156-157-176
University of Reading Ethics reference number: 07/48-49-50
Version 1.4 (31.07.08)

DOI: 10.3310/hta19380

Starting from when you entered the trial, should you or your child come into contact with any of the people/facilities listed below, please **tick** one of the circles.

	YOU: *If the contact/visit was **for yourself,** tick one of the circles in this section:*	**YOUR CHILD:** *If the contact/visit was **for your child,** tick one of the circles in this section:*
Family Doctor (GP)	○○○○○○○○○○○○○○○○○○○○○○○	○○○○○○○○○○○○○○○○○○○○○○○
Social Worker	○○○○○○○○○○○○○○○○○○○○○○○	○○○○○○○○○○○○○○○○○○○○○○○
Practice nurse	○○○○○○○○○○○○○○○○○○○○○○○	○○○○○○○○○○○○○○○○○○○○○○○
Psychologist	○○○○○○○○○○○○○○○○○○○○○○○	○○○○○○○○○○○○○○○○○○○○○○○
Psychiatrist	○○○○○○○○○○○○○○○○○○○○○○○	○○○○○○○○○○○○○○○○○○○○○○○
Community Psychiatric Nurse	○○○○○○○○○○○○○○○○○○○○○○○	○○○○○○○○○○○○○○○○○○○○○○○
Education Welfare Officer	○○○○○○○○○○○○○○○○○○○○○○○	○○○○○○○○○○○○○○○○○○○○○○○
Educational Psychologist	○○○○○○○○○○○○○○○○○○○○○○○	○○○○○○○○○○○○○○○○○○○○○○○
Family Liaison Officer (School)	○○○○○○○○○○○○○○○○○○○○○○○	○○○○○○○○○○○○○○○○○○○○○○○
Teacher (other than usual contact)	○○○○○○○○○○○○○○○○○○○○○○○	○○○○○○○○○○○○○○○○○○○○○○○
Paediatrician (children's doctor)	○○○○○○○○○○○○○○○○○○○○○○○	○○○○○○○○○○○○○○○○○○○○○○○
Audiology	○○○○○○○○○○○○○○○○○○○○○○○	○○○○○○○○○○○○○○○○○○○○○○○
Speech and language	○○○○○○○○○○○○○○○○○○○○○○○	○○○○○○○○○○○○○○○○○○○○○○○
Opthalmology	○○○○○○○○○○○○○○○○○○○○○○○	○○○○○○○○○○○○○○○○○○○○○○○
Hospital A&E department	○○○○○○○○○○○○○○○○○○○○○○○	○○○○○○○○○○○○○○○○○○○○○○○
Occupational Therapist	○○○○○○○○○○○○○○○○○○○○○○○	○○○○○○○○○○○○○○○○○○○○○○○
Paediatric Dietician	○○○○○○○○○○○○○○○○○○○○○○○	○○○○○○○○○○○○○○○○○○○○○○○
Paediatric Physiotherapist	○○○○○○○○○○○○○○○○○○○○○○○	○○○○○○○○○○○○○○○○○○○○○○○
Paediatric Play Specialist	○○○○○○○○○○○○○○○○○○○○○○○	○○○○○○○○○○○○○○○○○○○○○○○
Family Therapist	○○○○○○○○○○○○○○○○○○○○○○○	○○○○○○○○○○○○○○○○○○○○○○○
Community Children's Nurse	○○○○○○○○○○○○○○○○○○○○○○○	○○○○○○○○○○○○○○○○○○○○○○○
Child & Adolescent Mental Health Nurse	○○○○○○○○○○○○○○○○○○○○○○○	○○○○○○○○○○○○○○○○○○○○○○○
Primary Mental Health Worker	○○○○○○○○○○○○○○○○○○○○○○○	○○○○○○○○○○○○○○○○○○○○○○○
Housing Department	○○○○○○○○○○○○○○○○○○○○○○○	○○○○○○○○○○○○○○○○○○○○○○○
Citizens Advice Bureau	○○○○○○○○○○○○○○○○○○○○○○○	○○○○○○○○○○○○○○○○○○○○○○○
Family centre	○○○○○○○○○○○○○○○○○○○○○○○	○○○○○○○○○○○○○○○○○○○○○○○
Home-start	○○○○○○○○○○○○○○○○○○○○○○○	○○○○○○○○○○○○○○○○○○○○○○○
Alcohol or drug counselling	○○○○○○○○○○○○○○○○○○○○○○○	○○○○○○○○○○○○○○○○○○○○○○○
Other (please specify) * _ _ _ _ _ _ _ _ _ _	○○○○○○○○○○○○○○○○○○○○○○○	○○○○○○○○○○○○○○○○○○○○○○○
Other (please specify) *_ _ _ _ _ _ _ _ _ _	○○○○○○○○○○○○○○○○○○○○○○○	○○○○○○○○○○○○○○○○○○○○○○○

DOI: 10.3310/hta19380

*** If you can only remember the name of the person you saw then please write the name down.**

Drug Treatments

In this following section we would like to know whether you or your child have been prescribed, or purchased, any drugs or medications. Please keep a record below of any drugs/medications and whether it was prescribed by your GP or purchased yourself:

Drug name	Prescription	Duration of Treatment	For yourself or your child *(circle)*
_____	Yes/No	_____	Yourself/child
_____	Yes/No	_____	Yourself/child
_____	Yes/No	_____	Yourself/child
_____	Yes/No	_____	Yourself/child

Time off work and School

Finally, we are interested in whether you have taken any time off work or your usual activities and whether you child has had to have days off school due to ill health.

If you **are** in paid employment please keep a record of the days off work you take due to you or your child's ill health:

Please tick one circle for every day you take off due to ill health: ❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍

If you are **not** in paid employment please keep a record of the days, if any, of your usual activities you have had to give up due to you or your child's ill health:

Please tick one circle for every day you take off your usual activities (e.g. child care, hobbies, shopping):

❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍

Your Child: Time off School

Please keep a record of the number of whole days your child has off school

❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍

Number of **half** days off school

❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍❍

Travel Costs

Finally, if you have incurred any travel expenses since your last assessment as a result of the treatment we have provided please enter the approximate amount:

Nb: Please don't divulge the number of treatment sessions you have received to your research assistants!

Your use of Health and Social Services in the last 8 weeks

SERVICES THAT YOU AND YOUR CHILD HAVE USED IN THE LAST 8 WEEKS

Have you or your child had any visits or visited any of the following services since you joined the study? If so, please write the number of visits for yourself or your child in the appropriate box. If you cannot remember the exact number of visits, don't worry, please just give your best guess. Please ignore any services that you have not used. If you have used the diary about your use of services we sent you at the beginning of the study then please use that to fill in the answers below. Please do not include any appointments related to the trial itself such as the CBT therapy sessions. Thank you.

Visits to/from	Yourself	Your Child
Example GP	*1*	*3*
Family Doctor (GP)		
Social Worker		
Practice nurse		
Psychologist		
Psychiatrist		
Community Psychiatric Nurse		
Education Welfare Officer		
Educational Psychologist		
Family Liaison Officer (School)		
Teacher (other than usual contact)		
Paediatrician (children's doctor)		
Obstetrician (woman's doctor)		
Audiology		
Speech and language		
Opthalmology		

Hospital A & E Department		
Occupational Therapist		
Paediatric Dietician		
Paediatric Physiotherapist		
Paediatric Play Specialist		
Family Therapist		
Community Children's Nurse		
Child & Adolescent Mental Health Nurse		
Housing Department		
Citizens Advice Bureau		
Family Centre		
Home-start		
Alcohol or drug counselling		
Other (Please specify)		

Drug treatments

In this following section we would like to know whether you or your child have been prescribed, or purchased, any drugs or medications in the last 8 weeks.

Please note the name of the drug/medication and whether it was prescribed by your GP or purchased yourself:

Drug name	**Prescription**	**Duration of treatment**	**For yours**
_____	Yes/No	_____	Yourself/child
_____	Yes/No	_____	Yourself/child
_____	Yes/No	_____	Yourself/child
_____	Yes/No	_____	Yourself/child

Time off work and School

Finally, we are interested in whether you have taken any time off work or your usual activities and whether you child has had to have days off school due to ill health in the last 8 weeks.

Are you in paid employment? Yes/No *(circle)*

If yes, have you taken time off work in the last 8 weeks due to ill health?
Yes/No *(circle)*
If yes, please state how many: ☐ **Days**

If you are not in paid employment please state the number of days, if any, of your usual activities (e.g. child care, hobbies, shopping) you have had to give up in the last 8 weeks due to ill health: ☐ **Days**

Time off school
Has your child had to have days off school in the last 8 weeks due to ill health? **Yes/No** *(circle)*
If yes, please state how many: ☐ **Days**

Travel costs
Finally, if you have incurred any travel expenses in the last 8weeks as a result of your CBT treatment please enter the approximate amount: ☐

Thank you for completing this questionnaire. If you have any queries or concerns please do not hesitate to contact *** Tel:**

TABLE 89 Unit costs

Item	Unit cost (£)	Source	Notes
Family doctor (GP consultation in surgery)	40	Personal Social Services Research Unit. *Unit Costs of Health and Social Care 2012*. Kent: University of Kent; 2012	Table 10.8b. Cost including qualifications, excluding other direct care staff costs
Social worker	74	Personal Social Services Research Unit. *Unit Costs of Health and Social Care 2012*. Kent: University of Kent; 2012	Table 11.3. Cost per hour of face-to-face contact, including qualifications
Practice nurse (nurse consultation in surgery)	13.69	Personal Social Services Research Unit. *Unit Costs of Health and Social Care 2012*. Kent: University of Kent; 2012	Table 10.6. Cost including qualifications, excluding other direct care staff costs and based on duration of contact of 15.5 minutes
Psychologist	136	Personal Social Services Research Unit. *Unit Costs of Health and Social Care 2012*. Kent: University of Kent; 2012	Table 9.5. Cost per hour of client contact (includes A to E: A = wages/salary; B = salary oncosts; C = qualifications; D = overheads; E = capital overheads)
Consultant: psychiatrist	383	Personal Social Services Research Unit. *Unit Costs of Health and Social Care 2012*. Kent: University of Kent; 2012	Table 15.7. Cost per face-to-face contact, including qualifications
Community psychiatrist nurse (nurse – mental health)	76	Personal Social Services Research Unit. *Unit Costs of Health and Social Care 2012*. Kent: University of Kent; 2012	Table 10.2. Cost per hour of face-to-face contact (including qualifications)
Education welfare officer	20.44	*Local Government Earnings Survey 2011/12 – Observed Pay Rates*. URL: www.local.gov.uk/web/guest/local-government-intelligence/-/journal_content/56/10171/3015313/ARTICLE-TEMPLATE (accessed 22 April 2013)	Education welfare officer, median annual gross pay (FTE). Unit cost calculated using information on local government pension schemes and employer National Insurance contributions. Adjusted for inflation using RPI
Educational psychologist	37.29	*Local Government Earnings Survey 2011/12 – Observed Pay Rates*. URL: www.local.gov.uk/web/guest/local-government-intelligence/-/journal_content/56/10171/3015313/ARTICLE-TEMPLATE (accessed 22 April 2013)	Educational psychologist, median annual gross pay (FTE). Unit cost calculated using information on local government pension schemes and employer National Insurance contributions. Adjusted for inflation using RPI
Family liaison officer (school) (approximated with family support worker)	49	Personal Social Services Research Unit. *Unit Costs of Health and Social Care 2012*. Kent: University of Kent; 2012	Table 11.8. Costs per hour of client-related work
Teacher	35.41	Department of Education. *Statistical First Release. School Workforce in England, November 2011*. URL: www.education.gov.uk/rsgateway/DB/SFR/s001062/sfr06–2012v7.pdf (accessed 16 April 2013)	Table 9a. Average salary (£) in total, publicly funded school. Salary oncosts have been included in the calculation of the unit cost. Adjusted for inflation using RPI

continued

TABLE 89 Unit costs (*continued*)

Item	Unit cost (£)	Source	Notes
Paediatrician: outpatient department – paediatrics	225	*National Schedule of Reference Costs Year: '2011–2012'*. URL: www.gov.uk/government/publications/nhs-reference-costs-financial-year-2011-to-2012 (accessed 18 April 2013)	NHS trusts. Consultant led, first attendance, non-admitted, face to face. Service code: 420
Audiology: outpatient department – paediatric audiological medicine (A), audiological medicine (B), audiology (C)	110	*National Schedule of Reference Costs Year: '2011–2012'*. URL: www.gov.uk/government/publications/nhs-reference-costs-financial-year-2011-to-2012 (accessed 18 April 2013)	As above. Weighted average of (A), (B) and (C). (A) service code 254; (B) service code 310; (C) service code 840
Speech and language (community speech and language therapist)	33	Personal Social Services Research Unit. *Unit Costs of Health and Social Care 2012*. Kent: University of Kent; 2012	Table 9.3. Cost including qualifications
Ophthalmology: outpatient department –ophthalmology (A), paediatric ophthalmology (B), medical ophthalmology (C), orthoptics (D), optometry (E)	107	Personal Social Services Research Unit. *Unit Costs of Health and Social Care 2012*. Kent: University of Kent; 2012	As above. Weighted average of (A), (B), (C) and (D). (A) service code 130; (B) service code 216; (C) service code: 460; (D) service code 655; (E) service code 662
Hospital A&E department	108	*National Schedule of Reference Costs Year: '2011–2012'*. URL: www.gov.uk/government/publications/nhs-reference-costs-financial-year-2011-to-2012 (accessed 18 April 2013)	A&E services: no leading to admitted. Weighted average of all services in the category
Occupational therapist	33	Personal Social Services Research Unit. *Unit Costs of Health and Social Care 2012*. Kent: University of Kent; 2012	Table 9.2. Cost including qualifications
Paediatric dietitian	34	Personal Social Services Research Unit. *Unit Costs of Health and Social Care 2012*. Kent: University of Kent; 2012	Table 13.4. Cost including qualifications
Paediatric physiotherapist	74	*National Schedule of Reference Costs Year: '2011–2012'*. URL: www.gov.uk/government/publications/nhs-reference-costs-financial-year-2011-to-2012 (accessed 18 April 2013)	Community physiotherapy services: child, one-to-one services, service code N5C1
Paediatric play specialist	11.55	*Local Government Earnings Survey 2011/12 – Observed Pay Rates*. URL: www.local.gov.uk/web/guest/local-government-intelligence/-/journal_content/56/10171/3015313/ARTICLE-TEMPLATE (accessed 22 April 2013)	Playworker, median annual gross pay (FTE). Unit cost calculated using information on local government pension schemes and employer National Insurance contributions. Adjusted for inflation using RPI
Family therapist (family support worker)	49	Personal Social Services Research Unit. *Unit Costs of Health and Social Care 2012*. Kent: University of Kent; 2012	Table 11.8. Costs per hour of client-related work

TABLE 89 Unit costs (*continued*)

Item	Unit cost (£)	Source	Notes
Community children's nurse	93	*National Schedule of Reference Costs Year: '2011–2012'*. URL: www.gov.uk/government/publications/nhs-reference-costs-financial-year-2011-to-2012 (accessed 18 April 2013)	Community nursing services: nursing services for children, service code CN101
Child and adolescent mental health worker	68	Personal Social Services Research Unit. *Unit Costs of Health and Social Care 2012*. Kent: University of Kent; 2012	Table 12.6. Generic single-disciplinary CAMHS
Primary mental health worker	68	Personal Social Services Research Unit. *Unit Costs of Health and Social Care 2012*. Kent: University of Kent; 2012	Table 12.6. Generic single-disciplinary CAMHS
Housing department	19.81	*Local Government Earnings Survey 2011/12 – Observed Pay Rates*. URL: www.local.gov.uk/web/guest/local-government-intelligence/-/journal_content/56/10171/3015313/ARTICLE-TEMPLATE (accessed 22 April 2013)	Housing officer, median annual gross pay (FTE) England. Unit cost calculated using information on local government pension schemes and employer National Insurance contributions. Adjusted for inflation using RPI
Citizens advice bureau	15.50	Office for National Statistics (UK). *Labour Market, Earnings by Industry. Patterns of Pay: Results from the Annual Survey of Hours and Earnings, 1997–2012*. URL: www.ons.gov.uk/ons/taxonomy/search/index.html?nscl=Earnings+by+Industry&nscl-orig=Earnings+by+Industry&content-type=Dataset&content-type=Reference+table&sortDirection=DESCENDING&sortBy=pubdate (accessed on 19 April 2013)	Table 5_SIC07. Full-time employees' pay by industry sector (SIC 2007), United Kingdom, April 2008–12. Industry sector: other service activities. Unit cost calculated using information on stakeholders pension schemes and employer National Insurance contributions
Family centre (family support worker	49	Personal Social Services Research Unit. *Unit Costs of Health and Social Care 2012*. Kent: University of Kent; 2012	Table 11.8. Costs per hour of client-related work
Home-Start	95.59	McIntosh E, Barlow J, Davis H, Stewart-Brown. Economic evaluation of an intensive home visiting programme: a cost-effectiveness analysis from a societal perspective. *J Publ Health* 2009;**3**:423–33	Table 1, p. 427. Price inflated to 2011/12 prices using the HCHS index
Other health and social care resource use	81.12	Authors' calculations	Average of all other unit costs
Therapist: newly qualified clinical psychologist	39.15 (per hour); 87.98 (per hour of client contact)	Health & Social Care Information Centre. *NHS Staff Earnings, Estimates – April–June 2012*. URL: www.hscic.gov.uk/catalogue/PUB07388 (accessed 23 April 2013)	Table 3. Basic pay and earnings for Agenda for Change Band 7 (spine point 26), and calculated according to the methodology adopted in Personal Social Services Research Unit. *Unit Costs of Health and Social Care 2012*. Kent: University of Kent; 2012. Table 9.5

continued

TABLE 89 Unit costs (*continued*)

Item	Unit cost (£)	Source	Notes
Supervisor	£70.77 (per hour) £159.03 (per hour of client contact)	Health & Social Care Information Centre. *NHS Staff Earnings, Estimates – April–June 2012*. URL: www.hscic.gov.uk/catalogue/PUB07388 (accessed 23 April 2013)	Table 3. Basic pay and earnings for Agenda for Change Band 8b (spine point 41), and calculated according to the methodology adopted in Personal Social Services Research Unit. *Unit Costs of Health and Social Care 2012*. Kent: University of Kent; 2012. Table 9.5
Mileage allowance	£0.54 per mile	NHS Employers. *NHS Terms and conditions of service handbook. Amendment number 25 – Pay Circular (AforC) 1/2012.* URL: www.nhsemployers.org/~/media/Employers/Documents/Pay%20and%20reward/AfC_tc_of_service_handbook_fb.pdf (accessed 12 November 2013)	Car (all types of fuel), annual mileage up to 3500 miles (standard rate)

CAMHS, Child and Adolescent Mental Health Services; FTE, full-time equivalent; GP, general practitioner; SIC, standard industrial classification.
All costs in 2011/12 prices. For 2010/11 prices adjusted for inflation using RPI 2012 or HCHS 2011/12 as appropriate.

Health economic supplementary material section 1

Conditional models for multiple imputation using chained equations

Variable imputed: each category of supervision time.

Covariates in the model:

- treatment allocation
- minimisation factors, that is child age, child gender, type of child anxiety disorder (GAD, social phobia, SAD, other)
- baseline severity (ADIS-IV CSR) of the child's primary anxiety disorder
- baseline severity (ADIS-IV mother self-report) of the mother's primary anxiety disorder
- mothers' baseline depression (DASS-21 – depression)
- child baseline depression symptoms (SMFQ-c, child-reported)
- child behavioural problems (SDQ conduct, mother-reported)
- baseline presence of child social phobia
- all other categories of supervision time.

Variable imputed: total rewards.

Covariates in the model:

- treatment allocation
- minimisation factors, that is child age, child gender, type of child anxiety disorder (GAD, social phobia, SAD, other).

Variable imputed: baseline EQ-5D for child and mother.

Covariates in the model:

- treatment allocation
- minimisation factors, that is child age, child gender, type of child anxiety disorder (GAD, social phobia, SAD, other)
- baseline severity (ADIS-IV CSR) of the child's primary anxiety disorder
- baseline severity (ADIS-IV mother self-report) of the mother's primary anxiety disorder
- mothers' baseline depression (DASS-21 – depression)
- child baseline depression symptoms (SMFQ-c, child-reported)
- child behavioural problems (SDQ conduct, mother-reported)
- baseline presence of child social phobia.

Variable imputed: follow-up measurements of child and mother EQ-5D.

Covariates in the model:

- treatment allocation
- minimisation factors, that is child age, child gender, type of child anxiety disorder (GAD, social phobia, SAD, other)
- measurement of outcomes at previous time points.

TABLE 90 Health economic data completeness

Item	CCBT + MCBT, %[a]	CCBT + MCI, %[b]	CCBT, %[c]
CCBT time	34.8	25.4	38
MCBT time	23.2	NA	NA
MCI time	NA	33.8	NA
NDC time	NA	2.8	8.5
FH time	27.5	NA	11.3
Supervision time for CCBT	42.03	47.89	33.80
Supervision time for CCBT	13.04	NA	NA
Supervision time for MCI	NA	42.25	NA
Supervision time for NDC time	NA	73.24	59.15
Supervision time for FH	79.71	NA	74.65
Total cost rewards	75.36	70.42	81.69
Child: EQ-5D score – baseline	1.45	2.82	5.63
Child: EQ-5D score – assessment 1B	13.04	8.45	21.13
Child: EQ-5D score – assessment 2	33.33	21.13	32.39
Child: EQ-5D score – 6-month follow-up	36.23	39.44	40.85
Child: EQ-5D score – 12-month follow-up	50.72	46.48	53.52
Mother: EQ-5D score – baseline	8.70	9.86	15.49
Mother: EQ-5D score – assessment 1B	33.33	28.17	38.03
Mother: EQ-5D score – assessment 2	37.68	40.85	43.66
Mother: EQ-5D score – 6-month follow-up	37.68	40.85	43.66
Mother: EQ-5D score – 12-month follow-up	50.72	46.48	52.11

NA, not applicable.
a Percentage calculated with respect to the 69 patients in trial arm 1.
b Percentage calculated with respect to the 71 patients in trial arm 2.
c Percentage calculated with respect to the 71 patients in trial arm 3.

TABLE 91 Response rates of patient-held resource use diaries

Section	CCBT + MCBT, %[a]	CCBT + MCI, %[b]	CCBT, %[c]
Other health and social care resources: child and mother – period 'baseline to assessment 1B'	50.7	66.2	45.1
Medication use: child and mother – period 'baseline to assessment 1B'	39.1	39.4	32.4
Other health and social care resources: child and mother – period 'assessment 1B to assessment 2'	24.6	35.2	28.2
Medication use: child and mother – period 'assessment 1B to assessment 2'	18.8	32.4	26.8
Other health and social care resources: child and mother – period 'assessment 2- to 6-month follow-up'	46.4	43.6	42.3
Medication use: child and mother – period 'assessment 2- to 6-month follow-up'	46.4	43.6	42.3
Other health and social care resources: child and mother – period '6–12 months follow-up'	28.9	26.8	29.6
Medication use: child and mother – period '6–12 months follow-up'	33.3	32.4	42.3

a Percentage calculated with respect to the 69 patients in trial arm 1.
b Percentage calculated with respect to the 71 patients in trial arm 2.
c Percentage calculated with respect to the 71 patients in trial arm 3.

TABLE 92 Other health and social care resources: child – period between assessment 1A (baseline) and assessment 1B (mid-treatment)

	Mean (SD)		
Resource use (contacts): child	CCBT + MCBT	CCBT + MCI	CCBT
Family doctor	1.11 (1.59)	0.36 (0.76)	0.5 (0.80)
Social worker		0.13 (0.88)	0.25 (1.41)
Practice nurse	0.03 (0.17)	0.09 (0.28)	0.06 (0.25)
Psychologist	0.09 (0.50)	0.13 (0.74)	0.06 (0.25)
Education welfare officer		0.021 (0.15)	0.13 (0.71)
Educational psychologist	0.06 (0.34)	0.04 (0.21)	
Family liaison officer	0.11 (0.68)	0.04 (0.29)	
Teacher	0.34 (1.21)	0.62 (3.10)	0.66 (2.50)
Paediatrician	0.2 (0.63)	0.15 (0.47)	
Audiology	0.06 (0.34)		
Speech and language	0.03[a] (0.17)	0.02 (0.15)	0.06 (0.25)
Ophthalmology	0.06 (0.24)	0.04 (0.20)	
Hospital A&E department	0.11 (0.47)	0.09 (0.28)	0.06 (0.35)
Occupational therapist	0.09 (0.51)		
Paediatric physiotherapist		0.06 (0.32)	
Community children's nurse	0.14 (0.85)		
Child and adolescent mental health worker		0.02 (0.15)	
Primary mental health worker			0.03 (0.18)
Other	0.57[b] (1.03)	0.79[c] (1.59)	0.71[c] (1.36)
Observations	35	47	32

a Only 22 observations.
b Only 29 observations.
c Only 22 observations.

TABLE 93 Other health and social care resources: mother – period between assessment 1A (baseline) and assessment 1B (mid-treatment)

	Mean (SD)		
Resource use (contacts): mother	CCBT + MCBT	CCBT + MCI	CCBT
Family doctor	1.74 (2.19)	1.04 (1.52)	1.41 (3.24)
Social worker		0.13 (0.88)	0.09 (0.53)
Practice nurse	0.23 (0.49)	0.11 (0.31)	0.22 (0.75)
Psychologist			0.16 (0.57)
Psychiatrist		0.04 (0.29)	0.03 (0.18)
Community psychiatrist nurse			0.22 (1.24)
Education welfare officer		0.02 (0.15)	0.03 (0.18)
Family liaison officer			0.22(1.24)
Teacher	0.23 (0.60)	0.15 (0.72)	0.28 (0.81)
Paediatrician			0.06 (0.25)
Ophthalmologist	0.14 (0.60)		
Hospital A&E department	0.09 (0.28)	0.11 (0.37)	0.03 (0.18)
Family therapist			0.06 (0.35)
Community children nurse		0.13 (0.88)	
Primary mental health worker			0.03 (0.18)
Housing department		0.02 (0.15)	0.03 (0.18)
Citizens Advice Bureau	0.03 (0.17)		
Other	0.77[a] (1.54)	0.14[b] (0.58)	0.91[c] (1.85)
Observations	35	47	32

a Only 22 observations.
b Only 29 observations.
c Only 22 observations.

TABLE 94 Consumption of medications: mother and child – period between assessment 1A (baseline) and assessment 1B (mid-treatment)

	Mean (SD)		
Resource use: medications	CCBT + MCBT	CCBT + MCI	CCBT
Mother's consumption of prescription medications	0.70 (1.10)	0.89 (1.20)	0.78 (1.28)
Mother's consumption of 'over-the-counter' medications	0.15 (0.46)	0.18 (0.55)	0
Child's consumption of prescription medications	0.48 (0.89)	0.46 (0.84)	0.35 (0.49)
Child's consumption of 'over-the-counter' medications	0.11 (0.32)	0.36 (0.62)	0.22 (0.85)
Observations	27	28	23

TABLE 95 Other health and social care resources: child – period between assessment 1B (mid-treatment) and assessment 2 (post treatment)

	Mean (SD)		
Resource use (contacts): child	CCBT + MCBT	CCBT + MCI	CCBT
Family doctor	0.24 (0.44)	0.64 (1.04)	0.3 (0.47)
Social worker	0.76 (3.15)		0.4 (1.8)
Practice nurse	0.12 (0.49)	0.08 (0.28)	
Psychologist		0.32 (1.6)	
Education welfare officer	0.18 (0.73)		
Family liaison officer		0.04 (0.2)	
Teacher	0.24 (0.56)	0.24 (0.83)	0.2 (0.70)
Paediatrician	0.06 (0.24)	0.08 (0.4)	
Speech and language	0.06 (0.24)		
Ophthalmology		0.04 (0.2)	
Hospital A&E department	0.06 (0.24)	0.04 (0.2)	
Other		0.25[a] (0.77)	0.29[b] (0.77)
Observations	17	25	20

a Only 16 observations.
b Only 17 observations.

TABLE 96 Other health and social care resources: mother – period between assessment 1B (mid-treatment) and assessment 2 (post treatment)

	Mean (SD)		
Resource use (contacts): mother	CCBT + MCBT	CCBT + MCI	CCBT
Family doctor	1.06 (1.71)	0.8 (0.96)	1.9 (4.94)
Social worker			0.25 (0.79)
Practice nurse	0.06 (0.24)	0.12 (0.33)	0.1 (0.45)
Psychologist		0.4 (1.63)	
Community psychiatrist nurse		0.04 (0.2)	1.05 (4.70)
Education welfare officer	0.29 (0.85)		
Educational psychologist		0.04 (0.2)	
Family liaison officer		0.04 (0.2)	1.2 (4.71)
Teacher	0.12 (0.49)	0.08 (0.4)	0.1 (0.31)
Audiology	0.24 (0.66)		
Ophthalmology		0.04 (0.2)	
Hospital A&E department			0.2 (0.89)
Occupational therapist	0.18 (0.73)		
Housing department	0.41 (1.70)	0.08 (0.28)	
Citizens Advice Bureau			0.05 (0.22)
Other	1.77[a] (3.32)	0.38[b] (1.53)	1.16[c] (2.36)
Observations	17	25	20

a Only 13 observations.
b Only 21 observations.
c Only 19 observations.

TABLE 97 Consumption of medications: mother and child – period between assessment 1B (mid-treatment) and assessment 2 (post treatment)

	Mean (SD)		
Resource use: medications	CCBT + MCBT	CCBT + MCI	CCBT
Mother's consumption of prescription medications	0.46 (0.78)	0.96 (1.46)	0.63 (1.38)
Mother's consumption of 'over-the-counter' medications	0.31 (0.63)	0.17 (0.39)	0.05 (0.23)
Child's consumption of prescription medications	0.38 (0.65)	0.30 (0.63)	0.11 (0.32)
Child's consumption of 'over-the-counter' medications	0.31 (0.48)	0.17 (0.39)	0.05 (0.23)
Observations	13	23	19

TABLE 98 Other health and social care resources: child – period between assessment 2 (post treatment) and assessment 3 (6-month follow-up)

	Mean (SD)		
Resource use (contacts): child	CCBT + MCBT	CCBT + MCI	CCBT
Family doctor	0.66 (1.10)	0.45 (0.77)	0.93 (1.80)
Social worker			0.73 (2.90)
Practice nurse		0.13 (0.43)	0.07 (0.37)
Psychologist	0.13 (0.71)		0.17 (0.75)
Psychiatrist			0.03 (0.18)
Education welfare officer	0.19 (0.90)		
Educational psychologist			0.07 (0.37)
Family liaison officer	0.03 (0.18)		0.87 (3.88)
Teacher	0.38 (1.13)	0.35 (1.14)	0.6 (2.43)
Paediatrician	0.19 (0.60)	0.13 (0.50)	0.10 (0.55)
Audiology	0.03 (0.18)	0.10 (0.40)	
Ophthalmology	0.03 (0.18)		0.1 (0.40)
Hospital A&E department	0.16 (0.37)	0.06 (0.25)	0.07 (0.25)
Paediatric dietitian	0.03 (0.18)		0.27 (1.46)
Paediatric physiotherapist	0.03 (0.18)		0.03 (0.18)
Paediatric play specialist	0.19 (1.06)		
Community children's nurse	0.03 (0.18)		
Child and adolescent mental health worker			0.23 (1.10)
Other	0.83[a] (1.53)	0.36[b] (0.92)	0.63[c] (1.63)
Observations	32	31	30

a Only 12 observations.
b Only 11 observations.
c Only 16 observations.

TABLE 99 Other health and social care resources: mother – period between assessment 2 (post treatment) and assessment 3 (6-month follow-up)

	Mean (SD)		
Resource use (contacts): mother	CCBT + MCBT	CCBT + MCI	CCBT
Family doctor	1.34 (1.75)	0.81 (1.05)	1.77 (3.94)
Social worker			0.4 (2.19)
Practice nurse	0.16 (0.45)	0.26 (0.58)	0.13 (0.43)
Psychologist			0.17 (0.75)
Psychiatrist	0.06 (0.25)		0.03 (0.18)
Community psychiatrist nurse	0.31 (1.77)		0.2 (1.10)
Education welfare officer	0.25 (0.92)		0.07 (0.7)
Educational psychologist			0.03 (0.18)
Family liaison officer	0.03 (0.17)		0.73 (3.83)
Teacher	0.41 (1.50)	0.16 (0.73)	0.07 (0.37)
Audiology	0.13 (0.50)	0.10 (0.54)	0.13 (0.73)
Ophthalmology	0.06 (0.25)		
Hospital A&E department	0.13 (0.42)	0.06 (0.25)	0.07 (0.26)
Occupational therapist			0.17 (0.91)
Paediatric dietitian	0.06 (0.35)		
Family therapist	0.03 (0.18)		
Community children's nurse	0.03 (0.18)		
Citizens Advice Bureau	0.09 (0.53)		0.1 (0.55)
Other	0.53[a] (1.67)	0.69[b] (1.70)	0.93[c] (2.28)
Observations	32	31	30

a Only 11 observations.
b Only 13 observations.
c Only 15 observations.

TABLE 100 Consumption of medications: mother and child – period between assessment 2 (post treatment) and assessment 3 (6-month follow-up)

	Mean (SD)		
Resource use: medications	CCBT + MCBT	CCBT + MCI	CCBT
Mother's consumption of prescription medications	0.85 (1.23)	0.69 (0.75)	0.95 (1.24)
Mother's consumption of 'over-the-counter' medications	0.15 (0.49)	0.11 (0.32)	0.05 (0.22)
Child's consumption of prescription medications	0.60 (0.75)	0.53 (0.84)	0.38 (0.81)
Child's consumption of 'over-the-counter' medications	0.11 (0.46)	0.21 (0.42)	0.05 (0.22)
Observations	20	19	21

TABLE 101 Other health and social care resources: child – period between assessment 3 (6-month follow-up) and assessment 4 (12-month follow-up)

	Mean (SD)		
Resource use (contacts): child	CCBT + MCBT	CCBT + MCI	CCBT
Family doctor	0.96 (1.02)	0.35 (0.65)	0.60 (1.00)
Social worker	0.04 (0.21)		0.53 (2.92)
Practice nurse		0.22 (0.85)	0.27 (0.78)
Psychologist	0.04 (0.21)	0.09 (0.42)	0.57 (2.46)
Psychiatrist			0.03 (0.18)
Education welfare officer			0.03 (0.18)
Educational psychologist	0.04 (0.21)	0.04 (0.21)	
Family liaison officer	0.13 (0.63)		0.77 (3.84)
Teacher	0.04 (0.21)	0.17 (0.58)	0.13 (0.43)
Paediatrician	0.13 (0.63)	0.35 (0.93)	0.07 (0.37)
Audiology		0.09 (0.42)	
Ophthalmology			0.07 (0.37)
Hospital A&E department	0.04 (0.21)	0.04 (0.2085144)	0.03 (0.18)
Paediatric dietitian			0.23 (1.28)
Paediatric physiotherapist	0.04 (0.21)		
Child and adolescent mental health worker			0.03 (0.18)
Primary mental health worker			0.03 (0.18)
Other	0.05[a] (0.23)	0.05[b] (0.23)	0.30[c] (0.93)
Observations	23	23	30

a Only 19 observations.
b Only 19 observations.
c Only 23 observations.

TABLE 102 Other health and social care resources: mother – period between assessment 3 (6-month follow-up) and assessment 4 (12-month follow-up)

	Mean (SD)		
Resource use (contacts): mother	CCBT + MCBT	CCBT + MCI	CCBT
Family doctor	2.39 (3.49)	1.52 (1.98)	1.37 (1.97)
Social worker	0.22 (1.04)		0.33 (1.83)
Practice nurse	0.04 (0.21)	0.35 (1.27)	0.10 (0.31)
Psychologist	0.39 (1.88)	0.17 (0.83)	
Psychiatrist	0.04 (0.21)		
Education welfare officer			0.03 (0.18)
Educational psychologist	0.04 (0.21)		0.03 (0.18)
Family liaison officer	0.09 (0.29)		0.73 (3.83)
Teacher	0.13 (0.46)	0.74 (2.53)	0.13 (0.43)
Ophthalmology			0.033 (0.18)
Hospital A&E department	0.17 (0.49)	0.09 (0.42)	0.07 (0.37)
Occupational therapist	0.04 (0.21)		
Housing department		0.09 (0.42)	0.03 (0.18)
Citizens Advice Bureau	0.04 (0.21)		0.03 (0.18)
Family centre	0.04 (0.21)		0.07 (0.37)
Home-Start	0.04 (0.21)		
Other	0.71[a] (1.23)	0.37[b] (1.01)	0.43[c] (1.04)
Observations	23	23	30

a Only 21 observations.
b Only 19 observations.
c Only 23 observations.

TABLE 103 Consumption of medications: mother and child – period between assessment 3 (6-month follow-up) and assessment 4 (12-month follow-up)

	Mean (SD)		
Resource use: medications	CCBT + MCBT	CCBT + MCI	CCBT
Mother's consumption of prescription medications	0.65[a] (0.93)	0.45[a] (0.89)	0.54[b] (1.07)
Mother's consumption of 'over-the-counter' medications	0.14[c] (0.35)	0.41 (0.96)	0.26[d] (0.71)
Child's consumption of prescription medications	0.52 (0.67)	0.18 (0.50)	0.17 (0.38)
Child's consumption of 'over-the-counter' medications	0.22 (0.67)	0.23 (0.53)	0.21 (0.62)
Observations	23	22	29

a Only 20 observations.
b Only 28 observations.
c Only 22 observations.
d Only 27 observations.

TABLE 104 Cost of other health and social care resources: child – period between assessment 1A (baseline) and assessment 1B (mid-treatment)

	Mean (SD)		
Cost: child	CCBT + MCBT	CCBT + MCI	CCBT
Family doctor	£44.57 (63.45)	£14.46 (30.56)	£20.00 (32.12)
Social worker		£26.30 (180.29)	£51.50 (291.33)
Practice nurse	£0.39 (2.31)	£1.16 (3.86)	£0.86 (3.37)
Psychologist	£11.66 (68.96)	£17.36 (100.73)	£8.50 (33.45)
Education welfare officer		£0.43 (2.98)	£2.56 (14.45)
Educational psychologist	£2.13 (12.61)	£1.62 (7.69)	
Family liaison officer	£5.60 (33.13)	£2.09 (14.29)	
Teacher	£12.14 (42.89)	£21.85 (109.90)	£23.24 (88.40)
Paediatrician	£45.00 (142.30)	£33.51 (104.68)	
Audiology	£6.29 (37.19)		
Speech and language	£0.97[a] (5.65)	£0.70 (4.81)	£2.06 (8.12)
Ophthalmology	£6.11 (25.20)	£4.55 (21.83)	
Hospital A&E department	£12.34 (50.87)	£9.19 (30.46)	£6.75 (38.18)
Occupational therapist	£2.83 (16.73)		
Paediatric physiotherapist		£4.72 (23.93)	
Community children's nurse	£13.28 (78.60)		
Child and adolescent mental health worker		£1.44 (9.92)	
Primary mental health worker			2.13 (12.02)
Other	£46.35[b] (83.41)	£64.22[c] (128.77)	£57.26[d] (110.20)
Observations	35	47	32

a Only 34 observations.
b Only 21 observations.
c Only 24 observations.
d Only 17 observations.

TABLE 105 Cost of other health and social care resources: mother – period between assessment 1A (baseline) and assessment 1B (mid-treatment)

	Mean (SD)		
Cost: mother	CCBT + MCBT	CCBT + MCI	CCBT
Family doctor	£69.71 (87.50)	£41.70 (60.70)	£56.25 (129.66)
Social worker		£26.30 (180.28)	£19.31 (109.25)
Practice nurse	£3.13 (6.71)	£1.45 (4.27)	£2.99 (10.28)
Psychologist			£21.25 (78.08)
Psychiatrist		£16.30 (111.73)	£11.97 (67.71)
Community psychiatrist nurse			£16.63 (94.05)
Education welfare officer		£0.43 (2.98)	£0.64 (3.61)
Family liaison officer			£10.71 (60.63)
Teacher	£8.09 (21.19)	£5.27 (25.55)	£9.96 (28.77)
Paediatrician			£14.06 (55.34)
Ophthalmologist	£15.20 (64.32)		
Hospital A&E department	£9.26 (30.68)	£11.49 (40.50)	£3.38 (19.09)
Family therapist			£3.06 (17.32)
Community children nurse		£11.87 (81.39)	
Primary mental health worker			£2.12 (12.02)
Housing department		£0.42 (2.89)	£0.619 (3.50)
Citizens Advise Bureau	£0.44 (2.62)		
Other	£62.68[a] (125.00)	£11.19[b] (47.12)	£73.75[c] (150.02)
Observations	35	47	32

a Only 22 observations.
b Only 29 observations.
c Only 22 observations.

TABLE 106 Cost of other health and social care resources: child – period between assessment 1B (mid-treatment) and assessment 2 (post treatment)

	Mean (SD)		
Cost: child	CCBT + MCBT	CCBT + MCI	CCBT
Family doctor	£9.41 (17.49)	£25.60 (41.44)	£12.00 (18.81)
Social worker	£157.53 (649.51)		£82.40 (368.50)
Practice nurse	£1.61 (6.64)	£1.10 (3.79)	
Psychologist		£43.52 (217.6)	
Education welfare officer	£3.61 (14.87)		
Family liaison officer		£1.96 (9.8)	
Teacher	£8.33 (19.91)	£8.50 (29.41)	£7.08 (24.64)
Paediatrician	£13.24 (54.57)	£18 (90.00)	
Speech and language	£1.94 (8.00)		
Ophthalmology		£4.28 (21.4)	
Hospital A&E department	£6.35 (26.19)	£4.32 (21.6)	
Other		£20.28[a] (62.84)	£23.86[b] (62.60)
Observations	17	25	20

a Only 16 observations.
b Only 17 observations.

TABLE 107 Cost of other health and social care resources: mother – period between assessment 1B (mid-treatment) and assessment 2 (post treatment)

	Mean (SD)		
Cost: mother	CCBT + MCBT	CCBT + MCI	CCBT
Family doctor	£42.35 (68.51)	£32.00 (38.30)	£76.00 (197.63)
Social worker			£51.50 (161.99)
Practice nurse	£0.81 (3.32)	£1.64 (4.54)	£1.37 (6.12)
Psychologist		£54.4 (222.09)	
Community psychiatrist nurse		£3.04 (15.20)	£79.80 (356.88)
Education welfare officer	£6.01 (17.35)		
Educational psychologist		£1.49 (7.46)	
Family liaison officer		£1.96 (9.80)	£58.8 (230.71)
Teacher	£4.17 (17.17)	£2.83 (14.16)	£3.54 (10.90)
Audiology	£25.88 (73.06)		
Ophthalmology		£4.28 (21.40)	
Hospital A&E department			£21.6 (96.60)
Occupational therapist	£5.82 (24.01)		
Housing department	£8.16 (33.63)	£1.58 (5.49)	
Citizens Advice Bureau			£0.78 (3.47)
Other	£143.52[a] (269.36)	£30.90[b] (124.29)	£93.93[c] (191.70)
Observations	17	25	20

a Only 13 observations.
b Only 21 observations.
c Only 19 observations.

TABLE 108 Cost of other health and social care resources: child – period between assessment 2 (post treatment) and assessment 3 (6-month follow-up)

	Mean (SD)		
Cost: child	CCBT + MCBT	CCBT + MCI	CCBT
Family doctor	£26.25 (43.83)	£18.06 (30.70)	£37.33 (71.96)
Social worker			£151.07 (597.37)
Practice nurse		£1.77 (5.85)	£0.91 (5.00)
Psychologist	£17.00 (96.17)		£22.67 (101.54)
Psychiatrist			£12.76 (69.93)
Education welfare officer	£3.83 (18.31)		
Educational psychologist			£2.49 (13.62)
Family liaison officer	£1.53 (8.66)		£42.47 (189.88)
Teacher	£13.28 (39.97)	£12.56 (40.42)	£21.25 (86.04)
Paediatrician	£42.19 (133.27)	£29.03 (112.38)	£22.50 (123.24)
Audiology	£3.44 (19.45)	£10.65 (43.58)	
Ophthalmology	£3.34 (18.92)		£10.70 (43.08)
Hospital A&E department	£16.88 (39.84)	£6.97 (26.97)	£7.20 (27.40)
Occupational therapist			
Paediatric dietitian	£1.06 (6.01)		£9.07 (49.66)
Paediatric physiotherapist	£2.31 (13.08)		£2.47 (13.51)
Paediatric play specialist	£2.17 (12.25)		
Community children's nurse	£2.91 (16.44)		
Child and adolescent mental health worker			£15.87 (75.09)
Other	£67.60[a] (123.91)	£29.50[b] (74.99)	£50.70[c] (132.05)
Observations	32	31	30

a Only 12 observations.
b Only 11 observations.
c Only 16 observations.

TABLE 109 Cost of other health and social care resources: mother – period between assessment 2 (post treatment) and assessment 3 (6-month follow-up)

	Mean (SD)		
Cost: mother	CCBT + MCBT	CCBT + MCI	CCBT
Family doctor	£53.75 (70.10)	£32.26 (41.85)	£70.67 (157.46)
Social worker			£82.40 (451.32)
Practice nurse	£2.14 (6.13)	£3.53 (7.88)	£1.83 (5.94)
Psychologist			£22.67 (101.54)
Psychiatrist	£23.94 (94.19)		£12.77 (69.93)
Community psychiatrist nurse	£23.75 (134.35)		£15.2 (83.25)
Education welfare officer	£5.11 (18.72)		£1.36 (7.46)
Educational psychologist			£1.24 (6.81)
Family liaison officer	£1.53 (8.66)		£35.93 (187.77)
Teacher	£14.39 (53.10)	£5.71 (26.02)	£2.36 (2.93)
Audiology	£13.75 (54.11)	£10.65 (59.27)	£14.67 (80.33)
Ophthalmology	£6.69 (26.32)		
Hospital A&E department	£13.50 (45.49)	£6.97 (26.97)	£7.20 (27.40)
Occupational therapist			£5.50 (30.12)
Paediatric dietitian	£2.13 (12.02)		
Family therapist	£1.53 (8.66)		
Community children's nurse	£2.91 (16.44)		
Citizens Advice Bureau	£1.45 (8.22)		£1.55 (8.49)
Other	£81.12[a] (135.73)	£56.16[b] (138.08)	£75.71[c] (185.15)
Observations	32	31	30

a Only 11 observations.
b Only 13 observations.
c Only 15 observations.

TABLE 110 Cost of other health and social care resources: child – period between assessment 3 (6-month follow-up) and assessment 4 (12-month follow-up)

	Mean (SD)		
Cost: child	CCBT + MCBT	CCBT + MCI	CCBT
Family doctor	£38.26 (40.86)	£13.91 (25.89)	£24 (40.14)
Social worker	£8.96 (42.95)		£109.87 (601.76)
Practice nurse		£2.98 (11.64)	£3.65 (10.75)
Psychologist	£5.91 (28.36)	£11.83 (56.72)	£77.07 (334.44)
Psychiatrist			£12.77 (69.93)
Education welfare officer			£0.68 (3.73)
Educational psychologist	£1.62 (7.78)	£1.62 (7.78)	
Family liaison officer	£6.39 (30.65)		£37.57 (188.10)
Teacher	£1.54 (7.38)	£6.16 (20.40)	£4.72 (15.37)
Paediatrician	£29.35 (140.75)	£78.26 (210.29)	£15.00 (82.16)
Audiology		£9.57 (45.87)	
Ophthalmology			£7.13 (39.07)
Hospital A&E department	£4.70 (22.52)	£4.70 (22.52)	£3.60 (19.72)
Paediatric dietitian			£7.93 (43.45)
Paediatric physiotherapist	£3.22 (15.43)		
Child and adolescent mental health worker			£2.27 (12.42)
Primary mental health worker			£2.27 (12.42)
Other	£4.27[a] (18.61)	£4.27[b] (18.61)	£24.69[c] (75.13)
Observations	23	23	30

a Only 19 observations.
b Only 19 observations.
c Only 23 observations.

TABLE 111 Cost of other health and social care resources: mother – period between assessment 3 (6-month follow-up) and assessment 4 (12-month follow-up)

	Mean (SD)		
Cost: mother	CCBT + MCBT	CCBT + MCI	CCBT
Family doctor	£95.65 (139.47)	£60.87 (78.97)	£54.67 (78.95)
Social worker	£44.78 (214.77)		£68.67 (376.10)
Practice nurse	£0.60 (2.85)	£4.76 (17.32)	£1.37 (4.18)
Psychologist	£53.22 (255.22)	£23.65 (113.43)	
Psychiatrist	£16.65 (79.86)		
Education welfare officer			£0.68 (3.73)
Educational psychologist	£1.62 (7.78)		£1.24 (6.81)
Family liaison officer	£4.26 (14.12)		£35.93 (187.77)
Teacher	£4.62 (16.21)	£26.17 (89.46)	£4.72 (15.37)
Ophthalmology			£3.57 (19.54)
Hospital A&E department	£18.78 (53.03)	£9.39 (45.04)	£7.20 (39.44)
Occupational therapist	£1.43 (6.88)		
Housing department		£1.72 (8.26)	£0.66 (3.62)
Citizens Advice Bureau	£0.67 (3.23)		£0.52 (2.83)
Family centre	£2.13 (10.22)		£3.27 (17.89)
Home-Start	£4.16 (19.93)		
Other	£57.94[a] (103.07)	£29.89[b] (82.06)	£35.27[c] (84.11)
Observations	23	23	30

a Only 21 observations.
b Only 19 observations.
c Only 23 observations.

TABLE 112 Time off school (days) for the child and time off work and usual activities (days) for the mother: period between assessment 1A (baseline) and assessment 1B (mid-treatment)

	Mean (SD)		
Time off (days)	CCBT + MCBT	CCBT + MCI	CCBT
Time off school (days): child	1.46 (1.97)	0.28 (0.92)	1.88 (2.91)
Time off work (days): mother	0.50[a] (1.38)	0.28[b] (0.92)	2.00 (6.42)
Time off usual activities (days): mother	1.14 (3.04)	0.57 (2.38)	0.78 (2.76)
Observations	35	47	32

a Only 34 observations.
b Only 45 observations.

TABLE 113 Time off school (days) for the child and time off work and usual activities (days) for the mother: period between assessment 1B (mid-treatment) and assessment 2 (post treatment)

	Mean (SD)		
Time off (days)	CCBT + MCBT	CCBT + MCI	CCBT
Time off school (days): child	2.12 (4.09)	1.84 (2.64)	3.38 (10.02)
Time off work (days): mother	0.41 (1.70)	0.72 (1.74)	2.65 (8.29)
Time off usual activities (days): mother	0.06 (0.24)	1.96 (6.09)	0.65 (2.68)
Observations	17	25	20

TABLE 114 Time off school (days) for the child and time off work and usual activities (days) for the mother: period between assessment 2 (post treatment) and assessment 3 (6-month follow-up)

	Mean (SD)		
Time off (days)	CCBT + MCBT	CCBT + MCI	CCBT
Time off school (days): child	3.38 (6.74)	1.32 (2.28)	2.55 (4.69)
Time off work (days): mother	0.59 (1.62)	0.42 (1.12)	3.03 (8.66)
Time off usual activities (days): mother	1.00 (2.75)	1.06 (3.72)	0.23 (1.28)
Observations	32	31	30

TABLE 115 Time off school (days) for the child and time off work and usual activities (days) for the mother: period between assessment 3 (6-month follow-up) and assessment 4 (12-month follow-up)

	Mean (SD)		
Time off (days)	CCBT + MCBT	CCBT + MCI	CCBT
Time off school (days): child	3.23 (4.82)	0.61 (1.53)	3.15 (6.34)
Time off work (days): mother	1.45 (3.29)	1.00 (3.12)	1.03[a] (2.38)
Time off usual activities (days): mother	0.64 (2.98)	1.68 (1.99)	1.69[a] (6.43)
Observations	22	23	30

a Only 29 observations.

TABLE 116 Cost–utility (health service perspective): ITT approach – CCBT + MCBT vs. CCBT

CUA results	CCBT + MCBT ($n = 69$), mean (SE)	CCBT ($n = 71$), mean (SE)
Cost of intervention	£1888.84 (78.65)	£1092.25 (61.88)
QALY gain	0.794 (0.022)	0.827 (0.024)
Incremental cost (95% CI)	£796.59 (£599.48 to £993.70)	
Incremental benefit, QALY gain (95% CI)	–0.033 (–0.101 to 0.035)	
ICER, incremental cost per QALY gain	–£24,139	
(95% CI) bootstrap method	Lower limit, £47,106; upper limit, –£10,094	
(95% CI) Fieller's method	Lower limit, –£9251; upper limit, £46,271	
NMB for WTP = £20,000	–0.033 × £20,000 – £796.59 = –£1456.00	
NMB for WTP = £30,000	–0.033 × £30,000 – £796.59 = –£1786.59	

SE, standard error; WTP, willingness to pay.

TABLE 117 Cost–utility (health service perspective): ITT approach – CCBT + MCI vs. CCBT

CUA results	CCBT + MCI ($n = 71$), mean (SE)	CCBT ($n = 71$), mean (SE)
Cost of intervention	£1899.95 (80.72)	£1891.30 (87.14)
QALY gain	0.855 (0.018)	0.827 (0.024)
Incremental cost (95% CI)	£807.70 (£606.55 to £1008.85)	
Incremental benefit, QALY gain (95% CI)	0.028 (–0.030 to 0.086)	
ICER, incremental cost per QALY gain	£28,846	
(95% CI) bootstrap method	Lower limit, £10,129; upper limit, –£41,264	
(95% CI) Fieller's method	Lower limit, £10,207; upper limit, –£41,499	
NMB for WTP = £20,000	0.028 × £20,000 – £807.70 = –£247.70	
NMB for WTP = £30,000	0.028 × £30,000 – £807.70 = £32.30	

SE, standard error; WTP, willingness to pay.

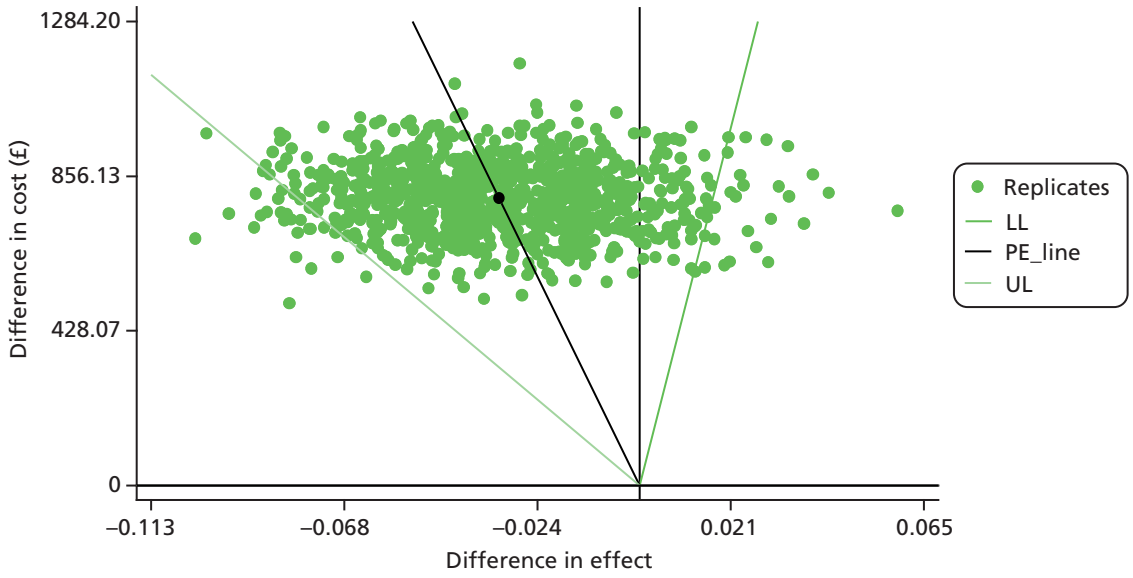


FIGURE 14 Cost-effectiveness plane showing bootstrapped replicates of the ICER: ITT analysis – CCBT + MCBT vs. CCBT. LL, lower limit; PE, point estimate; UL, upper limit.

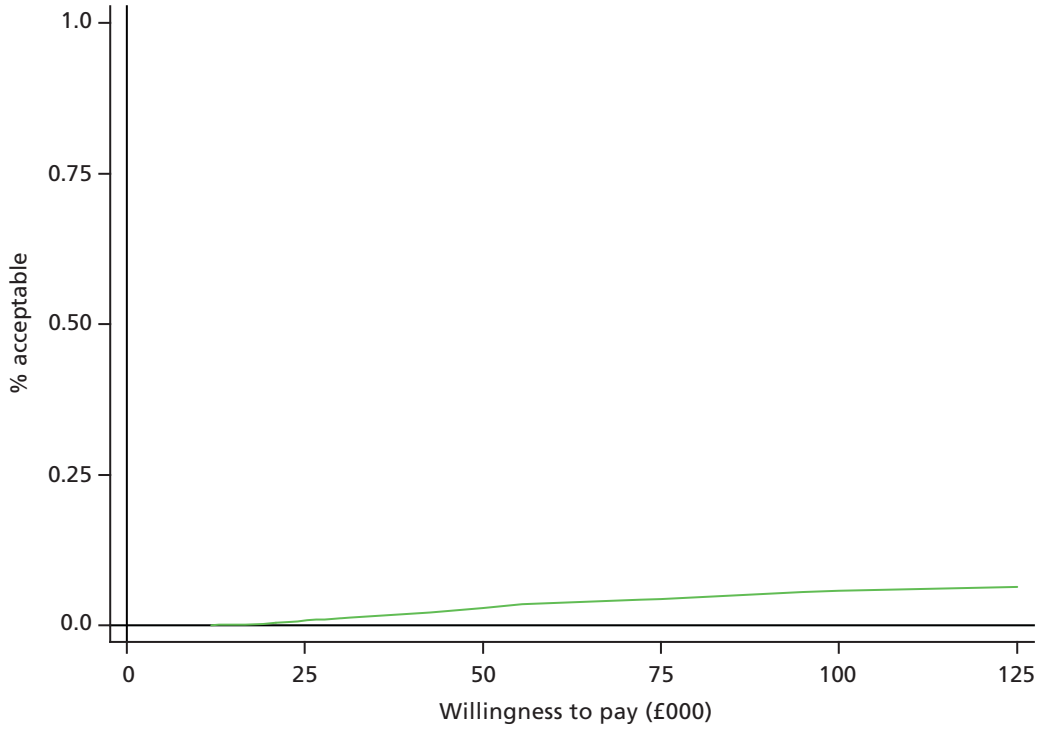


FIGURE 15 Cost-effectiveness acceptability curve showing the probability that the intervention is cost-effective at different willingness-to-pay thresholds: ITT analysis – CCBT + MCBT vs. CCBT.

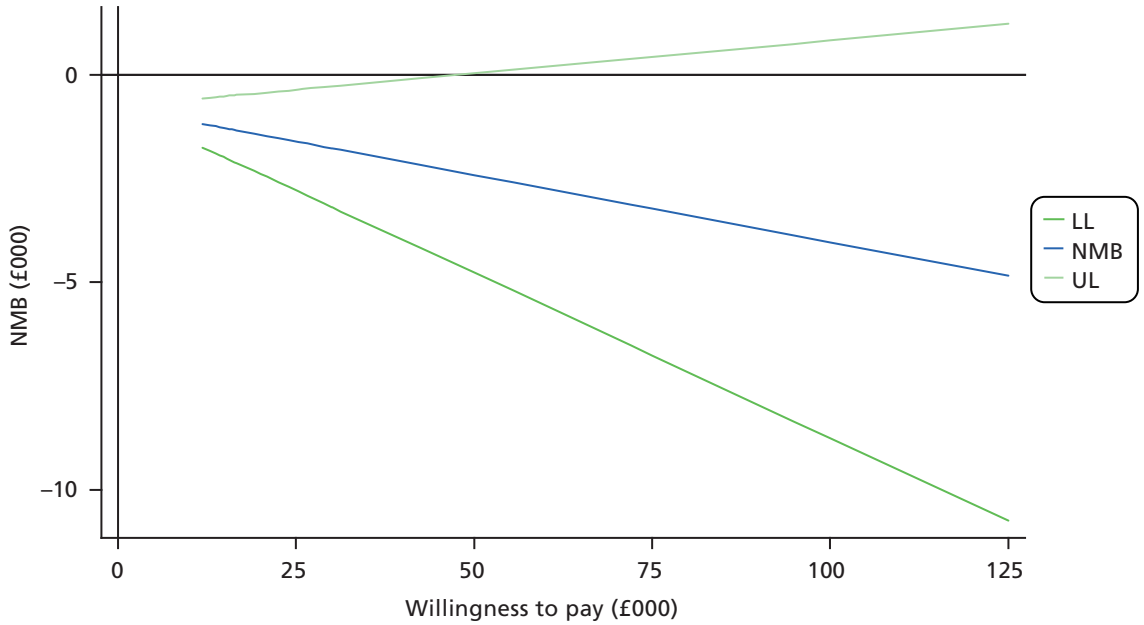


FIGURE 16 Net monetary benefit curve and limit curves: ITT analysis – CCBT + MCBT vs. CCBT. LL, lower limit; UL, upper limit.

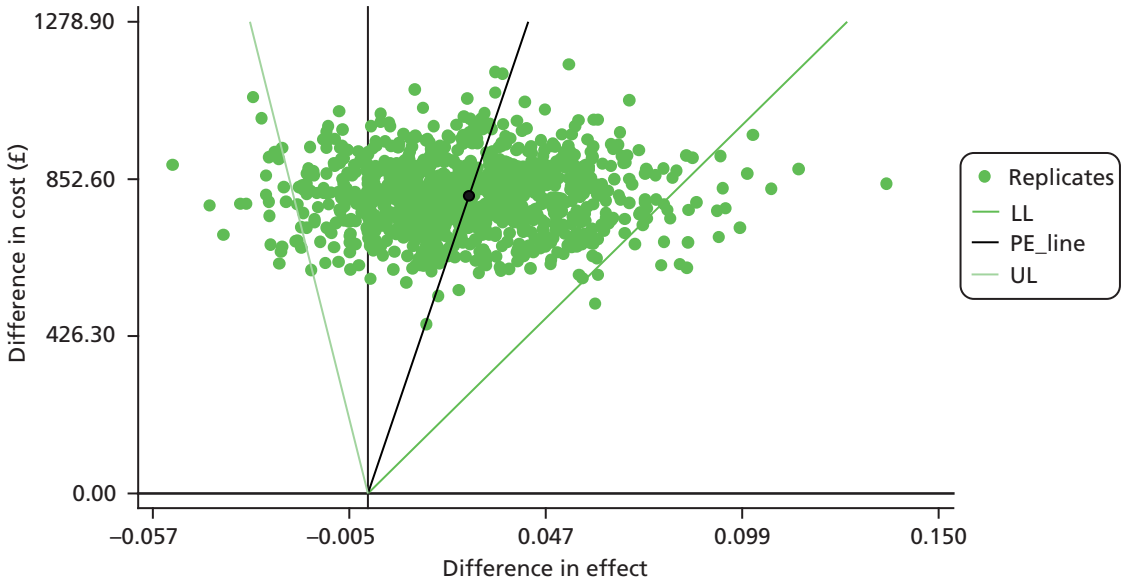


FIGURE 17 Cost-effectiveness plane showing bootstrapped replicates of the ICER: ITT analysis – CCBT + MCI vs. CCBT. LL, lower limit; PE, point estimate; UL, upper limit.

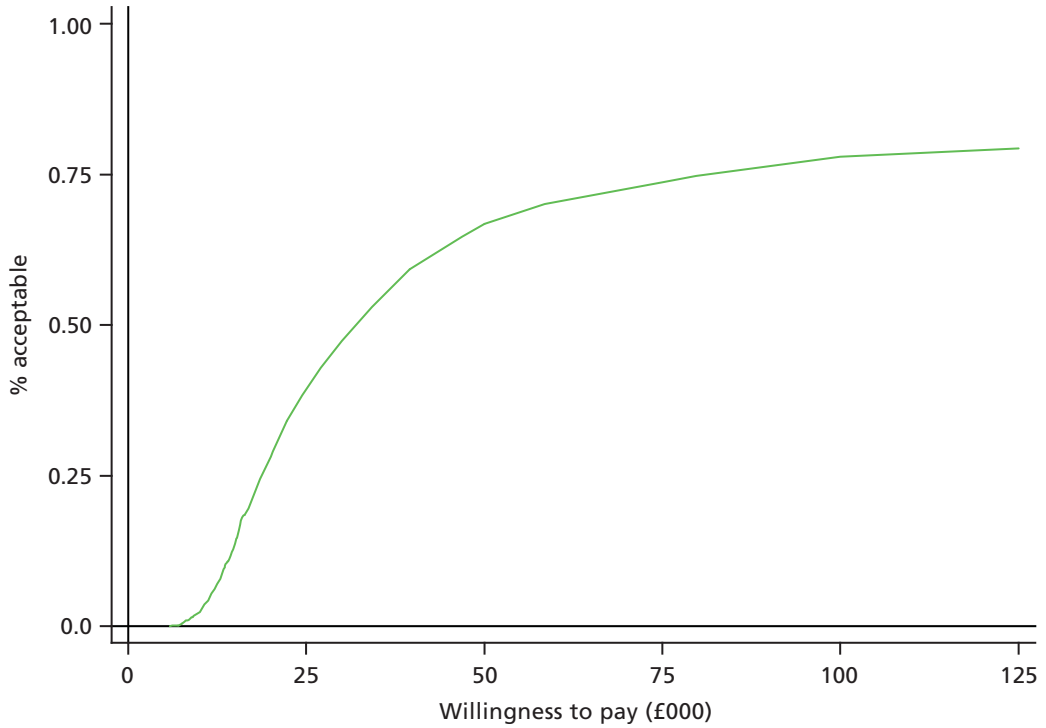


FIGURE 18 Cost-effectiveness acceptability curve showing the probability that the intervention is cost-effective at different willingness-to-pay thresholds: ITT analysis – CCBT + MCI vs. CCBT.

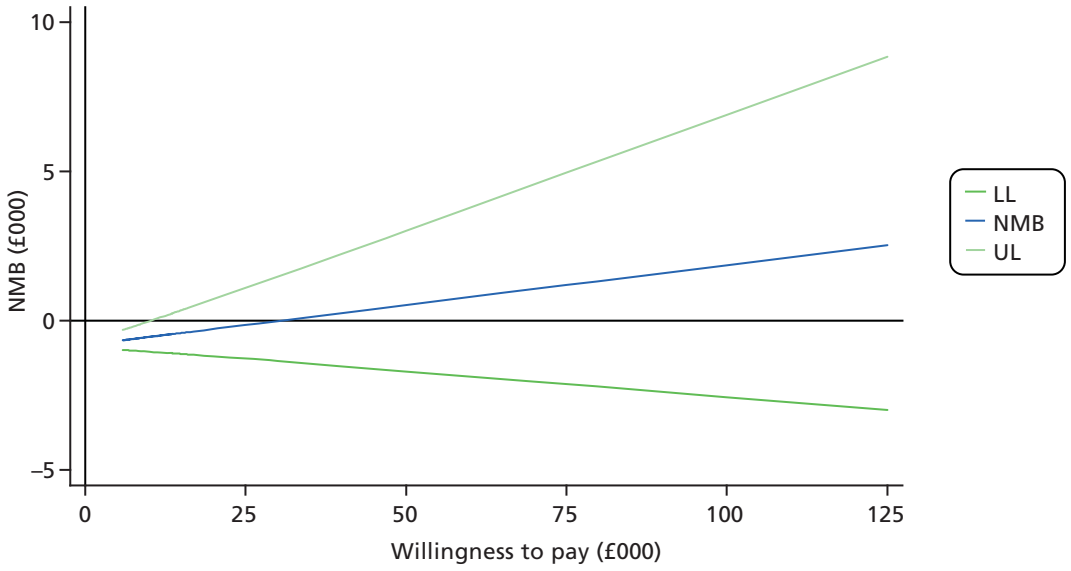


FIGURE 19 Net monetary benefit curve and limit curves: ITT analysis – CCBT + MCI vs. CCBT. LL, lower limit; UL, upper limit.

Appendix 4 Teacher-reported questionnaire

Child adjustment to school: teacher report

Instructions

For each item mark the box for not true, somewhat true or certainly true. It would help us if you answered all items as best you can, even if you are not absolutely certain or the item seems daft! Please give your answers on the basis of the child's behaviour over the **previous 2 weeks** of school.

	Not true	Somewhat true	Certainly true
Avoids or gets worried about presenting work or showing things to the class			
Avoids or gets worried about participating in group or sports activities			
Avoids or gets worried about approaching a group of children to ask to join in			
Avoids or gets worried about standing up for him/herself with peers			
Avoids or gets worried about answering questions in class			
Avoids or gets worried about speaking in class			
Avoids or gets worried about asking questions in class			
Avoids or gets worried about telling a teacher if he/she doesn't understand something			

Appendix 5 Summary statistics

TABLE 118 Descriptive statistics: SCAS questionnaires

Questionnaire	Treatment	*n*	*n* missing	Mean (SD)	Median (IQR)	Minimum	Maximum
SCAS-c							
Total score baseline	CCBT	67	4	40.24 (21.29)	35.0 (24.0–53.0)	2	105
	CCBT + MCBT	67	2	41.33 (18.26)	41.0 (29.0–56.0)	7	80
	CCBT + MCI	69	2	39.16 (17.38)	39.0 (29.0–47.0)	4	92
Total score 6 months	CCBT	44	27	21.05 (16.24)	18.0 (8.0–28.5)	0	73
	CCBT + MCBT	43	26	24.42 (17.41)	19.0 (12.0–39.0)	0	63
	CCBT + MCI	43	28	23.88 (17.37)	22.0 (9.0–35.0)	1	67
Total score 12 months	CCBT	33	38	18.24 (13.31)	16.0 (9.0–27.0)	1	54
	CCBT + MCBT	34	35	23.09 (14.92)	21.0 (10.0–34.0)	0	52
	CCBT + MCI	39	32	21.15 (18.65)	15.0 (9.0–34.0)	0	68
SCAS-c/p							
Total score baseline	CCBT	64	7	43.17 (15.64)	43.0 (32.5–50.0)	16	94
	CCBT + MCBT	63	6	42.19 (15.53)	39.0 (32.0–50.0)	17	82
	CCBT + MCI	65	6	41.60 (16.75)	40.0 (29.0–52.0)	16	94
Total score 6 months	CCBT	40	31	22.40 (16.33)	19.0 (14.0–27.5)	1	93
	CCBT + MCBT	43	26	23.21 (13.53)	19.0 (14.0–31.0)	3	61
	CCBT + MCI	39	32	22.26 (11.19)	22.0 (14.0–28.0)	5	51
Total score 12 months	CCBT	34	37	19.44 (13.14)	15.5 (10.0–29.0)	1	51
	CCBT + MCBT	32	37	24.63 (15.37)	25.0 (12.0–32.5)	1	66
	CCBT + MCI	36	35	18.28 (12.80)	17.0 (9.0–24.0)	2	58
	CCBT + MCBT	20	49	4.05 (3.02)	3.5 (2.0–5.5)	0	12
	CCBT + MCI	26	45	5.04 (3.46)	5.0 (3.0–7.0)	0	13
SCAS-t							
Total score baseline	CCBT	25	46	17.60 (13.39)	15.0 (10.0–22.0)	0	49
	CCBT + MCBT	37	32	14.38 (14.57)	9.0 (5.0–16.0)	1	66
	CCBT + MCI	42	29	18.67 (12.98)	15.0 (10.0–26.0)	0	47
Total score 6 months	CCBT	11	60	11.91 (13.16)	6.0 (1.0–15.0)	0	43
	CCBT + MCBT	16	53	8.63 (7.05)	6.5 (3.5–12.0)	2	29
	CCBT + MCI	22	49	11.68 (11.51)	7.0 (4.0–16.0)	0	46
Total score 12 months	CCBT	9	62	9.44 (9.86)	6.0 (5.0–8.0)	1	32
	CCBT + MCBT	8	61	15.75 (11.51)	14.0 (8.0–20.5)	2	39
	CCBT + MCI	10	61	7.70 (5.19)	7.5 (3.0–11.0)	0	17

IQR, interquartile range.

TABLE 119 Descriptive statistics: CAIS questionnaires

Questionnaire	Treatment	*n*	*n* missing	Mean (SD)	Median (IQR)	Minimum	Maximum
CAIS-c							
Total score baseline	CCBT	66	5	18.29 (12.83)	16.5 (9.0–24.0)	1	58
	CCBT + MCBT	67	2	23.15 (16.34)	20.0 (10.0–37.0)	0	70
	CCBT + MCI	68	3	18.91 (14.02)	15.0 (7.5–28.0)	0	63
Total score 6 months	CCBT	42	29	7.48 (7.39)	5.0 (2.0–11.0)	0	27
	CCBT + MCBT	43	26	10.02 (8.56)	8.0 (3.0–14.0)	0	29
	CCBT + MCI	43	28	9.74 (9.39)	7.0 (2.0–16.0)	0	39
Total score 12 months	CCBT	32	39	6.75 (7.36)	4.0 (1.0–11.0)	0	29
	CCBT + MCBT	33	36	11.82 (15.16)	7.0 (2.0–18.0)	0	78
	CCBT + MCI	38	33	7.82 (11.23)	3.5 (1.0–10.0)	0	49
CAIS-c/p							
Total score baseline	CCBT	58	13	23.17 (16.04)	18.5 (11.0–32.0)	1	66
	CCBT + MCBT	56	13	25.46 (15.07)	25.0 (15.0–34.5)	0	60
	CCBT + MCI	58	13	20.55 (12.66)	17.0 (10.0–28.0)	1	58
Total score 6 months	CCBT	40	31	13.18 (12.87)	9.0 (3.0–22.0)	0	54
	CCBT + MCBT	43	26	11.65 (9.67)	9.0 (5.0–16.0)	1	44
	CCBT + MCI	42	29	11.17 (9.17)	9.0 (4.0–18.0)	0	38
Total score 12 months	CCBT	33	38	11.48 (12.14)	9.0 (3.0–16.0)	0	58
	CCBT + MCBT	33	36	14.39 (12.15)	14.0 (6.0–19.0)	0	45
	CCBT + MCI	38	33	7.92 (6.58)	7.0 (3.0–13.0)	0	24

IQR, interquartile range.

TABLE 120 Descriptive statistics: SDQ conduct questionnaires

Questionnaire	Treatment	*n*	*n* missing	Mean (SD)	Median (IQR)	Minimum	Maximum
SDQ-c conduct							
Score baseline	CCBT	68	3	2.97 (2.01)	3.0 (1.0–4.0)	0	8
	CCBT + MCBT	66	3	3.05 (1.88)	3.0 (2.0–4.0)	0	8
	CCBT + MCI	70	1	2.84 (1.72)	3.0 (2.0–4.0)	0	8
Score 6 months	CCBT	44	27	2.07 (1.61)	2.0 (1.0–3.0)	0	6
	CCBT + MCBT	44	25	2.05 (1.38)	2.0 (1.0–3.0)	0	6
	CCBT + MCI	43	28	2.14 (1.93)	2.0 (1.0–3.0)	0	6
Score 12 months	CCBT	33	38	1.64 (1.48)	2.0 (0.0–3.0)	0	5
	CCBT + MCBT	35	34	2.06 (1.66)	2.0 (1.0–2.0)	0	8
	CCBT + MCI	39	32	1.95 (2.31)	1.0 (0.0–3.0)	0	8
SDQ-c/p conduct							
Score baseline	CCBT	65	6	2.46 (1.96)	2.0 (1.0–3.0)	0	8
	CCBT + MCBT	65	4	3.05 (1.82)	3.0 (2.0–4.0)	0	9
	CCBT + MCI	70	1	2.57 (1.88)	2.0 (1.0–4.0)	0	8
Score 6 months	CCBT	41	30	2.00 (1.90)	2.0 (1.0–3.0)	0	8
	CCBT + MCBT	43	26	1.77 (1.62)	1.0 (1.0–3.0)	0	6
	CCBT + MCI	42	29	1.45 (1.40)	1.0 (0.0–2.0)	0	6
Score 12 months	CCBT	34	37	1.26 (1.64)	1.0 (0.0–2.0)	0	8
	CCBT + MCBT	34	35	1.97 (1.47)	2.0 (1.0–3.0)	0	5
	CCBT + MCI	38	33	1.82 (2.04)	1.0 (0.0–3.0)	0	8

IQR, interquartile range.

TABLE 121 Descriptive statistics: SMFQ questionnaires

Questionnaire	Treatment	*n*	*n* missing	Mean (SD)	Median (IQR)	Minimum	Maximum
SMFQ-c							
Total score baseline	CCBT	67	4	7.81 (6.76)	5.0 (2.0–13.0)	0	24
	CCBT + MCBT	68	1	9.03 (5.52)	8.5 (5.0–12.0)	0	24
	CCBT + MCI	69	2	7.42 (5.70)	6.0 (3.0–10.0)	0	23
Total score 6 months	CCBT	43	28	4.51 (5.29)	3.0 (0.0–7.0)	0	19
	CCBT + MCBT	44	25	5.20 (4.99)	4.5 (0.5–10.0)	0	16
	CCBT + MCI	41	30	4.00 (5.17)	1.0 (0.0–7.0)	0	22
Total score 12 months	CCBT	31	40	3.00 (3.91)	1.0 (0.0–5.0)	0	12
	CCBT + MCBT	35	34	4.31 (5.42)	3.0 (0.0–6.0)	0	25
	CCBT + MCI	38	33	4.61 (6.74)	1.0 (0.0–6.0)	0	26
SMFQ-c/p							
Total score baseline	CCBT	59	12	9.39 (6.61)	7.0 (4.0–14.0)	0	24
	CCBT + MCBT	58	11	10.74 (7.24)	10.0 (5.0–15.0)	0	26
	CCBT + MCI	62	9	8.79 (7.25)	7.0 (3.0–14.0)	0	25
Total score 6 months	CCBT	41	30	5.12 (5.81)	3.0 (1.0–9.0)	0	25
	CCBT + MCBT	43	26	4.65 (5.25)	3.0 (1.0–7.0)	0	20
	CCBT + MCI	42	29	4.33 (4.74)	3.5 (1.0–7.0)	0	23
Total score 12 months	CCBT	34	37	4.06 (5.43)	1.5 (0.0–6.0)	0	20
	CCBT + MCBT	34	35	6.29 (5.84)	5.0 (1.0–10.0)	0	22
	CCBT + MCI	38	33	3.71 (4.78)	1.0 (0.0–6.0)	0	18

TABLE 122 Summary of behavioural scores at baseline and assessment 2, and the change from baseline to assessment 2

Questionnaire	Treatment	*n*	Mean (SD)	Median (IQR)	Minimum	Maximum
Positive behaviour						
Difference baseline–assessment 2	CCBT	42	0.01 (0.40)	–0.01 (–0.26 to 0.35)	–1.20	0.75
	CCBT + MCBT	45	0.01 (0.33)	0.02 (–0.28 to 0.24)	–0.57	0.94
	CCBT + MCI	49	0.08 (0.42)	0.10 (–0.19 to 0.37)	–1.19	1.04
Score 2	CCBT	42	3.17 (0.36)	3.22 (2.93 to 3.43)	2.32	3.82
	CCBT + MCBT	45	3.07 (0.36)	3.04 (2.86 to 3.31)	2.30	3.96
	CCBT + MCI	49	3.16 (0.47)	3.17 (2.95 to 3.49)	1.81	4.34
Total score baseline	CCBT	42	3.16 (0.45)	3.14 (2.88 to 3.47)	2.08	4.03
	CCBT + MCBT	45	3.06 (0.39)	3.04 (2.75 to 3.38)	2.29	4.03
	CCBT + MCI	49	3.08 (0.55)	3.11 (2.74 to 3.39)	1.89	4.33
Overprotection						
Difference baseline–assessment 2	CCBT	42	–0.04 (0.18)	0.00 (–0.07 to 0.00)	–1.00	0.28
	CCBT + MCBT	45	–0.03 (0.10)	0.00 (–0.02 to 0.00)	–0.33	0.22
	CCBT + MCI	49	–0.04 (0.09)	0.00 (–0.07 to 0.00)	–0.33	0.07
Score 2	CCBT	42	1.04 (0.10)	1.00 (1.00 to 1.00)	1.00	1.50
	CCBT + MCBT	45	1.02 (0.05)	1.00 (1.00 to 1.00)	1.00	1.22
	CCBT + MCI	49	1.01 (0.03)	1.00 (1.00 to 1.00)	1.00	1.11
Total score baseline	CCBT	42	1.08 (0.17)	1.00 (1.00 to 1.11)	1.00	2.00
	CCBT + MCBT	45	1.05 (0.09)	1.00 (1.00 to 1.08)	1.00	1.33
	CCBT + MCI	49	1.05 (0.09)	1.00 (1.00 to 1.07)	1.00	1.33
Promotion of avoidance						
Difference baseline–assessment 2	CCBT	42	–0.04 (0.13)	0.00 (–0.11 to 0.00)	–0.47	0.28
	CCBT + MCBT	45	–0.01 (0.13)	0.00 (–0.07 to 0.00)	–0.53	0.33
	CCBT + MCI	49	–0.04 (0.11)	0.00 (–0.07 to 0.00)	–0.40	0.13
Score 2	CCBT	42	1.06 (0.10)	1.00 (1.00 to 1.08)	1.00	1.44
	CCBT + MCBT	45	1.05 (0.09)	1.00 (1.00 to 1.07)	1.00	1.33
	CCBT + MCI	49	1.03 (0.06)	1.00 (1.00 to 1.07)	1.00	1.33
Total score baseline	CCBT	42	1.10 (0.12)	1.08 (1.00 to 1.13)	1.00	1.47
	CCBT + MCBT	45	1.06 (0.09)	1.00 (1.00 to 1.08)	1.00	1.53
	CCBT + MCI	49	1.06 (0.10)	1.00 (1.00 to 1.11)	1.00	1.40
Intrusiveness						
Difference baseline–assessment 2	CCBT	42	–0.06 (0.47)	–0.04 (–0.28 to 0.13)	–1.45	1.28
	CCBT + MCBT	45	0.01 (0.46)	0.05 (–0.14 to 0.28)	–1.08	1.00
	CCBT + MCI	49	–0.10 (0.46)	–0.05 (–0.27 to 0.13)	–1.43	0.87
Score 2	CCBT	42	1.52 (0.44)	1.48 (1.20 to 1.84)	1.00	2.88
	CCBT + MCBT	45	1.60 (0.39)	1.47 (1.31 to 1.84)	1.00	2.45
	CCBT + MCI	49	1.48 (0.38)	1.41 (1.13 to 1.78)	1.00	2.43

continued

TABLE 122 Summary of behavioural scores at baseline and assessment 2, and the change from baseline to assessment 2 (*continued*)

Questionnaire	Treatment	*n*	Mean (SD)	Median (IQR)	Minimum	Maximum
Total score baseline	CCBT	42	1.58 (0.52)	1.48 (1.16 to 1.88)	1.00	2.93
	CCBT + MCBT	45	1.60 (0.50)	1.40 (1.20 to 1.87)	1.00	2.86
	CCBT + MCI	49	1.58 (0.49)	1.51 (1.16 to 1.80)	1.00	2.99
Expressed anxiety						
Difference baseline–assessment 2	CCBT	42	0.03 (0.34)	0.04 (–0.23 to 0.22)	–0.64	0.96
	CCBT + MCBT	45	0.02 (0.38)	–0.01 (–0.17 to 0.24)	–1.16	0.94
	CCBT + MCI	49	–0.04 (0.40)	–0.04 (–0.26 to 0.19)	–1.03	1.43
Score 2	CCBT	42	1.61 (0.36)	1.59 (1.37 to 1.73)	1.07	2.74
	CCBT + MCBT	45	1.64 (0.41)	1.56 (1.33 to 1.92)	1.00	2.66
	CCBT + MCI	49	1.59 (0.36)	1.57 (1.41 to 1.79)	1.00	2.96
Total score baseline	CCBT	42	1.58 (0.27)	1.49 (1.37 to 1.75)	1.18	2.23
	CCBT + MCBT	45	1.62 (0.33)	1.54 (1.40 to 1.86)	1.11	2.62
	CCBT + MCI	49	1.63 (0.38)	1.53 (1.36 to 1.83)	1.00	2.60
Quality of relationship						
Difference baseline–assessment 2	CCBT	42	0.00 (0.36)	0.05 (–0.20 to 0.22)	–0.83	0.87
	CCBT + MCBT	45	0.06 (0.37)	0.04 (–0.13 to 0.30)	–0.72	0.83
	CCBT + MCI	49	0.01 (0.44)	–0.02 (–0.33 to 0.31)	–0.95	1.42
Score 2	CCBT	42	3.37 (0.33)	3.38 (3.17 to 3.63)	2.40	3.93
	CCBT + MCBT	45	3.36 (0.42)	3.38 (3.13 to 3.67)	2.36	4.32
	CCBT + MCI	49	3.34 (0.39)	3.33 (3.20 to 3.60)	2.36	4.13
Total score baseline	CCBT	42	3.37 (0.40)	3.44 (3.04 to 3.67)	2.53	4.07
	CCBT + MCBT	45	3.30 (0.42)	3.37 (2.93 to 3.56)	2.27	4.00
	CCBT + MCI	49	3.33 (0.51)	3.40 (3.08 to 3.56)	1.91	4.55
POI						
Difference baseline–assessment 2	CCBT	34	–5.94 (10.15)	–6.0 (–11.0 to 2.0)	–36	9
	CCBT + MCBT	38	–6.53 (11.26)	–6.0 (–15.0 to 0.0)	–32	35
	CCBT + MCI	34	–10.35 (10.22)	–8.5 (–15.0 to 4.0)	–41	7
Score 2	CCBT	34	21.74 (13.27)	20.0 (12.0 to 32.0)	2	56
	CCBT + MCBT	38	21.82 (13.87)	20.0 (10.0 to 28.0)	3	59
	CCBT + MCI	34	17.76 (9.18)	16.5 (10.0 to 25.0)	1	39
Total score baseline	CCBT	34	27.68 (13.45)	27.0 (17.0 to 40.0)	5	49
	CCBT + MCBT	38	28.34 (11.58)	29.5 (20.0 to 35.0)	8	54
	CCBT + MCI	34	28.12 (11.99)	27.5 (19.0 to 36.0)	4	54

IQR, interquartile range; POI, Parent Over-Involvement Questionnaire.

TABLE 123 Summary of mothers' self-report questionnaires at baseline and assessment 1B, and change from baseline to assessment 1B

Questionnaire	Treatment	*n*	Mean (SD)	Median (IQR)	Minimum	Maximum
PSWQ						
Difference baseline–assessment 1B	CCBT	40	–3.4 (10.2)	–2.5 (–7.0 to 2.5)	–37	18
	CCBT + MCBT	42	–5.3 (12.5)	–1.5 (–12.0 to 3.0)	–41	17
	CCBT + MCI	44	–3.0 (8.0)	–3.0 (–8.0 to 4.5)	–20	9
Self-report total score assessment 1B	CCBT	40	35.9 (13.8)	38.0 (25.0 to 47.0)	9	64
	CCBT + MCBT	42	35.6 (14.3)	36.0 (25.0 to 45.0)	12	64
	CCBT + MCI	44	33.9 (13.5)	35.0 (22.0 to 46.0)	3	59
Self-report total score baseline	CCBT	40	39.2 (13.7)	41.5 (28.5 to 49.5)	15	64
	CCBT + MCBT	42	40.9 (13.4)	42.0 (34.0 to 52.0)	6	62
	CCBT + MCI	44	36.8 (13.2)	36.5 (28.5 to 45.5)	8	62
SIAS						
Difference baseline–assessment 1B	CCBT	41	–0.9 (8.4)	–1.0 (–4.0 to 2.0)	–23	22
	CCBT + MCBT	44	–1.6 (8.7)	–1.5 (–6.0 to 4.5)	–28	15
	CCBT + MCI	47	–0.1 (8.3)	0.0 (–6.0 to 5.0)	–21	16
Self-report total score assessment 1B	CCBT	41	22.9 (14.2)	21.0 (12.0 to 30.0)	3	67
	CCBT + MCBT	44	25.0 (13.5)	25.0 (14.5 to 31.5)	4	63
	CCBT + MCI	47	23.5 (14.6)	18.0 (13.0 to 36.0)	0	62
Self-report total score baseline	CCBT	41	23.8 (12.8)	23.0 (14.0 to 31.0)	1	55
	CCBT + MCBT	44	26.5 (15.4)	24.0 (13.5 to 38.5)	6	66
	CCBT + MCI	47	23.7 (13.7)	22.0 (15.0 to 31.0)	0	61
SPS						
Difference baseline–assessment 1B	CCBT	41	–0.9 (9.5)	0.0 (–5.0 to 2.0)	–31	26
	CCBT + MCBT	45	–0.6 (7.2)	0.0 (–6.0 to 3.0)	–16	18
	CCBT + MCI	46	0.5 (7.3)	0.5 (–3.0 to 2.0)	–22	22
Self-report total score assessment 1B	CCBT	41	13.5 (12.4)	9.0 (4.0 to 20.0)	0	53
	CCBT + MCBT	45	16.6 (14.1)	14.0 (6.0 to 26.0)	0	65
	CCBT + MCI	46	13.7 (12.7)	10.0 (4.0 to 18.0)	0	47
Self-report total score baseline	CCBT	41	14.4 (11.5)	12.0 (5.0 to 21.0)	0	42
	CCBT + MCBT	45	17.2 (13.0)	15.0 (7.0 to 26.0)	0	47
	CCBT + MCI	46	13.2 (11.7)	9.0 (4.0 to 22.0)	0	45
DASS-21						
Depression score difference baseline–assessment 1B	CCBT	38	–1.7 (6.9)	–1.0 (–6.0 to 0.0)	–20	18
	CCBT + MCBT	43	–1.9 (5.2)	–2.0 (–6.0 to 0.0)	–10	10
	CCBT + MCI	45	–1.7 (5.6)	–2.0 (–6.0 to 2.0)	–16	10
Self-report depression score assessment 1B	CCBT	38	10.0 (9.6)	8.0 (4.0 to 14.0)	0	42
	CCBT + MCBT	43	9.8 (9.7)	8.0 (2.0 to 14.0)	0	36
	CCBT + MCI	45	10.2 (8.0)	8.0 (4.0 to 14.0)	0	32

continued

TABLE 123 Summary of mothers' self-report questionnaires at baseline and assessment 1B, and change from baseline to assessment 1B (*continued*)

Questionnaire	Treatment	*n*	Mean (SD)	Median (IQR)	Minimum	Maximum
Self-report depression score baseline	CCBT	38	11.7 (8.8)	10.0 (6.0 to 14.0)	0	40
	CCBT + MCBT	43	11.7 (9.2)	8.0 (6.0 to 18.0)	0	40
	CCBT + MCI	45	11.9 (10.3)	10.0 (4.0 to 16.0)	0	42
Anxiety score difference baseline–assessment 1B	CCBT	38	–0.3 (6.1)	0.0 (–2.0 to 2.0)	–16	16
	CCBT + MCBT	44	–2.3 (6.7)	–2.0 (–6.0 to 2.0)	–22	12
	CCBT + MCI	45	–1.7 (6.8)	–2.0 (–4.0 to 2.0)	–30	12
Self-report anxiety score assessment 1B	CCBT	38	7.3 (9.0)	6.0 (0.0 to 8.0)	0	40
	CCBT + MCBT	44	8.2 (8.2)	6.0 (2.0 to 12.0)	0	36
	CCBT + MCI	45	7.1 (8.1)	4.0 (2.0 to 8.0)	0	32
Self-report anxiety score baseline	CCBT	38	7.6 (7.3)	5.0 (0.0 to 14.0)	0	24
	CCBT + MCBT	44	10.5 (8.0)	9.0 (4.0 to 16.0)	0	34
	CCBT + MCI	45	8.8 (8.4)	6.0 (2.0 to 14.0)	0	34
Stress score difference baseline–assessment 1B	CCBT	41	–1.4 (6.7)	–2.0 (–6.0 to 2.0)	–16	14
	CCBT + MCBT	45	–1.9 (9.1)	–2.0 (–8.0 to 2.0)	–20	28
	CCBT + MCI	45	–0.7 (5.9)	–2.0 (–4.0 to 2.0)	–16	16
Self-report stress score assessment 1B	CCBT	41	16.0 (9.9)	16.0 (10.0 to 22.0)	0	42
	CCBT + MCBT	45	16.0 (9.3)	14.0 (8.0 to 22.0)	0	40
	CCBT + MCI	45	15.4 (8.2)	16.0 (8.0 to 22.0)	0	32
Self-report stress score baseline	CCBT	41	17.3 (10.1)	16.0 (10.0 to 22.0)	0	42
	CCBT + MCBT	45	17.9 (9.9)	18.0 (10.0 to 22.0)	2	42
	CCBT + MCI	45	16.1 (9.0)	14.0 (10.0 to 22.0)	0	40

IQR, interquartile range.

TABLE 124 Summary of mothers' self-report questionnaires at baseline and assessment 2, and change from baseline to assessment 2

Questionnaire	Treatment	*n*	Mean (SD)	Median (IQR)	Minimum	Maximum
PSWQ						
Difference baseline–assessment 2	CCBT	35	–6.9 (12.0)	–6.0 (–13.0 to –1.0)	–40	21
	CCBT + MCBT	41	–7.3 (12.5)	–5.0 (–14.0 to 1.0)	–37	13
	CCBT + MCI	35	–6.0 (9.3)	–8.0 (–11.0 to –2.0)	–23	16
Self-report total score 2	CCBT	35	31.5 (13.7)	29.0 (19.0 to 42.0)	10	59
	CCBT + MCBT	41	33.3 (15.2)	33.0 (23.0 to 43.0)	1	64
	CCBT + MCI	35	30.9 (12.9)	30.0 (22.0 to 43.0)	2	54
Self-report total score baseline	CCBT	35	38.4 (13.2)	41.0 (29.0 to 49.0)	15	60
	CCBT + MCBT	41	40.6 (12.9)	42.0 (34.0 to 50.0)	6	64
	CCBT + MCI	35	36.9 (13.7)	36.0 (28.0 to 47.0)	8	64
SIAS						
Difference baseline–assessment 2	CCBT	34	–2.9 (10.8)	–4.0 (–8.0 to –1.0)	–35	28
	CCBT + MCBT	40	–5.5 (13.5)	–2.0 (–11.5 to 3.0)	–41	17
	CCBT + MCI	36	–4.5 (8.0)	–5.5 (–10.0 to 0.0)	–29	16
Self-report total score 2	CCBT	34	20.5 (14.7)	17.0 (11.0 to 30.0)	0	66
	CCBT + MCBT	40	22.3 (14.5)	16.5 (12.5 to 29.0)	3	65
	CCBT + MCI	36	19.1 (12.8)	17.0 (10.5 to 29.0)	0	48
Self-report total score baseline	CCBT	34	23.4 (13.4)	31.0 (22.5 to 31.0)	1	55
	CCBT + MCBT	40	27.9 (15.8)	26.5 (14.0 to 39.0)	6	66
	CCBT + MCI	36	23.7 (14.4)	22.5 (14.0 to 29.0)	0	61
SPS						
Difference baseline–assessment 2	CCBT	35	–3.6 (8.0)	–3.0 (–8.0 to –1.0)	–21	18
	CCBT + MCBT	41	–4.7 (7.9)	–3.0 (–9.0 to 0.0)	–28	12
	CCBT + MCI	36	–1.8 (7.1)	–2.0 (–7.0 to 1.0)	–16	28
Self-report total score 2	CCBT	35	9.7 (9.7)	7.0 (2.0 to 13.0)	0	45
	CCBT + MCBT	41	11.8 (11.5)	8.0 (3.0 to 16.0)	0	52
	CCBT + MCI	36	11.0 (10.9)	6.0 (3.0 to 19.5)	0	43
Self-report total score baseline	CCBT	35	13.3 (10.9)	12.0 (5.0 to 18.0)	0	42
	CCBT + MCBT	41	16.5 (12.7)	14.0 (7.0 to 23.0)	0	47
	CCBT + MCI	36	12.8 (11.3)	9.5 (3.5 to 19.0)	0	45
DASS-21						
Depression score difference baseline–assessment 2	CCBT	32	–3.2 (8.8)	–4.0 (–1.00 to 1.0)	–24	18
	CCBT + MCBT	36	–4.0 (7.0)	–4.0 (–6.0 to 0.0)	–20	14
	CCBT + MCI	33	–2.1 (5.2)	–2.0 (–4.0 to 0.0)	–14	8
Self-report depression score assessment 2	CCBT	32	8.9 (10.6)	4.0 (2.0 to 14.0)	0	42
	CCBT + MCBT	36	8.2 (8.8)	6.0 (2.0 to 12.0)	0	40
	CCBT + MCI	33	7.8 (7.3)	6.0 (2.0 to 14.0)	0	26

continued

TABLE 124 Summary of mothers' self-report questionnaires at baseline and assessment 2, and change from baseline to assessment 2 (*continued*)

Questionnaire	Treatment	*n*	Mean (SD)	Median (IQR)	Minimum	Maximum
Self-report depression score baseline	CCBT	32	12.1 (10.2)	10.0 (4.0 to 17.0)	0	40
	CCBT + MCBT	36	12.1 (8.8)	9.0 (6.0 to 17.0)	2	40
	CCBT + MCI	33	9.9 (8.2)	10.0 (4.0 to 14.0)	0	28
Anxiety score difference baseline–assessment 2	CCBT	32	–0.6 (7.4)	–2.0 (–4.0 to 2.0)	–20	18
	CCBT + MCBT	36	–3.1 (6.8)	–4.0 (–7.0 to 0.0)	–14	26
	CCBT + MCI	33	–2.0 (5.0)	–2.0 (–4.0 to 0.0)	–14	12
Self-report anxiety score assessment 2	CCBT	32	7.3 (10.3)	3.0 (0.0 to 9.0)	0	42
	CCBT + MCBT	36	6.7 (8.0)	5.0 (0.0 to 11.0)	0	40
	CCBT + MCI	33	4.5 (5.3)	2.0 (0.0 to 8.0)	0	16
Self-report anxiety score baseline	CCBT	32	7.9 (8.0)	5.0 (2.0 to 14.0)	0	30
	CCBT + MCBT	36	9.8 (6.8)	9.0 (4.0 to 15.0)	0	24
	CCBT + MCI	33	6.5 (5.0)	6.0 (2.0 to 10.0)	0	18
Stress score difference baseline–assessment 2	CCBT	34	–3.8 (8.0)	–4.0 (–8.0 to 0.0)	–22	14
	CCBT + MCBT	41	–2.5 (6.5)	–4.0 (–6.0 to 0.0)	–14	12
	CCBT + MCI	35	–2.5 (6.7)	–2.0 (–6.0 to 0.0)	–16	12
Self-report stress score assessment 2	CCBT	34	12.9 (9.2)	11.0 (6.0 to 20.0)	0	32
	CCBT + MCBT	41	14.7 (9.4)	14.0 (10.0 to 18.0)	0	42
	CCBT + MCI	35	12.1 (8.8)	12.0 (4.0 to 20.0)	0	28
Self-report stress score baseline	CCBT	34	16.7 (9.7)	16.0 (10.0 to 22.0)	0	40
	CCBT + MCBT	41	17.2 (8.4)	18.0 (12.0 to 22.0)	2	36
	CCBT + MCI	35	14.6 (8.2)	12.0 (8.0 to 20.0)	0	32

IQR, interquartile range.

TABLE 125 Summary of cognition scores at baseline and assessment 2, and the change from baseline to assessment 2

Questionnaire	Treatment	*n*	Mean (SD)	Median (IQR)	Minimum	Maximum
Pre-task 'child scared'						
Difference baseline–assessment 2	CCBT	40	–0.70 (1.78)	–0.67 (–2.00 to 0.33)	–3.67	4.00
	CCBT + MCBT	45	–1.10 (1.62)	–1.00 (–1.67 to 0.00)	–6.33	1.67
	CCBT + MCI	46	–1.47 (1.55)	–1.33 (–2.33 to –0.33)	–5.33	1.00
Score post treatment	CCBT	40	3.62 (1.58)	3.33 (2.50 to 5.00)	1.00	7.67
	CCBT + MCBT	45	3.10 (1.57)	3.00 (1.67 to 4.33)	0.00	7.00
	CCBT + MCI	46	3.18 (1.69)	3.33 (2.00 to 4.33)	0.00	6.67
Total score baseline	CCBT	40	4.31 (1.86)	4.33 (3.00 to 5.50)	0.50	8.33
	CCBT + MCBT	45	4.21 (1.81)	4.00 (3.00 to 5.33)	0.33	8.33
	CCBT + MCI	46	4.65 (1.82)	4.67 (3.67 to 6.00)	0.00	8.33

TABLE 125 Summary of cognition scores at baseline and assessment 2, and the change from baseline to assessment 2 (*continued*)

Questionnaire	Treatment	*n*	Mean (SD)	Median (IQR)	Minimum	Maximum
Pre-task 'mother anxious'						
Difference baseline–assessment 2	CCBT	40	–0.85 (1.63)	–1.00 (–2.33 to 0.00)	–3.33	3.33
	CCBT + MCBT	45	–1.46 (1.95)	–1.33 (–2.67 to 0.00)	–7.00	2.33
	CCBT + MCI	46	–1.42 (1.73)	–1.33 (–2.67 to –0.33)	–5.67	2.33
Score post treatment	CCBT	40	3.03 (1.41)	3.00 (2.00 to 4.00)	0.00	6.67
	CCBT + MCBT	45	2.56 (1.89)	2.33 (1.33 to 3.33)	0.00	8.67
	CCBT + MCI	46	2.52 (1.81)	2.50 (1.00 to 3.67)	0.00	7.00
Total score baseline	CCBT	40	3.88 (1.74)	4.17 (3.00 to 5.17)	0.00	7.67
	CCBT + MCBT	45	4.02 (1.91)	4.33 (2.67 to 5.33)	0.00	8.00
	CCBT + MCI	46	3.95 (2.05)	3.83 (2.00 to 5.67)	0.33	8.00
Pre-task 'child in control'						
Difference baseline–assessment 2	CCBT	40	0.16 (1.04)	0.33 (–0.42 to 0.92)	–2.17	1.83
	CCBT + MCBT	45	0.83 (1.55)	0.83 (0.17 to 1.50)	–5.50	4.50
	CCBT + MCI	46	0.78 (1.41)	1.00 (–0.17 to 1.67)	–4.17	4.17
Score post treatment	CCBT	40	6.93 (1.47)	7.08 (6.33 to 8.00)	3.17	10.00
	CCBT + MCBT	45	7.32 (1.36)	7.50 (6.83 to 8.17)	3.00	9.50
	CCBT + MCI	46	7.49 (1.22)	7.42 (7.00 to 8.50)	4.33	9.83
Total score baseline	CCBT	40	6.77 (1.26)	6.83 (6.17 to 7.50)	4.00	9.33
	CCBT + MCBT	45	6.49 (1.58)	6.33 (5.50 to 7.67)	2.17	9.17
	CCBT + MCI	46	6.71 (1.13)	6.67 (5.83 to 7.50)	4.67	9.17
Pre-task 'mother in control'						
Difference baseline–assessment 2	CCBT	40	–0.18 (1.52)	–0.17 (–1.08 to 0.58)	–3.83	3.00
	CCBT + MCBT	45	–0.19 (1.73)	0.00 (–1.50 to 0.67)	–3.67	3.17
	CCBT + MCI	46	–0.06 (1.92)	0.17 (–1.33 to 1.17)	–4.00	3.67
Score post treatment	CCBT	40	4.61 (1.60)	4.83 (3.33 to 5.58)	1.00	7.50
	CCBT + MCBT	45	5.15 (2.48)	5.67 (2.83 to 7.17)	0.33	8.67
	CCBT + MCI	46	4.91 (1.69)	5.21 (3.67 to 6.17)	0.83	8.33
Total score baseline	CCBT	40	4.79 (1.65)	5.08 (3.75 to 6.00)	0.50	7.67
	CCBT + MCBT	45	5.33 (1.96)	5.17 (4.00 to 6.83)	1.17	10.00
	CCBT + MCI	46	4.98 (1.73)	5.25 (3.67 to 6.33)	1.25	7.83

IQR, interquartile range.

TABLE 126 Summary of child scores at baseline and assessment 2, and the change from baseline to assessment 2

Questionnaire	Treatment	*n*	Mean (SD)	Median (IQR)	Minimum	Maximum
SCAS-c						
Difference baseline–assessment 2	CCBT	45	–19.5 (17.2)	–17.0 (–29.0 to –8.0)	–68	13
	CCBT + MCBT	46	–15.0 (11.6)	–16.0 (–23.0 to –8.0)	–37	12
	CCBT + MCI	52	–14.7 (20.0)	–14.5 (–24.5 to –2.5)	–72	20
Total score post treatment	CCBT	45	21.0 (15.3)	15.0 (11.0 to 30.0)	0	86
	CCBT + MCBT	46	28.3 (15.2)	25.5 (16.0 to 41.0)	0	69
	CCBT + MCI	52	24.9 (15.2)	23.0 (13.5 to 34.5)	0	65
Total score baseline	CCBT	45	40.4 (21.7)	35.0 (24.0 to 53.0)	2	105
	CCBT + MCBT	46	43.3 (17.6)	40.0 (31.0 to 58.0)	8	80
	CCBT + MCI	52	39.6 (18.9)	40.0 (29.0 to 48.5)	4	92
CAIS-c						
Difference baseline–assessment 2	CCBT	44	–7.0 (17.3)	–8.0 (–17.0 to –1.0)	–35	52
	CCBT + MCBT	45	–8.4 (15.9)	–7.0 (–11.0 to –2.0)	–49	53
	CCBT + MCI	53	–5.6 (15.9)	–6.0 (–14.0 to 0.0)	–48	70
Total score post treatment	CCBT	44	10.8 (12.2)	8.0 (3.0 to 13.0)	0	58
	CCBT + MCBT	45	13.8 (13.2)	11.0 (4.0 to 21.0)	0	58
	CCBT + MCI	53	12.4 (14.4)	8.0 (3.0 to 16.0)	0	78
Total score baseline	CCBT	44	17.8 (12.5)	18.0 (8.5 to 24.5)	1	58
	CCBT + MCBT	45	22.2 (15.9)	17.0 (10.0 to 32.0)	1	60
	CCBT + MCI	53	18.1 (13.2)	15.0 (7.0 to 27.0)	0	63
SMFQ-c						
Difference baseline–assessment 2	CCBT	46	–4.9 (6.0)	–3.0 (–7.0 to –1.0)	–20	2
	CCBT + MCBT	47	–2.8 (4.7)	–3.0 (–5.0 to –1.0)	–12	12
	CCBT + MCI	54	–2.3 (5.7)	–2.0 (–5.0 to 1.0)	–15	15
Total score post treatment	CCBT	46	2.7 (4.0)	1.5 (0.0 to 4.0)	0	23
	CCBT + MCBT	47	6.0 (5.5)	4.0 (1.0 to 9.0)	0	24
	CCBT + MCI	54	5.0 (5.7)	3.0 (0.0 to 8.0)	0	25
Total score baseline	CCBT	46	7.6 (6.6)	5.0 (2.0 to 11.0)	0	24
	CCBT + MCBT	47	8.8 (4.9)	8.0 (5.0 to 12.0)	0	22
	CCBT + MCI	54	7.3 (5.6)	7.0 (3.0 to 11.0)	0	23

TABLE 126 Summary of child scores at baseline and assessment 2, and the change from baseline to assessment 2 (*continued*)

Questionnaire	Treatment	*n*	Mean (SD)	Median (IQR)	Minimum	Maximum
SDQ-c conduct problems scale						
Difference baseline–assessment 2	CCBT	47	–0.6 (1.6)	–1.0 (–2.0 to 0.0)	–4	1
	CCBT + MCBT	47	–0.6 (2.0)	0.0 (–2.0 to 1.0)	–5	3
	CCBT + MCI	55	–0.5 (1.8)	–1.0 (–1.0 to 0.0)	–4	5
Total score post treatment	CCBT	47	2.2 (1.6)	2.0 (1.0 to 3.0)	0	8
	CCBT + MCBT	47	2.4 (2.0)	2.0 (1.0 to 4.0)	0	8
	CCBT + MCI	55	2.3 (2.0)	2.0 (0.0 to 3.0)	0	7
Total score baseline	CCBT	47	2.8 (1.8)	3.0 (1.0 to 4.0)	0	7
	CCBT + MCBT	47	3.0 (1.9)	3.0 (2.0 to 4.0)	0	8
	CCBT + MCI	55	2.8 (1.6)	3.0 (2.0 to 4.0)	0	7

IQR, interquartile range.

TABLE 127 Summary of mothers' questionnaire scores at baseline and assessment 2, and the change from baseline to assessment 2

Questionnaire	Treatment	*n*	Mean (SD)	Median (IQR)	Minimum	Maximum
SCAS-p						
Difference baseline–assessment 2	CCBT	36	–18.3 (10.9)	–16.5 (–27.0 to –11.5)	–36	12
	CCBT + MCBT	39	–17.5 (12.2)	–21.0 (–25.0 to –7.0)	–38	10
	CCBT + MCI	38	–17.3 (11.5)	–16.0 (–24.0 to –9.0)	–46	5
Total score post treatment	CCBT	36	23.8 (14.5)	20.0 (14.0 to 29.0)	3	80
	CCBT + MCBT	39	26.0 (15.0)	24.0 (14.0 to 33.0)	2	62
	CCBT + MCI	38	23.8 (8.7)	23.5 (19.0 to 28.0)	6	41
Total score baseline	CCBT	36	42.0 (15.3)	41.5 (32.0 to 47.0)	16	94
	CCBT + MCBT	39	43.5 (17.2)	38.0 (32.0 to 57.0)	17	82
	CCBT + MCI	38	41.1 (13.3)	41.0 (30.0 to 50.0)	17	81
CAIS-p						
Difference baseline–assessment 2	CCBT	33	–10.5 (8.9)	–9.0 (–15.0 to –5.0)	–34	5
	CCBT + MCBT	35	–14.5 (10.5)	–16.0 (–19.0 to –6.0)	–45	2
	CCBT + MCI	31	–8.1 (8.5)	–8.0 (–14.0 to 0.0)	–26	8
Total score post treatment	CCBT	33	12.6 (12.0)	8.0 (3.0 to 18.0)	0	48
	CCBT + MCBT	35	11.2 (10.7)	9.0 (4.0 to 14.0)	0	38
	CCBT + MCI	31	11.4 (8.2)	11.0 (4.0 to 15.0)	1	33
Total score baseline	CCBT	33	23.1 (16.7)	18.0 (10.0 to 32.0)	1	66
	CCBT + MCBT	35	25.7 (16.2)	25.0 (12.0 to 35.0)	0	60
	CCBT + MCI	31	19.5 (11.9)	17.0 (10.0 to 28.0)	2	52

continued

TABLE 127 Summary of mothers' questionnaire scores at baseline and assessment 2, and the change from baseline to assessment 2 (*continued*)

Questionnaire	Treatment	*n*	Mean (SD)	Median (IQR)	Minimum	Maximum
SMFQ-p						
Difference baseline–assessment 2	CCBT	34	–4.1 (7.4)	–4.0 (–6.0 to 0.0)	–23	8
	CCBT + MCBT	38	–6.8 (5.6)	–6.0 (–10.0 to –3.0)	–23	5
	CCBT + MCI	35	–4.9 (6.6)	–3.0 (–9.0 to 0.0)	–23	5
Total score post treatment	CCBT	34	4.7 (5.1)	2.5 (1.0 to 8.0)	0	19
	CCBT + MCBT	38	4.6 (5.7)	2.5 (0.0 to 6.0)	0	22
	CCBT + MCI	35	3.9 (4.1)	2.0 (0.0 to 8.0)	0	14
Total score baseline	CCBT	34	8.8 (7.3)	6.0 (4.0 to 14.0)	0	24
	CCBT + MCBT	38	11.3 (7.7)	10.0 (5.0 to 16.0)	0	26
	CCBT + MCI	35	8.9 (7.3)	7.0 (2.0 to 14.0)	0	23
SDQ-p conduct problems scale						
Difference baseline–assessment 2	CCBT	37	–0.5 (1.6)	–1.0 (–1.0 to 0.0)	–6	3
	CCBT + MCBT	41	–0.9 (1.3)	–1.0 (–2.0 to 0.0)	–4	3
	CCBT + MCI	40	–0.9 (1.4)	–1.0 (–1.0 to 0.0)	–6	1
Total score post treatment	CCBT	37	1.7 (1.6)	1.0 (1.0 to 2.0)	0	8
	CCBT + MCBT	41	1.9 (1.7)	2.0 (0.0 to 3.0)	0	6
	CCBT + MCI	40	1.7 (1.8)	1.0 (0.0 to 2.5)	0	7
Total score baseline	CCBT	37	2.2 (1.7)	2.0 (1.0 to 3.0)	0	8
	CCBT + MCBT	41	2.8 (1.9)	3.0 (2.0 to 4.0)	0	9
	CCBT + MCI	40	2.6 (2.0)	2.0 (1.0 to 4.0)	0	8

IQR, interquartile range.

TABLE 128 Summary of teachers' questionnaire scores at baseline and assessment 2, and the change from baseline to assessment 2

Questionnaire	Treatment	*n*	Mean (SD)	Median (IQR)	Minimum	Maximum
SCAS-t						
Difference baseline–assessment 2	CCBT	7	–6.1 (9.4)	–8.0 (–16.0 to 0.0)	–18	8
	CCBT + MCBT	14	–3.3 (12.1)	–2.5 (–9.0 to 4.0)	–34	21
	CCBT + MCI	12	–6.0 (11.7)	–5.0 (–7.0 to –0.5)	–30	14
Total score post treatment	CCBT	7	13.4 (11.5)	10.0 (7.0 to 25.0)	0	33
	CCBT + MCBT	14	10.7 (9.4)	8.0 (7.0 to 10.0)	0	37
	CCBT + MCI	12	12.4 (11.9)	9.0 (5.5 to 16.0)	1	46
Total score baseline	CCBT	7	19.6 (19.5)	15.0 (2.0 to 43.0)	0	49
	CCBT + MCBT	14	14.0 (12.2)	9.5 (5.0 to 16.0)	3	42
	CCBT + MCI	12	18.4 (13.2)	11.5 (8.0 to 29.0)	4	40
CAS-t						
Difference baseline–assessment 2	CCBT	18	–1.6 (3.8)	–1.0 (–3.0 to 0.0)	–11	5
	CCBT + MCBT	24	–1.3 (4.6)	–2.0 (–3.0 to 1.0)	–16	8
	CCBT + MCI	25	–1.4 (4.2)	–2.0 (–4.0 to 2.0)	–9	7
Total score post treatment	CCBT	18	5.3 (4.3)	5.0 (2.0 to 8.0)	0	15
	CCBT + MCBT	24	3.4 (2.9)	3.0 (0.5 to 6.0)	0	9
	CCBT + MCI	25	3.8 (3.8)	3.0 (1.0 to 5.0)	0	16
Total score baseline	CCBT	18	6.9 (5.2)	5.5 (3.0 to 10.0)	0	16
	CCBT + MCBT	24	4.7 (4.2)	4.5 (1.0 to 6.0)	0	16
	CCBT + MCI	25	5.1 (4.3)	5.0 (2.0 to 8.0)	0	14
SDQ-t conduct problems scale						
Difference baseline–assessment 2	CCBT	18	0.4 (0.7)	0.0 (0.0 to 1.0)	0	2
	CCBT + MCBT	22	–0.3 (1.5)	0.0 (–1.0 to 1.0)	–4	3
	CCBT + MCI	23	–0.1 (1.2)	0.0 (0.0 to 0.0)	–3	3
Total score post treatment	CCBT	18	1.2 (1.8)	0.5 (0.0 to 2.0)	0	7
	CCBT + MCBT	22	1.1 (2.1)	0.0 (0.0 to 1.0)	0	8
	CCBT + MCI	23	0.8 (1.7)	0.0 (0.0 to 1.0)	0	7
Total score baseline	CCBT	18	0.7 (1.2)	0.0 (0.0 to 1.0)	0	5
	CCBT + MCBT	22	1.4 (2.3)	0.5 (0.0 to 2.0)	0	10
	CCBT + MCI	23	0.9 (1.7)	0.0 (0.0 to 1.0)	0	6

IQR, interquartile range.

Questionnaires: assessment 2 – data summaries by treatment arm (all available participants)

TABLE 129 Descriptive statistics: SCAS questionnaires post treatment

Questionnaire subscale	Treatment	*n*	*n* missing	Mean (SD)	Median (IQR)	Minimum	Maximum
SCAS-c total score post treatment	CCBT	49	22	21.0 (15.6)	15.0 (10.0–30.0)	0	86
	CCBT + MCBT	47	22	29.1 (16.0)	26.0 (16.0–42.0)	0	69
	CCBT + MCI	54	17	25.3 (15.5)	23.0 (14.0–35.0)	0	65
SCAS-p total score post treatment	CCBT	40	31	23.3 (13.8)	20.0 (14.5–28.5)	3	80
	CCBT + MCBT	41	28	25.5 (14.8)	22.0 (14.0–32.0)	2	62
	CCBT + MCI	40	31	23.9 (8.7)	23.5 (19.0–28.0)	6	41
SCAS-t total score post treatment	CCBT	18	53	11.9 (10.3)	8.5 (5.0–16.0)	0	36
	CCBT + MCBT	22	47	12.2 (9.1)	9.0 (7.0–17.0)	0	37
	CCBT + MCI	19	52	15.7 (12.8)	9.0 (7.0–20.0)	1	46

IQR, interquartile range.

TABLE 130 Descriptive statistics: CAIS questionnaires post treatment

Questionnaire subscale	Treatment	*n*	*n* missing	Mean (SD)	Median (IQR)	Minimum	Maximum
CAIS-c total score post treatment	CCBT	49	22	10.9 (12.5)	8.0 (2.0–13.0)	0	58
	CCBT + MCBT	45	24	13.8 (13.2)	11.0 (4.0–21.0)	0	58
	CCBT + MCI	56	15	12.5 (14.1)	9.5 (3.0–16.0)	0	78
CAIS-p total score post treatment	CCBT	39	32	12.3 (11.3)	8.0 (4.0–19.0)	0	48
	CCBT + MCBT	42	27	12.5 (10.9)	10.0 (5.0–16.0)	0	38
	CCBT + MCI	41	30	10.9 (8.2)	11.0 (4.0–15.0)	1	33

IQR, interquartile range.

TABLE 131 Descriptive statistics: SDQ and SMFQ questionnaires post treatment

Questionnaire subscale	Treatment	*n*	*n* missing	Mean (SD)	Median (IQR)	Minimum	Maximum
SDQ-c conduct problems scale post treatment	CCBT	50	21	2.2 (1.6)	2.0 (1.0–3.0)	0	8
	CCBT + MCBT	48	21	2.4 (2.0)	2.0 (1.0–4.0)	0	8
	CCBT + MCI	56	15	2.3 (2.0)	2.0 (0.5–3.0)	0	7
SDQ-p conduct problems scale post treatment	CCBT	40	31	1.7 (1.6)	1.5 (0.5–2.0)	0	8
	CCBT + MCBT	44	25	2.0 (1.7)	2.0 (0.5–3.0)	0	6
	CCBT + MCI	41	30	1.7 (1.8)	1.0 (0.0–2.0)	0	7
SDQ-t conduct problems scale post treatment	CCBT	23	48	1.1 (1.7)	0.0 (0.0–2.0)	0	7
	CCBT + MCBT	27	42	1.0 (2.0)	0.0 (0.0–1.0)	0	8
	CCBT + MCI	31	40	0.9 (1.6)	0.0 (0.0–2.0)	0	7
SMFQ-c total score post treatment	CCBT	50	21	3.1 (4.4)	1.5 (0.0–5.0)	0	23
	CCBT + MCBT	48	21	6.3 (5.8)	4.0 (1.5–9.5)	0	24
	CCBT + MCI	56	15	4.9 (5.6)	3.0 (0.0–8.0)	0	25
SMFQ-p total score post treatment	CCBT	40	31	4.2 (4.9)	2.0 (0.0–6.5)	0	19
	CCBT + MCBT	43	26	5.3 (5.9)	3.0 (1.0–8.0)	0	22
	CCBT + MCI	42	29	4.0 (4.5)	2.0 (0.0–7.0)	0	18

IQR, interquartile range.

Missing data for different variables

TABLE 132 Missing data by baseline demographics for different variables

		At least one missing at assessment 2											
		Primary outcome		Child questionnaires		Parent questionnaires		Teacher questionnaires		Behavioural		Cognitions	
Baseline characteristic	Category	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%
Gender	Male	18	17.8	35	34.7	72	71.3	75	74.3	40	39.6	40	39.6
	Female	16	14.5	29	26.4	72	65.5	81	73.6	35	31.8	38	34.5
Status	Single, never married	6	50.0	7	58.3	10	83.3	10	83.3	6	50.0	7	58.3
	Married (first time)	17	15.9	33	30.8	62	57.9	72	67.3	34	31.8	34	31.8
	Remarried	3	18.8	3	18.8	6	37.5	12	75.0	4	25.0	4	25.0
	Divorce/separated	5	11.4	9	20.5	41	93.2	34	77.3	16	36.4	18	40.9
	Living with partner	3	10.7	11	39.3	21	75.0	25	89.3	15	53.6	15	53.6
	Not recorded	0	0.0	1	25.0	4	100.0	3	75.0	0	0.0	0	0.0
Employment mother	Unemployed	15	24.2	20	32.3	43	69.4	48	77.4	26	41.9	29	46.8
	Part time	14	13.6	31	30.1	71	68.9	77	74.8	38	36.9	38	36.9
	Full time	5	14.3	9	25.7	22	62.9	22	62.9	8	22.9	8	22.9
	Not recorded	0	0.0	4	36.4	8	72.7	9	81.8	3	27.3	3	27.3
Employment father	Unemployed	3	25.0	4	33.3	8	66.7	8	66.7	3	25.0	3	25.0
	Part time	0	0.0	0	0.0	1	50.0	2	100.0	0	0.0	0	0.0
	Full time	25	16.3	49	32.0	94	61.4	112	73.2	55	35.9	55	35.9
	NA	3	42.9	4	57.1	7	100.0	5	71.4	4	57.1	4	57.1
	Not recorded	3	8.1	7	18.9	34	91.9	29	78.4	13	35.1	16	43.2

		At least one missing at assessment 2											
		Primary outcome		Child questionnaires		Parent questionnaires		Teacher questionnaires		Behavioural		Cognitions	
Baseline characteristic	Category	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%
Overall SES	Higher professional	13	12.3	28	26.4	63	59.4	75	70.8	34	32.1	34	32.1
	Other employed	14	19.7	24	33.8	53	74.6	54	76.1	26	36.6	26	36.6
	Unemployed	0	0.0	0	0.0	3	100.0	2	66.7	0	0.0	1	33.3
	Not recorded	7	22.6	12	38.7	25	80.6	25	80.6	15	48.4	17	54.8
ADIS-C/P primary diagnosis	SAD	1	2.4	6	14.6	21	51.2	24	58.5	10	24.4	10	24.4
	Social phobia	11	19.6	18	32.1	37	66.1	44	78.6	22	39.3	22	39.3
	GAD	7	14.6	17	35.4	32	66.7	35	72.9	15	31.3	17	35.4
	Other	15	22.7	23	34.8	54	81.8	53	80.3	28	42.4	29	43.9
ADIS-C/P primary diagnosis CSR (initial assessment)	Moderate 4	4	25.0	9	56.3	14	87.5	13	81.3	9	56.3	9	56.3
	Moderate 5	9	15.3	14	23.7	40	67.8	36	61.0	18	30.5	18	30.5
	Severe 6	16	14.2	35	31.0	74	65.5	88	77.9	37	32.7	39	34.5
	Severe 7	5	21.7	6	26.1	16	69.6	19	82.6	11	47.8	12	52.2
ADIS-C/P primary diagnosis CSR at assessment 1B	No diagnosis	0	0.0	2	66.7	2	66.7	2	66.7	2	66.7	2	66.7
	Mild 3	0	0.0	2	33.3	4	66.7	4	66.7	2	33.3	2	33.3
	Moderate 4	2	7.4	10	37.0	18	66.7	21	77.8	7	25.9	7	25.9
	Moderate 5	9	14.8	14	23.0	40	65.6	42	68.9	21	34.4	23	37.7
	Severe 6	8	8.5	21	22.3	63	67.0	69	73.4	29	30.9	30	31.9
	Severe 7	2	33.3	2	33.3	4	66.7	4	66.7	2	33.3	2	33.3
	Very severe 8	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0
	Not recorded	13	100.0	13	100.0	13	100.0	13	100.0	12	92.3	12	92.3

continued

TABLE 132 Missing data by baseline demographics for different variables (*continued*)

		At least one missing at assessment 2											
		Primary outcome		Child questionnaires		Parent questionnaires		Teacher questionnaires		Behavioural		Cognitions	
Baseline characteristic	Category	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%	*n*	%
Child age (years)	6	1	100.0	1	100.0	1	100.0	1	100.0	1	100.0	1	100.0
	7	5	31.3	7	43.8	11	68.8	13	81.3	8	50.0	9	56.3
	8	5	15.6	10	31.3	19	59.4	19	59.4	10	31.3	10	31.3
	9	5	15.2	11	33.3	17	51.5	24	72.7	10	30.3	10	30.3
	10	6	12.8	16	34.0	38	80.9	35	74.5	15	31.9	16	34.0
	11	4	8.5	7	14.9	29	61.7	35	74.5	14	29.8	14	29.8
	12	8	25.0	12	37.5	27	84.4	26	81.3	16	50.0	17	53.1
	13	0	0.0	0	0.0	2	66.7	3	100.0	1	33.3	1	33.3

NA, not applicable.

Questionnaire baseline results by treatment arm (all available participants)

TABLE 133 Descriptive statistics: SCAS questionnaires baseline

Questionnaire subscale	Treatment	*n*	*n* missing	Mean (SD)	Median (IQR)	Minimum	Maximum
SCAS-c total score post baseline	CCBT	67	4	40.2 (21.3)	35.0 (24.0–53.0)	2	105
	CCBT + MCBT	67	2	41.3 (18.3)	41.0 (29.0–56.0)	7	80
	CCBT + MCI	69	2	39.2 (17.4)	39.0 (29.0–47.0)	4	92
SCAS-p total score baseline	CCBT	64	7	43.2 (15.6)	43.0 (32.5–50.0)	16	94
	CCBT + MCBT	63	6	42.2 (15.5)	39.0 (32.0–50.0)	17	82
	CCBT + MCI	65	6	41.6 (16.7)	40.0 (29.0–52.0)	16	94
SCAS-t total score baseline	CCBT	25	46	17.6 (13.4)	15.0 (10.0–22.0)	0	49
	CCBT + MCBT	37	32	14.4 (14.6)	9.0 (5.0–16.0)	1	66
	CCBT + MCI	42	29	18.7 (13.0)	15.0 (10.0–26.0)	0	47

IQR, interquartile range.

TABLE 134 Descriptive statistics: CAIS questionnaires baseline

Questionnaire subscale	Treatment	*n*	*n* missing	Mean (SD)	Median (IQR)	Minimum	Maximum
CAIS-c total score baseline	CCBT	66	5	18.3 (12.8)	16.5 (9.0–24.0)	1	58
	CCBT + MCBT	67	2	23.1 (16.3)	20.0 (10.0–37.0)	0	70
	CCBT + MCI	68	3	18.9 (14.0)	15.0 (7.5–28.0)	0	63
CAIS-p total score baseline	CCBT	58	13	23.2 (16.0)	18.5 (11.0–32.0)	1	66
	CCBT + MCBT	56	13	25.5 (15.1)	25.0 (15.0–34.5)	0	60
	CCBT + MCI	58	13	20.6 (12.7)	17.0 (10.0–28.0)	1	58

IQR, interquartile range.

TABLE 135 Descriptive statistics: SDQ and SMFQ baseline

Questionnaire subscale	Treatment	*n*	*n* missing	Mean (SD)	Median (IQR)	Minimum	Maximum
SDQ-c conduct problems scale baseline	CCBT	68	3	3.0 (2.0)	3.0 (1.0–4.0)	0	8
	CCBT + MCBT	66	3	3.0 (1.9)	3.0 (2.0–4.0)	0	8
	CCBT + MCI	70	1	2.8 (1.7)	3.0 (2.0–4.0)	0	8
SDQ-p conduct problems scale baseline	CCBT	65	6	2.5 (2.0)	2.0 (1.0–3.0)	0	8
	CCBT + MCBT	65	4	3.0 (1.8)	3.0 (2.0–4.0)	0	9
	CCBT + MCI	70	1	2.6 (1.9)	2.0 (1.0–4.0)	0	8
SDQ-t conduct problems scale baseline	CCBT	44	27	0.9 (1.5)	0.0 (0.0–1.0)	0	6
	CCBT + MCBT	54	15	1.2 (1.9)	0.0 (0.0–2.0)	0	10
	CCBT + MCI	56	15	1.8 (1.5)	0.0 (0.0–1.0)	0	6
SMFQ-c total score baseline	CCBT	67	4	7.8 (6.8)	5.0 (2.0–13.0)	0	24
	CCBT + MCBT	68	1	9.0 (5.5)	8.5 (5.0–12.0)	0	24
	CCBT + MCI	69	2	7.4 (5.7)	6.0 (3.0–10.0)	0	23
SMFQ-p report total score baseline	CCBT	59	12	9.4 (6.6)	7.0 (4.0–14.0)	0	24
	CCBT + MCBT	58	11	10.7 (7.2)	10.0 (5.0–15.0)	0	26
	CCBT + MCI	62	9	8.8 (7.2)	7.0 (3.0–14.0)	0	25

IQR, interquartile range.

Summary of questionnaire scores at different time points by treatment arm

TABLE 136 Summary of child-reported questionnaire scores at baseline, 6 months, and change from baseline to 6 months

Questionnaire	Treatment	*n*	Mean (SD)	Median (IQR)	Minimum	Maximum
CAIS-c						
Total score difference baseline–6 months	CCBT	38	–10.87 (13.07)	–11.0 (–20.0 to 1.0)	–37	15
	CCBT + MCBT	43	–13.86 (15.74)	–11.0 (–21.0 to –5.0)	–62	13
	CCBT + MCI	41	–9.56 (13.48)	–9.0 (–17.0 to 0.0)	–47	13
Total score 6 months	CCBT	38	7.37 (7.01)	5.5 (2.0 to 11.0)	0	27
	CCBT + MCBT	43	10.02 (8.56)	8.0 (3.0 to 14.0)	0	29
	CCBT + MCI	41	9.63 (9.35)	7.0 (2.0 to 15.0)	0	39
Total score baseline	CCBT	38	18.24 (13.10)	18.0 (9.0 to 25.0)	1	58
	CCBT + MCBT	43	23.88 (16.41)	21.0 (11.0 to 37.0)	1	70
	CCBT + MCI	41	19.20 (13.44)	18.0 (8.0 to 27.0)	0	63
SCAS-c						
Total score difference baseline–6 months	CCBT	41	–17.80 (17.91)	–15.0 (–28.0 to –6.0)	–61	13
	CCBT + MCBT	43	–17.47 (16.35)	–18.0 (–26.0 to –6.0)	–51	29
	CCBT + MCI	41	–16.83 (21.80)	–13.0 (–28.0 to –5.0)	–70	22
Total score 6 months	CCBT	41	22.20 (16.22)	19.0 (10.0 to 30.0)	0	73
	CCBT + MCBT	43	24.42 (17.41)	19.0 (12.0 to 39.0)	0	63
	CCBT + MCI	41	23.73 (17.51)	22.0 (9.0 to 30.0)	1	67
Total score baseline	CCBT	41	40.00 (21.60)	35.0 (24.0 to 53.0)	2	105
	CCBT + MCBT	43	41.88 (16.63)	39.0 (31.0 to 54.0)	10	80
	CCBT + MCI	41	40.56 (18.60)	42.0 (30.0 to 48.0)	11	92
SDQ-c conduct subscale						
Total score difference baseline–6 months	CCBT	42	–0.86 (1.76)	–1.0 (–2.0 to 0.0)	–4	3
	CCBT + MCBT	44	–0.89 (2.08)	–1.0 (–2.0 to 1.0)	–6	3
	CCBT + MCI	42	–0.86 (1.47)	–1.0 (–2.0 to 0.0)	–4	2
Total score 6 months	CCBT	42	2.10 (1.64)	2.0 (1.0 to 3.0)	0	6
	CCBT + MCBT	44	2.05 (1.38)	2.0 (1.0 to 3.0)	0	6
	CCBT + MCI	42	2.17 (1.95)	2.0 (1.0 to 3.0)	0	6
Total score baseline	CCBT	42	2.95 (1.82)	3.0 (1.0 to 4.0)	0	8
	CCBT + MCBT	44	2.93 (1.90)	3.0 (1.5 to 4.5)	0	8
	CCBT + MCI	42	3.02 (1.79)	3.0 (2.0 to 4.0)	0	8

continued

TABLE 136 Summary of child-reported questionnaire scores at baseline, 6 months, and change from baseline to 6 months (*continued*)

Questionnaire	Treatment	*n*	Mean (SD)	Median (IQR)	Minimum	Maximum
SMFQ-c						
Total score difference baseline–6 months	CCBT	40	–3.45 (6.49)	–2.0 (–5.5 to 1.0)	–23	7
	CCBT + MCBT	44	–4.25 (6.03)	–3.0 (–6.0 to –0.5)	–24	7
	CCBT + MCI	39	–3.51 (6.12)	–4.0 (–7.0 to 0.0)	–20	15
Total score 6 months	CCBT	40	4.18 (5.01)	3.0 (0.0 to 6.0)	0	19
	CCBT + MCBT	44	5.20 (4.99)	4.5 (0.5 to 10.0)	0	16
	CCBT + MCI	39	4.03 (5.24)	1.0 (0.0 to 8.0)	0	22
Total score baseline	CCBT	40	7.63 (6.93)	5.0 (2.5 to 11.5)	0	24
	CCBT + MCBT	44	9.45 (5.94)	8.5 (5.0 to 13.0)	0	24
	CCBT + MCI	39	7.54 (5.88)	5.0 (3.0 to 11.0)	0	23

IQR, interquartile range.

TABLE 137 Summary of mother- and child-reported questionnaire scores at baseline, 6 months, and change from baseline to 6 months

Questionnaire	Treatment	*n*	Mean (SD)	Median (IQR)	Minimum	Maximum
CAIS-c/p						
Total score difference baseline–6 months	CCBT	35	–9.40 (10.26)	–7.0 (–17.0 to –1.0)	–33	8
	CCBT + MCBT	37	–13.78 (13.07)	–12.0 (–21.0 to –4.0)	–47	4
	CCBT + MCI	34	–8.47 (10.71)	–9.0 (–14.0 to 0.0)	–29	11
Total score 6 months	CCBT	35	13.51 (13.24)	9.0 (3.0 to 22.0)	0	54
	CCBT + MCBT	37	11.46 (10.00)	9.0 (5.0 to 16.0)	1	44
	CCBT + MCI	34	11.24 (9.24)	9.0 (5.0 to 17.0)	0	38
Total score baseline	CCBT	35	22.91 (15.48)	20.0 (11.0 to 30.0)	1	66
	CCBT + MCBT	37	25.24 (16.00)	25.0 (12.0 to 35.0)	0	60
	CCBT + MCI	34	19.71 (11.13)	17.0 (11.0 to 26.0)	2	52
SCAS-c/p						
Total score difference baseline–6 months	CCBT	36	–17.81 (11.43)	–19.0 (–25.5 to –11.5)	–44	3
	CCBT + MCBT	41	–17.32 (12.64)	–18.0 (–24.0 to –10.0)	–45	13
	CCBT + MCI	38	–18.29 (13.59)	–16.0 (–27.0 to –9.0)	–44	15
Total score 6 months	CCBT	36	23.11 (16.89)	20.0 (14.0 to 28.5)	1	93
	CCBT + MCBT	41	23.66 (13.68)	20.0 (14.0 to 31.0)	3	61
	CCBT + MCI	38	22.68 (11.01)	22.0 (15.0 to 28.0)	5	51
Total score baseline	CCBT	36	40.92 (14.95)	39.0 (31.0 to 46.0)	20	94
	CCBT + MCBT	41	40.98 (15.15)	38.0 (32.0 to 49.0)	17	82
	CCBT + MCI	38	40.97 (14.64)	41.0 (29.0 to 52.0)	16	81

TABLE 137 Summary of mother- and child-reported questionnaire scores at baseline, 6 months, and change from baseline to 6 months (*continued*)

Questionnaire	Treatment	*n*	Mean (SD)	Median (IQR)	Minimum	Maximum
SDQ-c/p conduct subscale						
Total score difference baseline–6 months	CCBT	39	–0.36 (1.50)	0.0 (–1.0 to 0.0)	–5	3
	CCBT + MCBT	42	–1.12 (1.21)	–1.0 (–2.0 to 0.0)	–4	2
	CCBT + MCI	41	–1.12 (1.50)	–1.0 (–2.0 to 0.0)	–4	1
Total score 6 months	CCBT	39	2.05 (1.92)	2.0 (1.0 to 3.0)	0	8
	CCBT + MCBT	42	1.79 (1.63)	1.0 (1.0 to 3.0)	0	6
	CCBT + MCI	41	1.44 (1.42)	1.0 (0.0 to 2.0)	0	6
Total score baseline	CCBT	39	2.41 (1.98)	2.0 (1.0 to 3.0)	0	8
	CCBT + MCBT	42	2.90 (1.69)	3.0 (2.0 to 4.0)	0	9
	CCBT + MCI	41	2.56 (1.90)	2.0 (1.0 to 4.0)	0	8
SMFQ-c/p						
Total score difference baseline–6 months	CCBT	36	–3.56 (6.53)	–2.5 (–5.5 to 1.0)	–21	10
	CCBT + MCBT	38	–6.76 (6.66)	–6.0 (–9.0 to –2.0)	–25	3
	CCBT + MCI	36	–4.64 (6.33)	–3.0 (–9.0 to –0.5)	–19	8
Total score 6 months	CCBT	36	5.31 (5.95)	3.0 (0.5 to 9.0)	0	25
	CCBT + MCBT	38	4.61 (5.53)	2.0 (0.0 to 6.0)	0	20
	CCBT + MCI	36	4.56 (4.87)	4.0 (1.0 to 7.5)	0	23
Total score baseline	CCBT	36	8.86 (6.86)	6.0 (4.0 to 13.0)	0	24
	CCBT + MCBT	38	11.37 (7.72)	10.0 (6.0 to 17.0)	0	26
	CCBT + MCI	36	9.19 (6.86)	8.5 (2.5 to 14.0)	0	23

IQR, interquartile range.

TABLE 138 Summary of teacher-reported questionnaire scores at baseline, 6 months, and change from baseline to 6 months

Questionnaire	Treatment	*n*	Mean (SD)	Median (IQR)	Minimum	Maximum
CAS-t						
Total score difference baseline–6 months	CCBT	11	–2.55 (5.82)	–1.0 (–9.0 to 1.0)	–13	5
	CCBT + MCBT	17	–2.35 (5.15)	–2.0 (–5.0 to 2.0)	–16	5
	CCBT + MCI	23	–1.30 (3.94)	0.0 (–5.0 to 1.0)	–9	5
Total score 6 months	CCBT	11	4.82 (5.08)	2.0 (0.0 to 8.0)	0	14
	CCBT + MCBT	17	3.35 (3.32)	2.0 (1.0 to 5.0)	0	10
	CCBT + MCI	23	4.74 (4.54)	4.0 (1.0 to 8.0)	0	16
Total score baseline	CCBT	11	7.36 (5.26)	6.0 (3.0 to 13.0)	0	16
	CCBT + MCBT	17	5.71 (5.58)	6.0 (0.0 to 10.0)	0	16
	CCBT + MCI	23	6.04 (4.72)	7.0 (1.0 to 9.0)	0	16
SCAS-t						
Total score difference baseline–6 months	CCBT	4	–1.25 (4.99)	–0.5 (–4.5 to 2.0)	–8	4
	CCBT + MCBT	9	–12.22 (12.28)	–9.0 (–13.0 to –8.0)	–37	4
	CCBT + MCI	15	–11.73 (11.63)	–9.0 (–24.0 to –3.0)	–36	1
Total score 6 months	CCBT	4	15.75 (19.05)	10.0 (3.0 to 28.5)	0	43
	CCBT + MCBT	9	5.56 (4.07)	4.0 (3.0 to 7.0)	2	15
	CCBT + MCI	15	10.73 (9.04)	7.0 (4.0 to 16.0)	0	31
Total score baseline	CCBT	4	17.00 (16.19)	14.5 (7.0 to 27.0)	0	39
	CCBT + MCBT	9	17.78 (13.23)	16.0 (12.0 to 17.0)	3	40
	CCBT + MCI	15	22.47 (13.08)	20.0 (10.0 to 36.0)	6	44
SDQ-t conduct subscale						
Total score difference baseline–6 months	CCBT	12	0.58 (2.11)	0.0 (0.0 to 0.5)	–1	7
	CCBT + MCBT	18	–0.06 (1.70)	0.0 (0.0 to 0.0)	–2	6
	CCBT + MCI	22	0.41 (1.37)	0.0 (0.0 to 0.0)	–1	5
Total score 6 months	CCBT	12	1.25 (2.18)	0.0 (0.0 to 1.5)	0	7
	CCBT + MCBT	18	0.61 (1.54)	0.0 (0.0 to 0.0)	0	6
	CCBT + MCI	22	0.86 (1.70)	0.0 (0.0 to 1.0)	0	5
Total score baseline	CCBT	12	0.67 (1.44)	0.0 (0.0 to 1.0)	0	5
	CCBT + MCBT	18	0.67 (1.08)	0.0 (0.0 to 1.0)	0	3
	CCBT + MCI	22	0.45 (1.14)	0.0 (0.0 to 0.0)	0	5

IQR, interquartile range.

TABLE 139 Summary of child-reported questionnaire scores at baseline, 12 months, and change from baseline to 12 months

Questionnaire	Treatment	*n*	Mean (SD)	Median (IQR)	Minimum	Maximum
CAIS-c						
Total score difference baseline–12 months	CCBT	29	–8.41 (12.18)	–6.0 (–15.0 to 0.0)	–34	16
	CCBT + MCBT	33	–15.24 (23.01)	–14.0 (–29.0 to –6.0)	–51	77
	CCBT + MCI	37	–9.86 (10.88)	–8.0 (–19.0 to –1.0)	–36	13
Total score 12 months	CCBT	29	6.38 (6.30)	4.0 (1.0 to 10.0)	0	25
	CCBT + MCBT	33	11.82 (15.16)	7.0 (2.0 to 18.0)	0	78
	CCBT + MCI	37	8.00 (11.33)	4.0 (1.0 to 10.0)	0	49
Total score baseline	CCBT	29	14.79 (11.48)	14.0 (3.0 to 22.0)	1	40
	CCBT + MCBT	33	27.06 (17.26)	22.0 (14.0 to 41.0)	1	60
	CCBT + MCI	37	17.86 (14.00)	15.0 (6.0 to 26.0)	0	63
SCAS-c						
Total score difference baseline–12 months	CCBT	31	–14.68 (17.11)	–12.0 (–25.0 to 0.0)	–52	21
	CCBT + MCBT	34	–21.44 (15.86)	–22.5 (–27.0 to –13.0)	–59	12
	CCBT + MCI	37	–17.78 (19.53)	–20.0 (–28.0 to –4.0)	–58	22
Total score 12 months	CCBT	31	18.94 (13.34)	18.0 (9.0 to 29.0)	1	54
	CCBT + MCBT	34	23.09 (14.92)	21.0 (10.0 to 34.0)	0	52
	CCBT + MCI	37	20.78 (19.04)	13.0 (9.0 to 33.0)	0	68
Total score baseline	CCBT	31	33.61 (18.20)	30.0 (22.0 to 45.0)	2	88
	CCBT + MCBT	34	44.53 (17.52)	42.5 (31.0 to 59.0)	10	80
	CCBT + MCI	37	38.57 (19.17)	41.0 (29.0 to 47.0)	4	92
SDQ-c conduct subscale						
Total score difference baseline–12 months	CCBT	31	–1.06 (1.73)	–1.0 (–2.0 to 0.0)	–5	3
	CCBT + MCBT	34	–0.97 (2.12)	–1.0 (–2.0 to 0.0)	–7	3
	CCBT + MCI	38	–1.08 (2.50)	–1.0 (–2.0 to 0.0)	–8	8
Total score 12 months	CCBT	31	1.65 (1.52)	2.0 (0.0 to 3.0)	0	5
	CCBT + MCBT	34	2.03 (1.68)	2.0 (1.0 to 2.0)	0	8
	CCBT + MCI	38	1.97 (2.33)	1.0 (0.0 to 3.0)	0	8
Total score baseline	CCBT	31	2.71 (1.81)	3.0 (1.0 to 4.0)	0	7
	CCBT + MCBT	34	3.00 (2.09)	3.0 (1.0 to 4.0)	0	8
	CCBT + MCI	38	3.05 (1.84)	3.0 (2.0 to 4.0)	0	8
SMFQ-c						
Total score difference baseline–12 months	CCBT	28	–2.89 (6.11)	–2.0 (–5.0 to 1.0)	–24	5
	CCBT + MCBT	35	–5.51 (5.73)	–6.0 (–11.0 to –2.0)	–13	9
	CCBT + MCI	37	–1.95 (5.68)	–2.0 (–5.0 to 1.0)	–20	12
Total score 12 months	CCBT	28	2.86 (3.67)	1.0 (0.0 to 5.0)	0	12
	CCBT + MCBT	35	4.31 (5.42)	3.0 (0.0 to 6.0)	0	25
	CCBT + MCI	37	4.73 (6.78)	1.0 (0.0 to 6.0)	0	26

continued

TABLE 139 Summary of child-reported questionnaire scores at baseline, 12 months, and change from baseline to 12 months (*continued*)

Questionnaire	Treatment	*n*	Mean (SD)	Median (IQR)	Minimum	Maximum
Total score baseline	CCBT	28	5.75 (5.69)	4.5 (1.5 to 8.0)	0	24
	CCBT + MCBT	35	9.83 (5.39)	11.0 (5.0 to 14.0)	0	22
	CCBT + MCI	37	6.68 (5.47)	5.0 (3.0 to 9.0)	0	23

IQR, interquartile range.

TABLE 140 Summary of mother- and child-reported questionnaire scores at baseline, 12 months, and change from baseline to 12 months

Questionnaire	Treatment	*n*	Mean (SD)	Median (IQR)	Minimum	Maximum
CAIS-c/p						
Total score difference baseline–12 months	CCBT	28	–9.32 (10.99)	–7.5 (–15.5 to –1.0)	–37	6
	CCBT + MCBT	27	–15.07 (11.07)	–16.0 (–22.0 to –5.0)	–37	2
	CCBT + MCI	31	–9.90 (10.31)	–8.0 (–16.0 to –1.0)	–39	5
Total score 12 months	CCBT	28	11.57 (12.64)	8.0 (3.5 to 15.5)	0	58
	CCBT + MCBT	27	12.74 (11.72)	8.0 (4.0 to 17.0)	0	42
	CCBT + MCI	31	8.03 (6.79)	7.0 (1.0 to 13.0)	0	24
Total score baseline	CCBT	28	20.89 (15.12)	17.0 (10.5 to 26.5)	1	66
	CCBT + MCBT	27	27.81 (16.82)	25.0 (16.0 to 44.0)	0	60
	CCBT + MCI	31	17.94 (11.52)	15.0 (10.0 to 24.0)	1	52
SCAS-c/p						
Total score difference baseline–12 months	CCBT	30	–21.97 (13.18)	–23.5 (–31.0 to –11.0)	–48	3
	CCBT + MCBT	31	–16.26 (14.23)	–15.0 (–26.0 to –6.0)	–43	12
	CCBT + MCI	33	–20.85 (15.57)	–19.0 (–29.0 to –12.0)	–59	6
Total score 12 months	CCBT	30	18.67 (13.68)	14.0 (9.0 to 29.0)	1	51
	CCBT + MCBT	31	24.90 (15.55)	25.0 (12.0 to 33.0)	1	66
	CCBT + MCI	33	19.12 (12.99)	17.0 (13.0 to 24.0)	2	58
Total score baseline	CCBT	30	40.63 (14.09)	39.5 (32.0 to 46.0)	16	74
	CCBT + MCBT	31	41.16 (17.02)	37.0 (29.0 to 55.0)	17	75
	CCBT + MCI	33	39.97 (14.44)	42.0 (29.0 to 50.0)	16	81
SDQ-c/p conduct subscale						
Total score difference baseline–12 months	CCBT	32	–0.75 (1.74)	0.0 (–2.0 to 0.0)	–6	2
	CCBT + MCBT	32	–1.13 (1.50)	–1.0 (–2.0 to 0.0)	–4	1
	CCBT + MCI	38	–0.95 (1.66)	–1.0 (–2.0 to 0.0)	–4	3
Total score 12 months	CCBT	32	1.25 (1.65)	1.0 (0.0 to 2.0)	0	8
	CCBT + MCBT	32	1.91 (1.47)	2.0 (0.5 to 3.0)	0	5
	CCBT + MCI	38	1.82 (2.04)	1.0 (0.0 to 3.0)	0	8

TABLE 140 Summary of mother- and child-reported questionnaire scores at baseline, 12 months, and change from baseline to 12 months (*continued*)

Questionnaire	Treatment	*n*	Mean (SD)	Median (IQR)	Minimum	Maximum
Total score baseline	CCBT	32	2.00 (1.95)	2.0 (1.0 to 3.0)	0	8
	CCBT + MCBT	32	3.03 (1.82)	3.0 (2.0 to 4.0)	0	7
	CCBT + MCI	38	2.76 (2.03)	2.0 (1.0 to 4.0)	0	8
SMFQ-c/p						
Total score difference baseline–12 months	CCBT	30	–4.00 (6.37)	–3.0 (–5.0 to –1.0)	–24	8
	CCBT + MCBT	29	–6.31 (6.20)	–5.0 (–9.0 to –1.0)	–24	4
	CCBT + MCI	33	–5.64 (6.95)	–3.0 (–10.0 to –1.0)	–22	4
Total score 12 months	CCBT	30	4.10 (5.36)	2.0 (0.0 to 6.0)	0	20
	CCBT + MCBT	29	6.21 (6.04)	5.0 (1.0 to 9.0)	0	22
	CCBT + MCI	33	3.45 (4.83)	1.0 (0.0 to 5.0)	0	18
Total score baseline	CCBT	30	8.10 (6.72)	5.5 (4.0 to 9.0)	1	24
	CCBT + MCBT	29	12.52 (8.17)	12.0 (7.0 to 19.0)	0	26
	CCBT + MCI	33	9.09 (7.15)	8.0 (2.0 to 14.0)	0	23

IQR, interquartile range.

TABLE 141 Summary of teacher-reported questionnaire scores at baseline, 12 months, and change from baseline to 12 months

Questionnaire	Treatment	*n*	Mean (SD)	Median (IQR)	Minimum	Maximum
CAS-t						
Total score difference baseline–12 months	CCBT	9	–2.22 (4.99)	–1.0 (–3.0 to 2.0)	–11	3
	CCBT + MCBT	10	0.40 (4.14)	–0.5 (–3.0 to 2.0)	–4	8
	CCBT + MCI	12	–1.75 (4.05)	–2.0 (–5.0 to 1.5)	–7	5
Total score 12 months	CCBT	9	5.00 (4.92)	2.0 (2.0 to 8.0)	0	14
	CCBT + MCBT	10	4.60 (3.41)	4.5 (2.0 to 7.0)	0	10
	CCBT + MCI	12	5.25 (2.93)	6.0 (3.5 to 7.5)	0	9
Total score baseline	CCBT	9	7.22 (3.63)	6.0 (5.0 to 10.0)	3	13
	CCBT + MCBT	10	4.20 (2.90)	3.5 (3.0 to 6.0)	0	10
	CCBT + MCI	12	7.00 (4.29)	6.5 (4.5 to 10.0)	1	16
SCAS-t						
Total score difference baseline–12 months	CCBT	4	–8.25 (3.77)	–8.0 (–11.0 to –5.5)	–13	–4
	CCBT + MCBT	4	4.25 (23.13)	2.0 (–12.5 to 21.0)	–21	34
	CCBT + MCI	5	–13.20 (16.30)	–15.0 (–20.0 to 2.0)	–36	3
Total score 12 months	CCBT	4	13.00 (12.70)	7.0 (6.0 to 20.0)	6	32
	CCBT + MCBT	4	22.00 (11.92)	18.5 (14.0 to 30.0)	12	39
	CCBT + MCI	5	8.80 (3.90)	10.0 (7.0 to 11.0)	3	13
Total score baseline	CCBT	4	21.25 (12.66)	18.0 (12.5 to 30.0)	10	39
	CCBT + MCBT	4	17.75 (16.82)	12.0 (6.5 to 29.0)	5	42
	CCBT + MCI	5	22.00 (14.25)	25.0 (10.0 to 31.0)	5	39
SDQ-t conduct subscale						
Total score difference baseline–12 months	CCBT	9	–0.11 (1.17)	0.0 (–1.0 to 0.0)	–2	2
	CCBT + MCBT	11	–0.27 (1.49)	0.0 (–1.0 to 0.0)	–4	2
	CCBT + MCI	12	0.58 (1.62)	0.0 (–0.5 to 1.5)	–1	4
Total score 12 months	CCBT	9	1.22 (1.92)	0.0 (0.0 to 1.0)	0	5
	CCBT + MCBT	11	0.36 (0.67)	0.0 (0.0 to 1.0)	0	2
	CCBT + MCI	12	1.33 (1.78)	0.5 (0.0 to 2.5)	0	5
Total score baseline	CCBT	9	1.33 (1.58)	1.0 (0.0 to 2.0)	0	5
	CCBT + MCBT	11	0.64 (1.29)	0.0 (0.0 to 1.0)	0	4
	CCBT + MCI	12	0.75 (1.48)	0.0 (0.0 to 1.0)	0	5

IQR, interquartile range.

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