Predictors of change in treatment outcome for parent-delivered guided CBT bibliotherapy for children with anxiety: Effects of age, severity and comorbidity at long term follow-up.

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Thesis declaration form

I confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis.

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Overview

This thesis is concerned with an exploration of low-intensity treatments for common mental health problems in childhood and adolescence. Part one is a narrative literature review of trials of low-intensity interventions for children and adolescents with depression or anxiety, including bibliotherapy, computerised CBT and attention-bias modification. Part two is a long term follow-up study examining the effects of age, symptom severity and comorbidity at initial assessment on outcomes for children who had received guided CBT bibliotherapy via their parents four years previously. Part three is a critical appraisal of the thesis, considering the wider methodological and conceptual challenges associated with research across the developmental period.

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PART ONE: LITERATURE REVIEW

The Effectiveness of Low-Intensity Therapies for Children and Young People with Depression and Anxiety

Abstract

Aims: To review the effectiveness of low-intensity therapies using minimal therapist contact as treatments for depression and anxiety in children and young people.

Method: PsycINFO and MEDLINE were searched for relevant studies. Studies were included if they included clinically referred young people (aged under 19 years) seeking help for depression or anxiety, treated using brief therapies which were fully or partly delivered by means other than a therapist, e.g. using a computer or bibliotherapy.

Results: 14 studies were reviewed. Findings suggested that therapist-assisted bibliotherapy or computerised cognitive behaviour therapy may be effective treatments for children and young people with anxiety. Attention bias modification warrants further research as a treatment for anxiety. Computerised cognitive behaviour therapy may be effective for adolescents with depression.

Conclusions: More research is required in this area, especially testing treatments for depression. Closer examination of factors affecting attrition, adherence and outcome is also necessary. Future studies should include participants from a wider range of socio-economic and ethnic backgrounds.

Introduction

Depression and anxiety are the most common mental health difficulties in childhood and adolescence (Cartwright-Hatton, McNicol & Doubleday, 2006; Ford, Goodman & Meltzer, 2003) and are associated with impaired child outcomes across emotional, social and educational domains (Pine, 1997; Fombonne et al., 2001). Comorbidity is extremely common (Ford, Goodman & Meltzer, 2003), with the majority of children with anxiety or depression meeting diagnostic criteria for more than one disorder.

Although psychotherapy, particularly cognitive behaviour therapy (CBT), has been shown to be effective in young people with depression and anxiety (Compton et al., 2004), many do not receive help (Essau, Conradt & Petermann, 2002), and there remains a lack of trained therapists working with children to deliver therapy to all who could benefit from it (Vos et al., 2005; Stallard et al., 2007).

The shortage of therapists in mental health services has led to the development of stepped-care approaches to delivering psychological therapies, which aim to maximise the number of patients who can be treated by reducing the amount of therapist contact to the minimum level necessary for treatment to be effective (Salloum, 2010). Patients with milder symptoms may be offered a 'low-intensity' brief treatment, whereas those who require more intensive treatment may be 'stepped-up' to receive treatments with greater therapist contact, either at the assessment stage or following the completion of a lower-intensity intervention. This approach underpins the Improving Access to Psychological Therapies initiative (Clark et al., 2009) which has led to the development of services across the UK to

deliver evidence-based psychological therapies to large numbers of adults at a primary care level. These services offer a tiered model of treatment, often beginning with standardised self-help interventions delivered by a graduate mental health worker either over the telephone or in person. As yet, low-intensity therapies have not been made widely available for children and young people, but in light of findings that the majority of people with mental health problems in adulthood had clinically significant mental health problems before the age of 18 (e.g. Kim-Cohen et al., 2003), there is increased emphasis on tackling problems earlier in the lifespan. As a result, greater attention is now being turned to developing low-intensity treatments for children and young people, in particular those which minimise the need for therapist contact by making use of alternative materials such as books, websites and computers.

Bibliotherapy self-help programmes and computerised therapy have both been tested as low-intensity treatments for adults with depression and anxiety and shown to deliver benefits (Bower, Richards & Lovell, 2001) and two computerised CBT packages are now recommended by the National Institute for Health and Care Excellence for use in the NHS (NICE, 2006). In light of this, similar programmes are now being developed for use with children and adolescents, to be delivered either directly to the young person themselves or via their parents (e.g. Cobham, 2012; March, Spence & Donovan, 2009). Some of these also include the support of a therapist alongside written or computerised materials, often using a mixture of face-to-face contact and telephone or email support. Initial feasibility studies suggest that these types of treatments are acceptable to families and can be

implemented in routine clinical care (Creswell et al., 2010). A number of randomised controlled trials have now been conducted to test these therapies systematically.

Previous Reviews

Three reviews to date have examined interventions for children and adolescents with depression and anxiety where low-intensity treatment is delivered using materials such as books or computers. Richardson, Stallard and Velleman (2010) reviewed the efficacy of computerised CBT (cCBT) for the prevention or treatment of depression and anxiety among children and adolescents aged up to 18 years. They included 10 studies using a range of methodologies, including case series designs, and found that all studies reported a reduction in clinical symptoms following cCBT. However, only two of the included studies were randomised controlled trials of treatments delivered to a clinical population, and both of these examined treatments for anxiety disorders. The authors indicated that preliminary investigations of cCBT had shown promising results but that more trials would be needed to establish the efficacy of the programmes being tested.

Rickwood and Bradford (2012) conducted a review of self-help interventions for mild anxiety in children and adolescents. This review included only six studies as the authors only included interventions which were delivered primarily without any professional support or the support of parents. The authors also chose to include studies using participants up to the age of 25 years, and so five of their included studies focused on young adult participants. The sixth was a case series examining

the use of 'Cool Teens' cCBT with adolescents, showing symptom reduction and good satisfaction at the end of treatment.

Salloum (2010) conducted a narrative review of interventions for anxiety which required minimal therapist contact. This included studies of pharmacotherapy and group treatments, as well as cCBT, brief CBT, telephone therapy and bibliotherapy. The review summarised the existing adult literature and recent efforts to develop interventions for children and young people but noted that only a few rigorous trials had been conducted: three trials of bibliotherapy and two of cCBT. These studies suggested that both bibliotherapy with therapist support and cCBT could be offered as possible treatments, although it remained unclear whether these treatments would be suitable for or acceptable to all those seeking help.

Aims of the Current Review

The current review aims to examine whether low-intensity treatments for depression and anxiety are effective for children and young people in a clinical context. Low-intensity treatments will be defined as those in which a limited amount of therapist contact is provided and elements of the intervention are delivered by alternative methods such as books or computers to reduce overall therapist contact time. This review will therefore consider a broader range of interventions than the Richardson et al., (2010) and Rickwood and Bradford (2012) reviews and will update the Salloum (2010) review to include recent trials in this area. Interventions will be evaluated in terms of symptom reduction and

improvements in diagnostic status, alongside secondary outcomes such as effects on behaviour and functioning and the acceptability of these interventions to families.

Method

Inclusion and exclusion criteria

Studies were included if they met the following criteria:

Target population and intervention

1. Studies of interventions targeted at children and adolescents (aged under 19 years) with depression and/or anxiety.

2. Preventative interventions such as those targeting school populations were excluded.

3. Studies of interventions developed specifically for people with learning disabilities or autism spectrum disorders were excluded.

4. Participants were drawn from clinical populations and accessed the intervention following self-referral or referral by a professional.

Content of Intervention

1. At least one of the groups in the study evaluated an intervention which was not fully delivered by a therapist, i.e. alternative methods such as books, CD-ROM, websites or electronic devices were used to deliver at least part of the intervention.

2. This therapist-assisted intervention was brief, i.e. it included no more than eight hours of contact with a therapist.

Outcome measures

Only studies measuring change on standardised measures of anxiety or depression symptoms or diagnoses were included.

Study design

1. Randomised controlled trials assessing the effect of an intervention on outcome.

2. Qualitative studies, case studies, reviews and pilot studies without control groups were excluded.

Publication details

1. Papers published in English in peer-reviewed journals.

2. Papers published between 1st January 2000 and 13th October 2013.

Papers published prior to this were excluded because the interventions of interest had not been developed at that time.

Search Strategy

Three search strategies were used. Firstly, two databases (PsychINFO and MEDLINE) were searched using four areas with the search terms in each area combined using the 'OR' operator: 1) 'depress*' , 'anxi*'; 2) 'Child', 'adolescent', 'paediatric', 'pediatric', 'youth' ; 3) 'treatment', 'intervention', 'therapy',

'psychotherapy', 'bibliotherapy', 'computer*', 'technology'; 4) 'randomi* controlled trial', 'clinical trial'. An asterix indicates that search terms were truncated so that any variant of the term would be included, e.g. 'anxi*' would include 'anxiety' or 'anxious'. These searches were then combined using the 'AND' operator.

Secondly, reference lists of all included studies and relevant reviews were searched to identify any additional studies. Finally, a cited reference search was performed to identify any further relevant studies.

A second reviewer examined the search results to select studies for inclusion. If the first and second reviewer disagreed, a third was consulted to reach a collaborative decision based on the inclusion and exclusion criteria.

Quality Assessment

Methodological quality of included studies was assessed using a 14-item checklist of standard assessment criteria as described by Kmet, Lee and Cook (2004). This assessment tool was chosen due to its focus on internal validity and the avoidance of bias or errors in design, conduct and analysis.

Results

The database searches identified 588 studies. Of these, seven met the inclusion and exclusion criteria (see Figure 1). Seven further studies were identified through reference list and citation searching, making a total of 14. Common reasons for exclusion were interventions being solely delivered by a therapist, participants being recruited from adult populations, or samples being drawn from non-clinical populations.

Target Population

Of the 14 included studies, 12 examined interventions solely targeting anxiety. One of these focused exclusively on Obsessive Compulsive Disorder (OCD), whereas the remaining ten included participants with a range of anxiety diagnoses. Although OCD is no longer classified as an anxiety disorder by the fifth edition of the American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders (DSM-5; American Psychiatric Association, 2013), the study was included in this review on the basis that OCD was included as an anxiety disorder in the fourth edition, which was in use at the time the study was conducted. One study used an intervention for depression, and one further study described an intervention used to treat both anxiety and depression. Design features of the included studies are summarised in Table 1.

Interventions

Six studies examined computerised cognitive-behaviour therapy (cCBT), five examined therapist-guided bibliotherapy using a cognitive-behavioural approach, one study used cognitive-behavioural bibliotherapy without any guidance from a therapist, and two studies used a computer-based attentional bias modification intervention. Two studies examined the same cCBT intervention (BRAVE-Online) using populations of different ages. Features of the interventions examined, comparison groups and outcomes are summarised in Table 2.

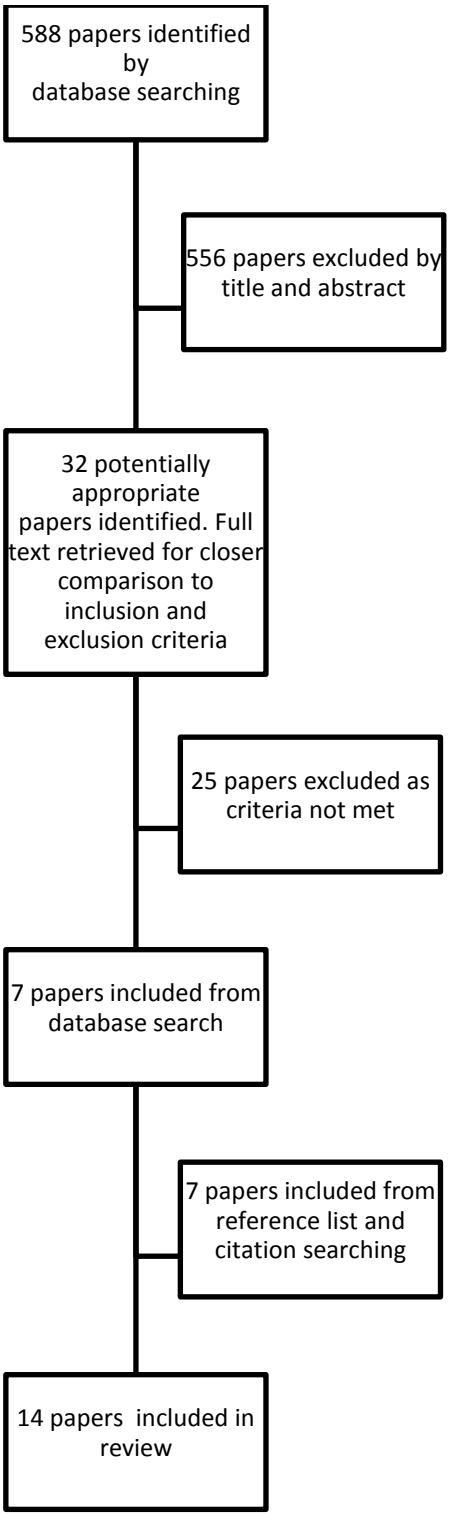

Figure 1. Flow diagram of studies included and excluded

Table 1
Summary of design features

Author Date	Target problem	Sample size	Age of participants	Outcome measures	Assessment points	Blinding of assessors	Quality assessment score (Total/maximum possible score)
Bolton et al. (2011)	OCD	96	10-18	Primary: CY-BOCS. Secondary: ADIS C/P, Child OCI, COIS-C/P, MASC, CDI, adapted version of MANSA.	Baseline, post-treatment, 3 month follow-up for treatment groups only.	Yes	96% (25/26)
Cobham (2012)	Anxiety	55	7-14	ADIS-C/P (in person at baseline assessment, via telephone thereafter), RCMAS, SCAS-C, CBCL (parent report, internalising subscale only).	Baseline, post-treatment, 3 and 6 month follow-ups for treatment groups only.	No	85% (22/26)
Eldar, Apter & Lotan (2012)	Anxiety	40	8-14	ADIS-C/P, CDI, SCARED (parent and child report). All measures translated into Hebrew.	Baseline, post-treatment.	Yes	86% (24/28)
Khanna & Kendall (2010)	Anxiety	49	7-13	ADIS-C/P, CDI, MASC, CGAS	Baseline, post-treatment, 3 month follow-up.	Yes	92% (24/26)
Leong et al. (2009)	Anxiety	27	7-14	ADIS-C/P (via telephone), RCMAS, CBCL, SDQ-P.	Baseline, post-treatment, 3 and 6 month follow-ups.	Yes	92% (24/26)
Lyneham & Rapee (2006)	Anxiety	100	6-12	ADIS-P (with parent only via telephone), SCAS-C/P, CDI, RCMAS, CBCL (internalising scale only), CATS, PSI, DASS.	Baseline, post-treatment, 12 month follow-up.	No	88% (23/26)
March, Spence & Donovan (2009)	Anxiety	73	7-12	ADIS-C/P (via telephone), CGAS, SCAS-C/P, CBCL (internalising scale only), CES-D.	Baseline, post-treatment, 6 month follow-up for treatment group.	Yes	92% (24/26)

Merry et al. (2012)	Depression	187	12-19	CDRS-R, RADS-2, MFQ, PQ-LES-Q, Kazdin hopelessness scale for children, SCAS-C, CGI	Baseline, post-treatment, 3 month follow-up.	Yes	96% (25/26)
Rapee, Abbott & Lyneham (2006)	Anxiety	267	6-12	ADIS-C/P, SCAS-C/P, CATS, CBCL	Baseline, post-treatment, 3 month follow-up for treatment groups.	No	92% (24/26)
Spence et al. (2011)	Anxiety	115	12-18	ADIS-C/P, CGAS, SCAS-C/P, CBCL	Baseline, post-treatment, 6 and 12 month follow-ups for treatment groups only.	Yes	96% (25/26)
Stallard et al. (2011)	Anxiety and Depression	20	11-16	SDQ-P, SCAS-C, AWS, SCQ, RSEI.	Baseline, post-treatment.	Yes	65% (17/26)
Thirlwall et al. (2013)	Anxiety	194	7-12	ADIS-C/P, SCAS-C/P, CAIS-P, SMFQ, Conduct problems subscale from SDQ-C/P.	Baseline, post-treatment, 6 month follow-up for treatment group.	Yes	96% (25/26)
Waters et al. (2013)	Anxiety	37	7-13	ADIS-C/P (via telephone), SCAS-C/P, CES-D.	Baseline, post-treatment	Yes	93% (26/28)
Wuthrich et al. (2012)	Anxiety	43	14-17	ADIS-C/P (via telephone), SCAS-C/P, Emotional Problems subscale from SDQ-P, CATS, ALIS.	Baseline, post-treatment, 3 month follow-up for treatment group.	Yes	96% (25/26)

Note CY-BOCS = Assessor-rated child version of Yale-Brown Obsessive-Compulsive Scale, Child OCI = Child Obsessive Compulsive Inventory, COIS-C/P = Child OCD Impact Scale, parent and child versions, MASC = Multidimensional Anxiety Scale for Children, CDI = Children's Depression Inventory, MANSA = Manchester Short Assessment of Quality of Life, RCMAS = Revised Children's Manifest Anxiety Scale, SCAS-C/P = Spence Children's Anxiety Scale, child and parent versions, CBCL = Child Behaviour Checklist, SCARED = Revised Screen for Child Anxiety Related Emotional Disorders, CGAS = Children's Global Assessment Scale (assessor-rated), SDQ-P = Strengths and Difficulties Questionnaire, parent version, CATS = Children's Automatic Thoughts Scale, PSI = Parenting Stress Index, parent report, DASS = Depression Anxiety Stress Scale- Short Version, parent report, CES-D = Centre for Epidemiological Studies for Depression Scale, CDRS-R = Children's Depression Rating Scale-Revised, RADS-2 = Reynolds Adolescent Depression Scale- second edition, MFQ = Mood and Feelings Questionnaire, PQ-LES-Q = Paediatric quality of life enjoyment and satisfaction questionnaire, CGI = Clinical Global Impression (assessor-rated), AWS = Adolescent Well Being Scale, SQC = Schema Questionnaire for Children, RSEI = Rosenberg Self-Esteem Inventory, CAIS-P = Child Anxiety Impact Scale, parent version, SMFQ = Short Mood and Feelings Questionnaire, parent and child versions, ALIS = Adolescent Life Interference Scale

Table 2

Summary of interventions and key outcomes

Author Date	Intervention and comparison groups	Key Outcomes
Bolton et al. (2011)	1) Brief CBT (5 sessions individual therapy) plus therapist-assisted bibliotherapy workbook for child. 2) Full CBT (12 sessions of individual therapy for child). 3) wait-list group.	Improvement on primary outcome variable for low-intensity treatment group compared to wait-list group. No significant difference between low and high intensity treatment at post-treatment. At follow-up, treatment groups significantly differed: full CBT group deteriorated slightly, brief CBT group improved.
Cobham (2012)	1) Therapist-assisted CBT bibliotherapy for parents: 2 hour parent group session then parents given parent and child workbooks and 6 fortnightly 20 min phone calls. 2) Individual therapy (12 sessions family-focused CBT; 6 for parent, 6 for child, using same workbooks). 3) wait-list group.	Based on numbers of children free of all anxiety disorder diagnoses at post-treatment, low-intensity treatment was better than wait-list but no different from high intensity treatment. In both treatment conditions, no further change was found at 3 or 6 month follow-up.
Eldar, Apter & Lotan (2012)	1) Attention-bias modification. Computer-based task training participants to disengage attention from threat-based stimuli. 4 sessions over 4 weeks. 2) Placebo condition 1: exposure to same threat stimuli as in treatment condition but without attention training. 3) Placebo condition 2: exposure to neutral stimuli only.	Significant reduction in anxiety symptoms in ABM condition but not placebo conditions. Change in diagnostic status in ABM condition significantly differed from placebo 2 but not placebo 1. Change on MASC and CDI was not significant.
Khanna & Kendall (2010)	1) Computerised CBT (Camp Cope-a-lot), with 12 'levels' for child to complete- 6 with therapist, 6 independently. Therapist also has 2 sessions with parent. 2) Individual CBT (12 sessions of individual therapy with child based on same session content as cCBT). 3) Computer-based attention, education and support control group.	cCBT & ICBT both significantly differed from control group based on percentage of participants in remission from primary diagnosis. Treatment groups did not significantly differ from each other at post-treatment or 3 month follow-up.

Leong et al. (2009)	1) Therapist-assisted CBT bibliotherapy to parents. 2 hour initial training for parent, then parent provided with parent and child workbooks, each with 6 sections to work through. Parent received fortnightly telephone calls from a therapist. 2) Clinician-delivered CBT to parent and child. 6 sessions for parent and 6 for child, focused on working through the same workbooks as in bibliotherapy condition.	No differences between low and high intensity treatment on any outcome measure at post treatment, 3 month follow-up or 6 month follow-up. Both groups improved. 61% of children in bibliotherapy condition were diagnosis free at post-treatment, compared to 57% in individual therapy condition.
Lyneham & Rapee (2006)	Therapist-assisted CBT bibliotherapy to parent. A self-help book for parents and parent and child workbooks were provided. 9 Manualised telephone or email contacts were provided to the parent by a therapist. Families divided into 1) telephone contact, 2) email contact, 3) parent-initiated contact groups.	Based on diagnostic status (presence of principal anxiety disorder diagnosis or any anxiety diagnosis), all 3 low-intensity treatment conditions performed significantly better than wait-list. Telephone contact was significantly better than email contact or parent-initiated contact.
March, Spence & Donovan (2009)	1) Computerised CBT using 'BRAVE' online. 10 weekly 60-minute sessions for the child and six weekly 60-minute parent sessions. Booster sessions provided 1 and 3 months after treatment completion. 2) Wait-list control group.	At post-treatment, the difference between low-intensity treatment and wait-list based on number of participants in remission from primary diagnosis approached but did not reach significance. Effects of group on number in remission from all anxiety diagnoses, Clinician Severity Ratings, CGAS scores and questionnaire measures did not reach significance. At 6 month follow-up for the treatment group, a significant reduction in number of participants meeting criteria for primary diagnosis and number meeting criteria for any diagnosis was found.
Merry et al. (2012)	1) Computerised CBT using 'SPARX' CD-ROM, accompanied by notebook summarising each module and leaving space for the adolescent to add notes. 2) Treatment as usual (TAU) consisting of primary care, school-based counselling or care in a youth clinic.	Non-inferiority shown between cCBT and TAU, with equal rates of remission in intention-to-treat analysis and slightly superior rates of remission in SPARX group in per-protocol analysis.

Rapee, Abbott & Lyneham (2006)	1) CBT Bibliotherapy for parent accompanied by workbook for child. No therapist contact provided but parents were given written instructions with a suggested timescale for working through the books provided. 2) Standard group CBT treatment. 3) Wait-list controls.	At post-treatment, bibliotherapy was significantly better than wait-list but not as good as group CBT, based on number of children free of anxiety disorders. Similar results at 3 month follow-up.
Spence et al. (2011)	1) Computerised CBT using 'BRAVE' online. 10 weekly sessions for adolescents and 5 for parents, each lasting 60 minutes. Booster sessions and 1 and 3 months after completion. Each session is followed by a feedback email from a therapist, in addition to automated emails with results of tasks. 2) Clinic CBT with same number, length and content of sessions as cCBT, accompanied by a relaxation CD and workbooks for adolescents and parents. 3) Wait-list controls.	On percentage free of primary diagnosis, cCBT and Clinic CBT groups were both significantly better than wait-list but did not differ from each other. On percentage free from all diagnoses, neither treatment was better than wait-list. Continued improvement was found in both treatment conditions on percentage free of primary diagnosis at 6 and 12 month follow-up.
Stallard et al. (2011)	1) Computerised CBT using 'Think, Feel, Do', consisting of 6 sessions with a CD-ROM. 30-45 minute sessions conducted on clinic site with a facilitator present throughout to support. 2) Wait-list controls.	Computerised CBT group improved on 7 subscales in pre-post comparison, controls improved on 3.
Thirlwall et al. (2013)	Therapist-assisted CBT bibliotherapy. Parents given a self-help book and either 1) 4 sessions with therapist (half in person, half via telephone), total therapist contact= average 2-3 hours, or 2) 8 sessions with therapist, (half in person, half via telephone) average therapist contact= 5-6 hours. 3) Wait-list controls.	At post-treatment, 8-session low-intensity treatment performed better than wait-list on number of participants recovered from primary diagnosis, 4-session treatment did not. At 6 month follow-up, participants in 4-session treatment had shown continued improvement so both treatment conditions were significantly better than wait-list.

Waters et al. (2013)	1) Attention-bias modification training; computer based task completed at home with minimal therapist contact. 12 sessions over 3 weeks, training children to focus attention away from threat-based stimuli. 2) Attention training control task, delivered in same format but training children to discriminate between neutral stimuli.	Significantly more improvement at post-treatment on percentage free of primary diagnosis and clinician-rated severity of primary diagnosis compared to controls. Parent and child rated symptom measures did not improve.
Wuthrich et al. (2012)	1) Computerised CBT using 'Cool Teens', an 8-module CD-ROM. Handouts were provided for parents, in addition to 8 brief phone calls to the adolescent and 3 to parents. 2) 12 week wait-list controls.	Significantly greater reduction in number of diagnoses, severity of primary diagnosis and mean severity of all diagnoses in low-intensity treatment group compared to wait-list. Gains were maintained at 3 month follow-up.

Participant demographics

Participants ranged in age from six to eighteen years. Seven of the studies included parents in the intervention; five of these delivered the intervention primarily to the parent in at least one arm of the trial. Sample sizes ranged from 20 to 267. Two of the studies were described as pilots with samples of 20 and 27.

Outcome Measures

All included studies used a range of standardised questionnaire measures to assess mood or anxiety. All of the 12 studies of interventions solely targeting anxiety also used the Anxiety Disorders Interview Schedule, child and parent versions (ADIS-C/P; Silverman & Albano, 1996). Thirteen of the included studies used parent-reported measures in addition to self-report measures. The fourteenth (Merry et al., 2012) used an observer-rated scale (Children's Depression Rating Scale-Revised) alongside self-report measures. Several studies measured satisfaction with the interventions offered, therapeutic alliance, or participant ratings of the experience of using a computer.

Outcome of Interventions

Computerised CBT for Depression

Of the six cCBT studies, two included participants presenting with depression. Merry et al. (2012) examined 'SPARX', a cCBT intervention for adolescents seeking help for depressive symptoms, in a non-inferiority trial comparing SPARX to treatment as usual (TAU) at post-treatment and three month follow-up. SPARX uses an interactive fantasy game to target negative automatic

thoughts and promote cognitive restructuring, provide psychoeducation and relaxation strategies, and encourage young people to complete real-life homework tasks. The intervention was delivered via a CD-ROM, designed for use on a home computer with basic minimum specifications, and did not include parents or clinicians in the treatment itself. TAU was assumed to be either face-to-face therapy with a psychologist or counsellor, or routine GP care, however only the number and duration of sessions and type of therapy was recorded. The authors found clinically significant improvement in symptoms for participants in both conditions. In the per-protocol analysis, based on those who completed at least four SPARX modules (86% of the SPARX group), remission rates on the primary outcome measure were higher in the SPARX group (44%) than in the TAU group (26%). However, no significant differences were found between the conditions using intention-to-treat analysis (60% in cCBT versus 55% in TAU). The authors concluded that the SPARX intervention was at least as effective as standard care, but could be more cheaply and widely disseminated as it is a solely self-help intervention requiring minimal resources from health services. Additionally, attrition was low (9%), user-rated satisfaction with the SPARX intervention was high and 81% of participants said they would recommend SPARX to a friend.

The authors used a large, randomised sample with broad enough inclusion criteria to be representative of young people seeking help for depression. However, there were two key limitations to the control group used. Firstly, the control group also received active treatment and so was not able to control for spontaneous remission or placebo effect. Additionally, there was considerable

heterogeneity in the nature of the TAU offered and data on the treatment offered were only available for 89% of the group. Based on the data available, the mean number of treatment as usual sessions offered was 4.8 (range 1-20) and the majority of young people were offered counselling. While this heterogeneity is not ideal, it does reflect the range of treatments offered to young people with depression in health service settings, including the large number of young people who are offered only minimal intervention. A key limitation is the lack of data from parents as only self-report and observer-rated measures were used. The authors were also unable to gather robust data on adherence in either condition and so were unable to address questions related to this.

Stallard, Richardson, Velleman and Attwood (2011) conducted a pilot study of cCBT using 'Think, Feel, Do' with young people with either depression or anxiety. Think, Feel, Do is a six session CD-ROM intervention based on the CBT workbook '*Think Good – Feel Good*' (Stallard, 2004). The 30-45 minute sessions are completed at home, accompanied by a facilitator, usually an assistant psychologist, whose role is to discuss and elaborate on the content and help the young person apply the strategies discussed to their own difficulties. Twenty young people who had been placed on a waiting list to receive CBT for depression or anxiety in a Child and Adolescent Mental Health Service (CAMHS) consented to take part while they were awaiting the start of their treatment. Five standardised questionnaire measures were used at baseline and post-treatment. For the analysis, these were broken down into 15 subscale scores for each participant. Young people who received cCBT showed improvement on seven of these subscales (relating to social phobia,

self-esteem, depression, cognitive schemas, parent-rated emotional difficulties, parent-rated hyperactivity, and total score on the strengths and difficulties questionnaire) in a pre-post comparison, whereas wait-list controls improved on three (relating to self-esteem, cognitive schemas and fear of physical injury). The pre-post time interval for the control group was approximately four weeks, whereas the cCBT group had an approximate time interval of six weeks. Mean satisfaction ratings from young people were medium to high.

As a pilot study, the sample size was very small and so there are clear limitations to the conclusions that can be drawn. Participants were recruited only from those who were on a waiting list for CBT, not from the waiting lists for other interventions such as family therapy and so the sample is not fully representative of those seeking treatment in the clinic. Furthermore, the limited sample meant that outcomes for young people with depression and those with anxiety could not be examined separately. The authors were appropriately tentative in their conclusions and noted the need for larger studies to examine the efficacy of cCBT for depression.

Overall, these studies suggest that cCBT for depression is a cost-effective and acceptable treatment for young people with depression, and may be as effective as standard care. However, further studies will be needed to confirm this and as yet no trials have directly compared cCBT for depression to therapist-directed CBT.

Computerised CBT for Anxiety Disorders

Three cCBT programmes for anxiety disorders in children and young people have so far been tested in RCTs. The largest of these trials was conducted by Spence et al. (2011) who tested 'BRAVE-Online' with a sample of 115 adolescents. Young people completed ten 60-minute sessions on a password-protected website then each session was followed by a feedback email from a therapist. Alongside this, parents completed five sessions and both the parent and the adolescent were given booster sessions one and three months after treatment ended. Sessions included CBT strategies such as graded exposure, relaxation, cognitive restructuring, problem-solving and psychoeducation. The online treatment was compared to a clinic-based treatment with the same content, and a wait-list control group. Twelve weeks after beginning treatment, cCBT and clinic CBT showed comparable outcomes, with 18% of online participants and 21% of clinic participants in remission from all anxiety diagnoses on intention-to-treat analysis. Both groups performed significantly better than wait-list controls, where only 4% remitted. Children in the cCBT and clinic CBT conditions, but not those in the wait-list group, also showed improvement on the Children's Global Assessment Scale (Shaffer et al., 1983), suggesting improvement in overall functioning. Both parents and young people reported moderate to high satisfaction with the cCBT intervention, although parent-rated satisfaction was slightly higher in the clinic CBT group. The authors noted that twelve weeks after beginning treatment, a large number of families had not yet completed all the sessions, which they hypothesised may have contributed to the lower than expected response rate at this assessment.

Follow-up data at both six and twelve months suggested that participants in both treatment conditions continued improving after treatment ended, such that 55% of online participants and 59% of clinic participants were diagnosis free one year later.

Although this study had several methodological advantages, including blinding of assessors and clearly described fidelity checks, the sampling procedure had a number of limitations. The participants were drawn from a relatively affluent and well-educated population and inclusion was restricted to only four anxiety diagnoses: generalised anxiety, separation anxiety, social phobia and specific phobia. BRAVE-online has therefore not yet been tested with the full range of anxiety diagnoses that occur in adolescents, such as panic disorder and agoraphobia. The authors also noted that at the 12-month follow-up assessment, significantly fewer adolescents had completed all treatment sessions in the cCBT condition (57%) than in the clinic CBT condition (79%), although the reasons for this were not explored further.

BRAVE-Online was also tested by March, Spence and Donovan (2009) with a younger sample of 73 children aged seven to 12, comparing the treatment to wait list controls. This sample was also largely drawn from a relatively affluent, middle-class population and 88% of children lived with both biological parents. The authors also excluded children whose primary diagnosis was panic disorder, obsessive compulsive disorder or post-traumatic stress disorder. At post-treatment, differences in numbers free of anxiety diagnoses between the cCBT group and wait-list controls approached but did not reach significance, although a significant difference emerged at six month follow-up. At post-treatment, 17% of

participants in the treatment group were diagnosis free, whereas this figure increased to 61% at follow-up. Participants in the cCBT condition showed greater improvement from pre- to post-treatment on clinician-rated global functioning than those in the wait-list group, and continued improvement was found at follow-up. Satisfaction ratings in the cCBT group were moderate, and as in the Spence et al. (2011) study, large numbers of young people did not complete all the available treatment sessions. At post-treatment, the mean number of sessions completed was 5.13 out of a possible 6 for parents and 7.5 out of 10 for children.

'Camp Cope-a-lot' is a cCBT intervention developed specifically for children or younger adolescents and their parents, to be completed with the support of a therapist. Khanna and Kendall (2010) conducted the only trial to date of this intervention, with a sample of 49 seven to 13 year olds. The authors compared the intervention to a 12-session individual CBT control group and a further group who received an attention, education and support control intervention, finding comparable outcomes in the cCBT and clinic-based CBT groups at both post-treatment and three month follow-up. Both treatments resulted in better outcomes on symptom-based and global functioning measures than the attention-based control intervention, with 81% in the cCBT group found to be free of their primary diagnosis at post-treatment, compared to 70% in the clinic CBT group and 19% in the control group. The authors reported that 43% of children in the overall sample met criteria for a secondary diagnosis following treatment but did not report group differences in recovery from all diagnoses. Satisfaction ratings from both parents and children did not differ between the clinic group and cCBT group,

and almost all families completed all available sessions in all three conditions. The inclusion of an attention control group is a key strength of this study, however socioeconomic data on the sample were not available and parent self-report measures were not used, so the extent to which the sample is representative is not clear.

Wuthrich et al. (2012) tested a cCBT intervention with a sample of 43 adolescents aged 14-17. 'Cool Teens' comprises eight sessions delivered via a CD-ROM and also includes parents in the treatment. Participants in the treatment group had better outcomes than wait-list controls at post-treatment and three month follow-up. However, recovery rates were modest as only 20% of adolescents in the treatment group were free of anxiety diagnosis at follow-up. The authors hypothesised that anxiety may be more difficult to treat in adolescents than in children, and highlighted that 50% of the sample had social anxiety, which may be particularly difficult to treat. User feedback on the modules of the intervention suggested that the content and presentation was highly acceptable to young people, however no data were reported on the mean number of intervention sessions completed by young people.

These studies suggest that computerised CBT is an effective treatment for children and adolescents with anxiety, and young people can continue to improve after the end of treatment. However, the samples used may not have been fully representative and the cCBT interventions have not yet been directly compared to one another.

Unassisted Bibliotherapy for Anxiety

Only one study tested bibliotherapy without assistance from a therapist. Rapee, Abbott and Lyneham (2006) examined CBT-based bibliotherapy delivered to parents as a treatment for child anxiety, using a sample of 267 children aged six to 12. In this study, parents in the treatment group were supplied with the commercially available book '*Helping your Anxious Child: A Step-by-Step Guide for Parents'* (Rapee, Spence, Cobham & Wignall, 2000), an accompanying workbook for the child containing the summaries and worksheets mentioned in the book, and a suggested timeline for the parent to complete the treatment with the child. Parents were not given any support from a therapist aside from the written materials. This intervention was compared to a wait-list control group and a group CBT intervention for both parents and children consisting of nine two-hour sessions over 12 weeks, using the same hand-outs and worksheets as used in the book. More children in the bibliotherapy condition (18% in intention-to-treat analysis) were free of an anxiety disorder at post-treatment than in the wait-list condition (6%), however the group CBT (49%) performed better than bibliotherapy. Participants in the group CBT condition also had better outcomes at three month follow-up.

In the bibliotherapy condition, 32% of participants dropped out of treatment or failed to complete post-treatment assessments, compared to 16% of participants in the group CBT condition and 14% in the wait-list condition. Children who completed treatment had lower rates of comorbidity and lower scores on measures of anxiety and externalising behaviour problems. At both post-treatment and

follow-up, completers in the bibliotherapy and group CBT conditions showed improvement on measures of externalising behaviour problems, whereas children in the wait-list group did not. However, intention-to-treat analysis showed that children in the bibliotherapy condition did not improve more than children on the wait-list and improved less than children who received group CBT.

The methodological quality of this study was high, and a large, representative sample of children presenting to a specialist anxiety clinic was used. The authors chose not to include therapist guidance in order to conduct a conservative study of the benefits of self-help, which is likely to be relevant to the relatively low response rate compared to group treatment and the high rate of drop-out. However, data on adherence were not systematically collected from parents in the bibliotherapy condition and so it was impossible to establish whether the children who did not recover had not responded to the treatment or had simply not had a sufficient amount of the intervention. The authors hypothesised that the addition of guidance from a therapist may improve outcomes while still allowing treatment to be offered to a larger number of families than resources currently allow. The authors also noted that the high drop out from the study led to less favourable outcomes on intention-to-treat analysis. They suggested that client understanding and motivation were likely to be relevant to treatment success but noted that further research is needed to investigate factors affecting implementation and outcome.

Therapist-assisted Bibliotherapy for Anxiety

Five studies examined CBT-based bibliotherapy accompanied by support from a therapist. Two of these compared therapist-assisted bibliotherapy to a wait-list control, whereas two compared it to a face-to-face CBT intervention with comparable content to the bibliotherapy materials and a wait-list control group. One study was a pilot comparing bibliotherapy to face-to-face CBT (Leong, Cobham, de Groot & McDermott, 2009).

Cobham (2012) found that a 12-week therapist-assisted bibliotherapy intervention delivered to parents achieved very similar outcomes to a 12-week face-to-face programme (comprising six sessions for the parent followed by six for the child) and participants in both treatment conditions had better outcomes than participants in the wait-list group. The sample used consisted of 55 children aged seven to 14. The authors found that 95% of children in the bibliotherapy condition were free of any anxiety diagnosis at post-treatment, compared to 78% in the face-to-face CBT condition and 0% in the wait-list group. At six month follow-up, 85% of participants in the bibliotherapy condition remained free of anxiety diagnosis, compared to 70% in the face-to-face CBT condition. Satisfaction with the interventions did not differ between groups, with both interventions rated highly by parents. All included families completed treatment. Bolton et al. (2011) found a similar pattern of findings at post-treatment with a sample of 96 children aged 10-18 with a diagnosis of obsessive-compulsive disorder (OCD). In this case guided bibliotherapy consisted of five face-to-face sessions for the child then workbooks for the child to complete with therapist support. Entirely face-to-face therapy (12

sessions) delivered slightly, although not significantly, better outcomes at post-treatment on both symptom-based and quality of life measures but children in the bibliotherapy condition showed continued improvement when assessed again at three month follow-up. Very few families failed to complete treatment in any of the conditions. Both of these studies were of good quality, and mirrored the results of Leong et al. (2009) in their pilot study.

Two further large, good quality trials compared bibliotherapy to wait-list controls. Both Thirlwall et al. (2013) and Lyneham and Rapee (2006) examined more than one variant of therapist-assisted bibliotherapy delivered to parents to investigate the amount and type of therapist support needed to achieve good outcomes. Lyneham and Rapee (2006) used written materials accompanied by either scheduled email contact, scheduled telephone contact, or contact by either method that was initiated by the parent, with a sample of 100 six to 12 year olds. Participants in all three treatment conditions had better outcomes than wait-list controls, and participants who received telephone contact achieved better outcomes than participants who received other types of contact. The authors noted that programme implementation was poor in both the email contact and parent initiated contact conditions, as parents reported attempting the programme for only five weeks on average. Furthermore, when parents were left to initiate contact with the therapist, 21% dropped out of treatment and of those remaining, few took up the offer of support. Only nine of the 29 families in this group ever made contact with their therapist. This contrasted with the scheduled telephone and email contact conditions where parents on average made use of almost all the

therapist contacts offered (mean = 8.3 telephone contacts or 21 emails) and drop-out rates were low.

Thirlwall et al. (2013) compared bibliotherapy with eight sessions of therapist contact to bibliotherapy with four sessions of therapist contact and wait-list controls, using a sample of 194 children aged seven to 12. In both treatment conditions, half of the therapist contacts were made in person and half were short (20 minute) telephone contacts. At post-treatment, the 8-session treatment performed better than wait-list but the 4-session treatment did not: 34% of those in the 8-session treatment group had recovered from all anxiety diagnoses, compared to 15% in the 4-session treatment and 11% in the wait-list group. At six month follow-up, 53% of those in the 8-session treatment group and 55% of those in the 4-session group had recovered from all diagnoses. No effects on comorbid mood or behaviour problems were found in any of the groups. Although participants were recruited from consecutive referrals to the clinic, the sample included only children whose main caregiving parent did not meet criteria for an anxiety disorder, as parental anxiety has been found to be negatively associated with child treatment outcomes. As a result the children in this sample had a relatively good prognosis. Bibliotherapy with briefer therapist support has therefore not yet been tested with a sample fully representative of the range of children who present to services with anxiety.

Overall, bibliotherapy delivered to parents appears to provide comparable outcomes to face-to-face therapy for children with anxiety, and scheduled contact with a therapist appears to make an important contribution to these interventions.

Attention Bias Modification for Anxiety

Two trials of attention-bias modification training have been conducted with clinically anxious children. Eldar et al. (2012) conducted the first of these with 40 young people aged eight to 14, comparing the intervention to two training-based control tasks. The attention bias modification (ABM) intervention attempts to reduce implicit attentional bias towards threat by reinforcing attention to neutral stimuli in the presence of threat-based stimuli. In placebo condition one, participants were trained to focus their attention on both neutral and threat stimuli, whereas in placebo condition two they were presented with only neutral stimuli in order to control for the effect of exposure to threat stimuli. Reduction in symptom counts and symptom severity was significantly higher in the ABM condition than in either control condition. 33% of children in the ABM condition no longer met criteria for their primary diagnosis at post-treatment, which was more than in the placebo two group (0%) but not significantly more than in the placebo one group (13%). The proportions of participants in each group in remission from all anxiety diagnoses were not reported. All of the children who were randomised to a treatment group completed treatment.

Care was taken in this study to control for the effect of exposure to the threat-based stimuli (photographs of angry faces), which was necessary due to the reduction in anxiety symptoms found in the placebo one condition. However, this study has three notable limitations. Firstly, the number of participants in each group was small, especially in the placebo two condition that was added later in the study after randomisation had begun. Secondly, the authors excluded 31 children

who did not show a significant attentional bias towards threat at the pre-treatment assessment, resulting in a potentially unrepresentative sample. This exclusion criterion was used to prevent any children without an attentional bias being trained to avoid threat, as this was considered to present a possible risk. The authors also noted that their decision to include children with a range of anxiety diagnoses meant that their generic threat stimulus may not have been optimally effective for all children.

Waters, Pittaway, Mogg, Bradley and Pine (2013) conducted a similar trial with 37 clinically anxious children aged seven to 13, but included children regardless of whether they showed a pre-existing bias towards threat-based stimuli. Of those who completed attention-bias modification, 50% of children in the ABM group did not meet criteria for their primary diagnosis after attention training, compared to 8% in the control condition. On intention-to-treat analysis, 33% in the ABM group no longer met criteria, compared to 6% in the control group. Children in the ABM group also showed reduction in clinician-rated severity of their primary diagnosis and reduction in the mean number of diagnoses, whereas children in the control group did not.

The authors suggested that even children without a pre-existing attentional bias towards threat benefitted from this treatment, and the treatment did not appear to present a risk to this group. However, they also noted that despite improvements on clinician rated diagnostic status and severity, child and parent rated anxiety symptoms did not improve and satisfaction with the treatment was rated low to average. As in the Eldar et al. (2012) trial, the threat stimuli used

were not tailored to the child's specific anxiety and the sample was small. Additionally, although the authors reported that the participants were referred to their project, they did not describe the source of these referrals and possible sampling biases were not discussed.

These early studies suggest that ABM warrants further investigation as a treatment for anxious children. This treatment has not yet been used with adolescents or tested with large, representative samples of anxious children.

Discussion

This review aimed to examine whether low-intensity interventions using reduced therapist contact are effective treatments for children and adolescents with depression and anxiety disorders. Fourteen trials met criteria for inclusion, with twelve of these using interventions based on well-established cognitive behavioural approaches. Although the use of low-intensity, minimal contact therapies has become widespread with adult populations, and a large amount of outcome data has been collected in primary care psychological services to measure effectiveness, this approach has only been applied to treatments for young people relatively recently, resulting in a small number of trials eligible for inclusion. Further trials of preventative interventions for young people have been conducted, however this review focused exclusively on whether these interventions are effective for young people seeking help from professional services as a step towards addressing the high level of unmet need in child and adolescent mental health services.

Guided bibliotherapy using written materials provided to parents appears to be an effective therapy for children in middle childhood with a range of anxiety disorders. The evidence suggests that this type of intervention works well when parents are offered the regular support of a therapist at scheduled times but is much less effective if parents are given self-help materials without support. The optimal method and amount of contact needed is yet to be established, but the current studies suggest that contact does not need to be face-to-face to be helpful to parents as telephone contact could also be helpful, and a small number of sessions may be sufficient. Interestingly, the full benefits of treatment may not be apparent at the end of therapy, but instead may only be accurately assessed later, perhaps up to a year after therapy has ended. It may be that families take more time to work through an exposure hierarchy or to break cycles of avoidance than would typically be the case in a therapist-directed treatment, but are able to continue to apply these principles once therapist support comes to an end. As yet, guided bibliotherapy has not been attempted with very young children or adolescents. As adolescents become more independent from their parents, it may be that interventions which rely less on parents and are delivered more directly to the young person are more suitable. However, exposure to anxiety provoking situations may be usefully facilitated by parents and so the inclusion of parents in interventions in a supportive role may still be helpful in adolescence.

The three cCBT interventions for anxiety tested so far have also suggested that this is a promising approach to treatment for anxious children and young people. BRAVE-Online (Spence et al., 2011; March et al., 2009) appears to be

effective with both children and adolescents, and as with guided bibliotherapy interventions, improvements in anxiety symptoms appear to continue beyond the end of the intervention itself. Camp Cope-a-lot (Khanna & Kendall, 2010) showed very good outcomes for younger children but has only been tested in one trial to date. Of the cCBT interventions reviewed here, Camp Cope-a-lot included the most therapist input, which could have contributed to the better outcomes. Findings for Cool Teens (Wuthrich et al., 2012) were more modest, and it is as yet unclear whether this reflects a shortcoming of the particular intervention used or whether anxiety disorders are simply more difficult to treat in adolescents. As the results of BRAVE-Online with adolescents and Cool Teens appear to contradict one another, further studies are needed to explore this. The possible effects of factors such as comorbidity, including comorbid social anxiety, also require examination.

Treatment of anxiety using attention bias modification (Eldar et al., 2012; Waters et al. 2013) may also bring benefits, however as there have only been two small studies using a clinical population, and the samples used may not have been fully representative of children with anxiety more generally, these findings are only preliminary. The tasks used in the interventions may be more effective if the young person is trained to shift their attention away from threat stimuli which map closely on to the focus of their own specific anxiety, rather than a generic threat stimulus as was used in this study. As this treatment requires only minimal time and resources to deliver, the effectiveness of ABM warrants further study.

A clear finding of this review is the lack of research examining reduced contact therapies for depression. Only one full scale trial and one pilot were found,

both using cCBT, and as yet no trials have been conducted comparing cCBT to a face-to-face CBT intervention. Although there is promising evidence from one trial suggesting that cCBT is not inferior to treatment as usual for depression, treatment as usual often consisted of very little in this study. It is also unknown whether other types of reduced contact therapy, such as guided bibliotherapy, would be effective with this population. It is plausible that an intervention that presents information using interactive or audio-visual formats, such as on a website or CD-ROM, might be more suitable than written materials for young people with depression, as lack of motivation and concentration may make it more difficult for users to read a self-help guide, but this has not yet been investigated. It also remains unclear the extent to which including parents in an intervention may be useful. One possible barrier to research in this area is the need to manage risk effectively, as reduced contact interventions would be unsuitable for young people with high or fluctuating levels of risk. Young people may be less likely to disclose suicidal ideation during this type of therapy as they may not have a sufficiently developed therapeutic relationship to be able to do so, which may result in escalating risk going undetected. However, these approaches have been successfully implemented with adults using appropriate screening and risk management strategies and so this remains a productive avenue for future research.

The findings of this review suggest some wider questions which will need to be addressed by future research on reduced contact interventions. Data on adherence to treatments need to be systematically examined in order to establish whether treatment non-response reflects an ineffective treatment or an insufficient

amount of the intervention being completed. It may be that outcomes for some families could be improved by increasing the amount of therapist support to improve adherence, whereas this may not be necessary for all. Attrition is also an important consideration as families may be more likely to drop out of this type of treatment than from conventional face-to-face therapy, perhaps disproportionately affecting disadvantaged groups or those with additional difficulties.

It is likely that reduced contact therapies will be successful for some children and young people but are not suitable for others. A stepped care approach to treatment incorporating reduced contact therapies will be greatly aided if clinicians can make informed judgements at assessment about who is likely to benefit, and who may need more intensive contact with a therapist in order to recover. Predictors of successful outcome have not yet been identified and potential barriers to treatment success, such as high initial symptom severity or the presence of comorbid behaviour problems, are as yet unknown. The effect of reduced contact therapies on wider problems, such as conduct problems and school refusal, also warrants further study.

The majority of the included studies also used relatively affluent and ethnically homogenous samples, with higher than average levels of parental education. Many of the studies recruited participants by distributing information and advertisements inviting families to self-refer, or relied on referrals from schools or school counsellors, creating likely bias in the samples used. Further research should investigate whether reduced contact therapies are effective among

populations who are less likely to access conventional services, including low socio-economic status and ethnic minority populations.

The trials included here demonstrate the importance of follow-up assessments, both to ensure that treatment gains are maintained after the end of therapy, but also to show the effect of longer-term use of the strategies learned in the intervention. Future research in this area should include follow-up assessments as a matter of course in order to ensure an accurate picture of efficacy.

The results of this review suggest that reduced contact therapies represent a useful treatment option and are worthy of further testing. Future research ought to aim to establish whether these treatments are effective with all age groups or whether different methods of delivery are more suited to childhood or adolescence. The extent to which parents need to be included in interventions also requires further examination, whether parents are used to convey the content of the intervention to the child instead of a therapist, or used only to encourage and facilitate the young person completing the intervention more independently. The results here are encouraging in that it appears meaningful treatment gains can be achieved with relatively minimal resources, suggesting that with the adoption of reduced contact therapies services will be able to help a much larger proportion of children and adolescents with depression and anxiety than are currently being reached.

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PART TWO: EMPIRICAL PAPER

Predictors of change in treatment outcome for parent-delivered guided CBT bibliotherapy for children with anxiety: Effects of age, severity and comorbidity at long term follow-up.

Abstract

Aims: Parent-delivered guided CBT bibliotherapy has been developed to meet high levels of need for interventions for children with anxiety without requiring intensive resources. Initial trials have shown this treatment can be effective for children with a range of anxiety disorders. This study aims to examine whether age, symptom severity and comorbidity predict treatment outcomes at four year follow-up.

Method: Anxious children aged 7-12 years who received parent-delivered guided bibliotherapy as part of an RCT were contacted three to five years later. Structured diagnostic interviews were conducted with 57 families.

Results: Overall, small effect sizes suggested that the treatment was broadly successful. Initial symptom severity predicted clinician-rated improvement and recovery from primary anxiety diagnosis and being free of any diagnosis of a child mental health disorder. Presence of comorbid anxiety disorders at baseline predicted recovery from any anxiety or any overall diagnosis at follow-up. Age, symptom severity and comorbid externalising behaviour problems predicted whether children had received further mental health treatment during the follow-up period.

Conclusions: Findings suggested that children with more severe symptoms of anxiety at initial assessment were less likely to do well following a low-intensity guided bibliotherapy intervention and were more likely to require further treatment. Older children and those with behaviour problems were also more likely to need more input later. Further research should examine the ongoing mental health needs of those who do not recover following a low-intensity intervention.

Introduction

Anxiety disorders are common in early and middle childhood, affecting on average one child in every UK school class (Ford, Goodman & Meltzer, 2003). Cognitive behaviour therapy (CBT), usually delivered to individuals or groups, has been shown to be effective for children and young people with anxiety disorders (Cartwright-Hatton, Roberts, Chistabesan, Fothergill & Harrington, 2004; Compton et al., 2004; James, James, Cowdrey, Soler & Choke, 2013). However, face-to-face CBT requires extensive resources and so is not always available to those who need it, due to a lack of trained therapists within child and adolescent mental health services (Stallard et al., 2007).

In order to meet the need for effective, evidence-based interventions for anxiety in children's mental health services, researchers have begun to examine approaches to delivering CBT that rely less heavily on face-to-face contact with a therapist than traditional CBT approaches. This has included computerised CBT (e.g. Spence et al., 2011) and guided bibliotherapy for parents (Lyneham & Rapee, 2006; Thirlwall et al., 2013). These can potentially be used within a stepped-care model to improve access to psychotherapy, where low-intensity interventions are offered to clients with mild to moderate difficulties and high-intensity interventions, requiring greater input from a therapist, are offered to clients with more severe problems or those who do not respond to low-intensity treatment (Bower & Gilbody, 2007).

Initial trials of guided bibliotherapy delivered via parents have shown that this approach can bring about rates of recovery comparable with those found in

trials of child CBT delivered by a therapist (Lyneham & Rapee, 2006; Thirlwall et al., 2013). Thirlwall et al. (2013) carried out the first trial of this type of treatment in the UK healthcare system, comparing bibliotherapy accompanied by either four or eight sessions of therapist support for parents to a wait-list control group. In both treatment groups, half of the therapist contacts were in person with the remaining half delivered over the phone. At post-treatment, only participants who had received the eight-session treatment were more likely to have recovered than the wait-list group, however at six-month follow-up there was evidence of continued improvement in the briefer treatment group, such that participants who received the four-session treatment had similar recovery rates to those who had received the longer treatment. At follow-up, 55% of those in the brief treatment condition no longer met criteria for any anxiety disorder, compared to 53% in the longer treatment condition. The authors hypothesised that delivering the treatment to parents not only minimised disruption to children, but also had the potential to allow parents to continue implementing treatment strategies after the intervention had ended and so may facilitate continuation and maintenance of gains. Little is yet known about long term outcomes of parent-delivered guided bibliotherapy as trials have not followed up participants beyond six months. As Barrett (2000) highlights, studies of more intensive, therapist-directed CBT also shed little light on long term outcomes, constituting a significant shortcoming in the literature as short-term follow-ups fail to consider a developmental perspective, such as how psychological difficulties may change in form across time, or suggest mechanisms of long term change.

Stepped-care approaches, including guided bibliotherapy are likely to play a significant role in future mental health services due to the growing body of literature suggesting that they deliver positive treatment outcomes while using substantially fewer resources than conventional treatment (Salloum, 2010). This treatment model relies upon clinicians being able to determine at assessment which young people are likely to benefit from low-intensity interventions and which young people may need to be 'stepped-up' to higher-intensity treatments in order to recover. It is therefore important to establish which clinical and demographic variables, measured at the outset, predict outcome in this type of treatment.

Research on therapist-directed CBT has begun to explore predictors of treatment outcome, but few studies follow-up participants beyond 12 months post-treatment. Nilsen, Eisemann and Kvernmo (2012) conducted a systematic review of studies investigating predictors and moderators of CBT for children with anxiety. Studies explored possible effects of age, gender, ethnicity, initial symptom severity and comorbidity. The authors found that few clinical or demographic features of clients reliably predicted outcomes in CBT for children with anxiety. However methodological limitations meant that few firm conclusions could be drawn, for example few samples included enough children with non-anxiety comorbid conditions to be able to reliably detect effects of these conditions on outcome.

Rapee et al. (2013) suggested that comorbidity is a particularly important consideration for clinicians as up to 80% of young people with an anxiety disorder also meet criteria for at least one other clinical diagnosis. Several studies have found that the presence of one or more comorbid anxiety disorders does not

appear to adversely affect outcome at post-treatment (Rapee, 2003; Compton et al., 2014). However, Rapee (2003) found some suggestion that children with comorbidity showed a slight decline on parent-reported emotional and behavioural problems when assessed again one year later. Rapee et al. (2013) subsequently highlighted that although most of the research examining the effects of comorbidity on treatment response by looking at change in symptom severity across time has not shown significant effects, the few studies that have looked at outcome in categorical terms (e.g. diagnosis-free, treatment responder status) suggest that children with comorbid conditions, especially non-anxiety diagnoses, are less likely to recover. The authors examined outcomes from both perspectives, finding that while children with additional diagnoses did respond at a similar rate to children without, those with additional anxiety disorders, externalising disorders or mood disorders were less likely to become diagnosis-free within the standard treatment period and had higher levels of symptoms at post-treatment and follow-up. Children with comorbid mood disorders appeared to have the worst outcomes. The authors concluded that children and young people with comorbid mood disorders responded to treatment but were generally more severe in their clinical presentation and so may require longer treatment or additional treatment components. This replicates a similar finding by Berman, Weems, Silverman and Kurtines (2000) that children with comorbid low mood were less likely to be categorised as treatment successes. It is therefore plausible that children with comorbid anxiety, mood or externalising disorders would be less likely to respond to a brief intervention delivered by a parent using self-help materials.

Initial symptom severity has also been identified as a possible predictor of treatment outcome in trials of therapist-delivered child CBT, although again the existing findings are mixed. Nilsen et al. (2012) found that four of six studies showed a non-significant effect of severity on treatment outcome, two studies found significant effects, and one found a non-significant trend. Compton et al. (2014) found that parent-reported and independently evaluated initial symptom severity did predict treatment outcome in the Child/Adolescent Anxiety Multimodal Study (CAMS), the largest trial of treatment for childhood anxiety to date. Children with more severe anxiety symptoms at the outset also had more severe symptoms on questionnaire measures following treatment and were less likely to be classified as treatment responders. It is not yet known whether a low-intensity treatment delivered by parents is suitable for children with more severe symptoms or whether children with more severe anxiety should instead be offered more intensive treatments.

It is also not known whether parents are able to deliver guided bibliotherapy treatments with children across the age span. Older children, who are more independent from their parents, may be less motivated by positive reinforcement from parents or less likely to attempt exposure-based tasks at the parent's suggestion, while younger children may benefit from parental support in planning and carrying out exposure tasks and challenging anxious cognitions. Barrett, Dadds and Rapee (1996) found that the addition of family anxiety management sessions to standard CBT improved treatment outcomes for children aged seven to ten, but had no additional benefit for children aged 11 to 14, suggesting that parental

involvement may be more relevant for younger children. In contrast, Bodden et al. (2008) found both child CBT and family CBT were more effective for younger children. It is not yet known whether the effectiveness of guided bibliotherapy delivered via parents varies according to child age.

Rationale and Aims

Overall, greater understanding of how features of the child such as age, symptom severity and comorbidity affect outcomes for guided parent delivered CBT would be useful. Progress in this area would help inform treatment choice, allowing families to be directed towards the most appropriate treatments and methods of delivery for their needs and personal circumstances. It is also important to consider how trajectories of change appear over a longer time period, as it is not yet known whether all children maintain the gains made during guided bibliotherapy, or whether some show different patterns of response. This study will therefore examine the effects of child demographic and clinical features on maintenance of outcomes across a four year follow-up period for a guided parent-delivered CBT treatment for anxious children. Specifically the study will evaluate the impact of age, initial symptom severity, and co-morbid internalising and externalising symptoms on outcomes at post-treatment, six months, and four years post-intervention.

Method

Participants

Participants were families who took part in the Thirlwall et al. (2013) trial of guided CBT bibliotherapy. They were recruited to the trial between April 2008 and December 2010 from consecutive referrals made from primary and secondary care to the Berkshire Child Anxiety Clinic at the University of Reading. Families were eligible for inclusion if the child was aged between seven and 12 at the time of initial assessment and had a primary diagnosis of generalised anxiety disorder, specific phobia, separation anxiety disorder, social phobia or panic disorder/agoraphobia as assessed by parent and child report on the ADIS-C/P (Thirlwall et al., 2013). Families were ineligible if the child had a significant intellectual impairment, the child scored above the clinical cut-off on the Social Communications Questionnaire and autistic spectrum disorder had not been ruled out by the referrer, if the primary caregiving parent had a disabling mental health condition or learning difficulty, or if the primary caregiving parent had a current anxiety disorder.

In total, 194 families took part in the trial (see Figure 1). Of these, 166 (86%) were white, 119 (61%) of families included a parent with a higher or professional occupation and 112 (58%) of parents were in their first marriage. Following initial assessment, 64 (33%) were randomised to the 'full' treatment group, 61 (31%) to the 'brief' treatment group and 69 (36%) to a 12 week wait-list group. Of the 125 families assigned to immediate treatment, 96 (77%) completed post-treatment assessments and 87 (70%) of these participated in follow-up assessments six

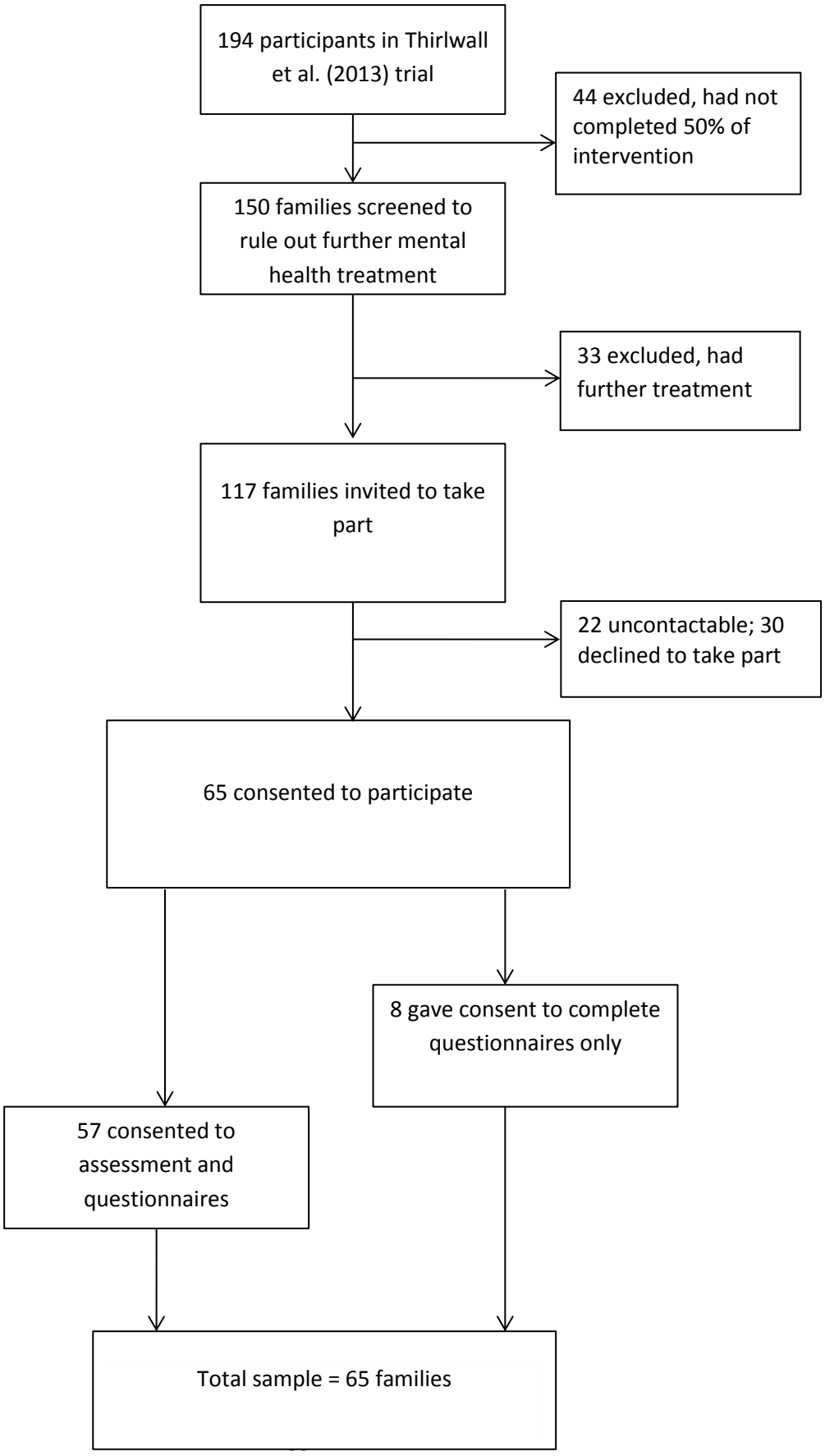

Figure 1. Participant flow, withdrawals and exclusions.

months later. Of the 69 families in the wait-list condition, 63 (91%) began either full or brief treatment 12 weeks later and 45 (65%) also completed assessments at the end of treatment.

Families were invited to participate in the present follow-up study if they had completed at least 50% of the treatment sessions offered and gave consent to be contacted for future research. Families were excluded if the child had received any further psychotherapy or pharmacotherapy for a mental health problem so that only treatment effects of the bibliotherapy intervention were being measured. Invitation letters were sent to families, informing them about the study and asking them to contact the clinic if they wished to opt out. Families were then contacted by telephone to invite them to complete a follow-up assessment.

Of the 150 families who had completed at least 50% of the treatment, 30 declined to participate, 33 were excluded as the child had received further treatment for a mental health problem, and 22 could not be reached by telephone, email or letter (see Figure 1). Of those who had received further treatment, 17 had further treatment for anxiety, two had medication for ADHD, two had subsequently been diagnosed with ASD, two had developed eating disorders and ten did not give a reason for the treatment given. Of the families who declined to participate in the follow-up assessment, the most common reason given was lack of time, (n = 8); a further six initially consented then had to cancel their appointments and three stated that they thought the treatment had been unsuitable.

A total of 65 (56% of eligible) families participated in the follow-up assessments. Structured interviews were completed with 57 families using the

ADIS-C/P and completed questionnaires. In 48 of these families both the child and primary-caregiving parent completed the ADIS-C/P interview; in nine families only the parent participated. A further eight families completed questionnaires only (see Figure 1).

Ethical Considerations

Ethical approval for the study was granted by Berkshire Research Ethics Committee and the University of Reading Ethics Committee (see Appendix A). Families were provided with information sheets for both parents and children. Informed consent was given in writing by parents. In families where the child or adolescent was also participating in the assessment, their assent was given in writing (see Appendix B).

Measures

The primary and secondary outcome measures used at post-treatment and six month follow-up were repeated.

Primary Outcome Measures:

1. *Anxiety Disorders Interview Schedule for DSM-IV: child and parent versions* (ADIS-C/P: Silverman & Albano, 1996). The ADIS-C/P is a semi-structured interview for both child and parent that primarily assesses anxiety disorders according to DSM-IV diagnostic criteria, but also gathers data on mood and externalising behaviour problems and other mental health problems. When criteria for a particular diagnosis have been met, a Clinician Severity Rating (CSR) is assigned for that diagnosis on a scale from 0 to 8, where ratings of four and above are considered clinically significant. The ADIS-C/P has been shown to have excellent

psychometric properties (Silverman, Saavedra & Pina, 2001). ADIS-C/P assessments were carried out by one of two assessors. For each assessor, the first 20 assessments were discussed and double coded with an experienced assessor whose reliability was established. Reliability was then formally checked and if kappa levels exceeded .85 the assessor was deemed to be reliable. Every sixth assessment thereafter was discussed with the consensus assessor to prevent rater drift. Both assessors achieved kappa levels in excess of .95 on diagnostic classifications and intraclass correlations of over .95 on clinician severity ratings.

Face-to-face assessments were completed with 47 families, either in the family home or in the Berkshire Child Anxiety Clinic, and 10 assessments were completed by telephone. The telephone version of the interview has been shown to have excellent to good reliability with the face-to-face version (Lyneham & Rapee, 2005).

2. *Clinical Global Impression- Improvement Scale* (CGI-I: Guy, 1976). The CGI-I is a seven-point clinician-rated scale measuring the child's improvement from baseline, where lower scores indicate greatest improvement. A score of one indicates that the child is 'very much' improved and no longer meets diagnostic criteria for any disorder, whereas a score of four indicates no change and seven indicates that the child's presentation is very much worse, with loss of functioning. A score of one or two (i.e. 'much' or 'very much' improved) is generally considered to represent a good treatment outcome. As with the ADIS-C/P, the first 20 ratings were discussed with an experienced rater and reliability was formally assessed. Both assessors achieved kappa levels in excess of .85.

Secondary Outcome Measures:

1. *Spence Children's Anxiety Scales: child and parent versions* (SCAS-C/P: Spence, 1998). The SCAS-C/P is a 44-item scale rating anxiety symptom severity, in line with DSM-IV diagnostic criteria. Both child and parent are asked to rate each item on a four-point scale, indicating the frequency of anxiety symptoms, e.g. "I would feel afraid of being at home on my own" (0 = never, 1 = sometimes, 2 = often, 3 = always). The scale assesses anxiety in six areas: separation anxiety, social anxiety, obsessive compulsive problems, panic or agoraphobia, generalised anxiety and fear of physical injury. Scores on the SCAS-C/P correlate highly with other measures of anxiety symptoms (Muris, Schmidt & Merckelbach, 2000) and have demonstrated adequate test-retest reliability (Spence, 1998). Cronbach's Alpha was .92 for child report and .91 for parent report in this study.

2. *Child's Anxiety Impact Scale: child and parent versions* (CAIS-C/P: Langley, Bergman, McCracken, & Piacentini, 2004). This scale assesses the impact of anxiety on functioning in home, family and social domains. Parents and children rate 34 items to indicate the extent to which anxiety has caused problems, such as "in the past month, how much trouble has your child had making new friends due to anxiety?" (0 = not at all, 1 = just a little, 2 = pretty much, 3 = very much). The CAIS-C/P has been shown to have good psychometric properties (Langley et al., 2013). Cronbach's Alpha was .83 for child report and .86 for parent report in this study.

3. *Short Mood and Feelings Questionnaire: child and parent versions* (SMFQ-C/P; Angold, Costello, Messer, & Pickles, 1995). The SMFQ-C/P is a 13-item

questionnaire measuring symptoms of depression, corresponding to DSM-IV diagnostic criteria. Parents and children rate items such as "S/he didn't enjoy anything at all" (0 = not true, 1 = sometimes, 2 = true). The SMFQ has been widely used as a screening tool and has good psychometric properties (Sharp, Goodyer & Croudace, 2006). Cronbach's Alpha was .89 for child report and .74 for parent report in this study.

4. *Strengths and Difficulties Questionnaire* (Goodman, 1997). The SDQ is a 25-item behavioural checklist completed by parent and child. Five scales are generated, measuring emotional symptoms, conduct problems, hyperactivity, peer relationship problems and pro-social behaviour. Only the conduct problems scale was used in this study as anxiety and depression were assessed in more depth by the other measures. Parents and children rate items such as "Often has temper tantrums or hot tempers" (0 = not true, 1 = somewhat true, 2 = often true). Good test-retest reliability has been shown (Goodman, 2001). Cronbach's Alpha was .64 for child report and .41 for parent report on the conduct problems scale in this study.

Intervention

The intervention used by Thirlwall et al. (2013) was a guided parent-delivered CBT treatment for anxious children. Parents were given a self-help book ('Overcoming Your Child's Fears and Worries', Creswell & Willetts, 2007) and received one of two forms of therapist support; 'Full' guided parent-delivered CBT (which consisted of four hour-long face-to-face sessions and four 20 minute telephone contacts) and 'Brief' guided parent-delivered CBT (which consisted of

two hour-long face-to-face sessions and two 20 minute telephone contacts). Parents completed homework tasks between sessions, both independently and with their child. The role of the therapist was to support and encourage parents to work through the self-help book, rehearse skills and to problem-solve any difficulties that arose. The therapists guiding parents consisted of Clinical Psychologists, Trainee Clinical Psychologists and graduate psychology students. Face-to-face sessions took place at a location that suited the family, either within the clinic itself, at CAMHS clinics throughout Berkshire or in family homes. Telephone sessions took place by prior arrangement and wherever possible these were scheduled to take place on the same day of the week and time as face-to-face appointments had.

Analytic Strategy

To investigate possible predictors of treatment outcome based on diagnostic data and clinician-rated improvement, the SPSS Generalised Estimating Equations (GEE) procedure was used to fit separate longitudinal regression models for each candidate predictor. This method was chosen as it is able to include data from all time points in the analysis. This maximised the sample size available for analysis and allowed examination of any interactions between the candidate predictors and time. This was prioritised as differing effects of candidate predictors at the four time points could shed light on changing trajectories of recovery over time.

Each model included the candidate predictor, time (post-treatment, six month follow-up or four year follow-up) and the interaction term. Each GEE

analysis was first run using five different correlation structure options (independent, autoregressive, exchangeable, M-dependent and unstructured) then the correlation structure with the lowest quasi-likelihood under the independence model criterion (QIC) was selected. Age at initial assessment was dichotomised into younger and older participants in all GEE analyses.

Mother-reported SCAS scores at initial assessment were used as the measure of initial symptom severity in the predictor analyses as the questionnaire takes into account anxiety in all domains and mother-report may have had greater validity than child-report for the younger children in the trial. Mother-reported SDQ-conduct scores were used to measure externalising behaviour problems and child-reported SMFQ was used to measure symptoms of low mood. The presence of more than one ADIS-IV anxiety diagnosis was used as the measure of anxiety comorbidity.

Data Preparation

Participants with missing data could be included in the analysis if data from baseline and one further assessment were available. The diagnostic outcome variables were categorized as binary and so distributions were not relevant. Distributions of CGI-I scores were examined for skewness and kurtosis and found to be positively skewed so a logarithmic transformation was applied before conducting predictor analyses.

Results

Sample Characteristics

Long term follow-up (LTFU) assessments took place 39 to 61 months after the initial assessment, with a mean follow-up period of 50 months (*SD* = 6.2 months). Young people were aged 11 to 17 at follow-up. Participants who took part in LTFU assessments were compared to participants who did not on the baseline measures used as predictors. Multivariate ANOVA showed that the two groups did not differ on mother-reported SDQ-conduct, $F(1, 162) = 3.02$, *n.s.*, or child-reported SMFQ scores, $F(1, 162) = .671$, *n.s.*, but the LTFU group were younger, $F(1, 162) = 8.92$, $p = .003$, and had lower scores on mother-reported SCAS, $F(1, 162) = 7.94$, $p = .005$. Participants in the LTFU group had a mean age of 9 years 0 months at initial assessment, compared to a mean age of 9 years 9 months for those who did not take part. A chi-square test comparing the numbers of participants in each group who had one or more comorbid anxiety diagnosis was not significant, $\chi^2(1, N = 194) = .993$, *n.s.*

Table 1.
Scores on child and parent reported questionnaires at initial assessment

	Child self-report				Parent report			
	LTFU sample		Non-LTFU sample		LTFU sample		Non-LTFU sample	
Measure	*M*	*SD*	*M*	*SD*	*M*	*SD*	*M*	*SD*
SCAS	35.31	16.89	39.59	18.20	32.84	12.85	40.42	17.91
CAIS	14.60	11.26	17.03	13.09	12.16	10.35	16.26	13.81
SMFQ	6.68	5.22	7.45	5.79	5.58	5.66	7.04	6.08
SDQ-C	2.47	2.01	2.76	1.82	1.73	1.80	2.21	1.77

Note SCAS = Spence Children's Anxiety Scale, CAIS = Child Anxiety Impact Scale, SMFQ = Short Mood and Feelings Questionnaire, SDQ-C = Strengths and Difficulties Questionnaire- Conduct scale

Diagnostic Status

Diagnostic data from ADIS assessments at LTFU were available for 57 participants. Participants were categorised according to whether they met diagnostic criteria for a) their primary diagnosis, b) any anxiety disorder and c) any anxiety, mood or behaviour disorder. The majority of children did not report difficulties which met the threshold for diagnosis. Frequencies are shown in Table 2. Percentages of participants meeting diagnostic criteria for their primary diagnosis at all four time points are shown in Figure 2. Chi-square tests showed no differences in frequencies of meeting diagnostic criteria between participants who had received the brief and long versions of the treatment and so all subsequent analyses were collapsed.

Table 2.
Frequencies of participants meeting diagnostic criteria at long term follow-up

Type of diagnosis	No longer met criteria at LTFU
Primary diagnosis	45 (79%)
Any ADIS-IV anxiety disorder	36 (63%)
Any ADIS-IV anxiety, mood or behaviour disorder	35 (61%)

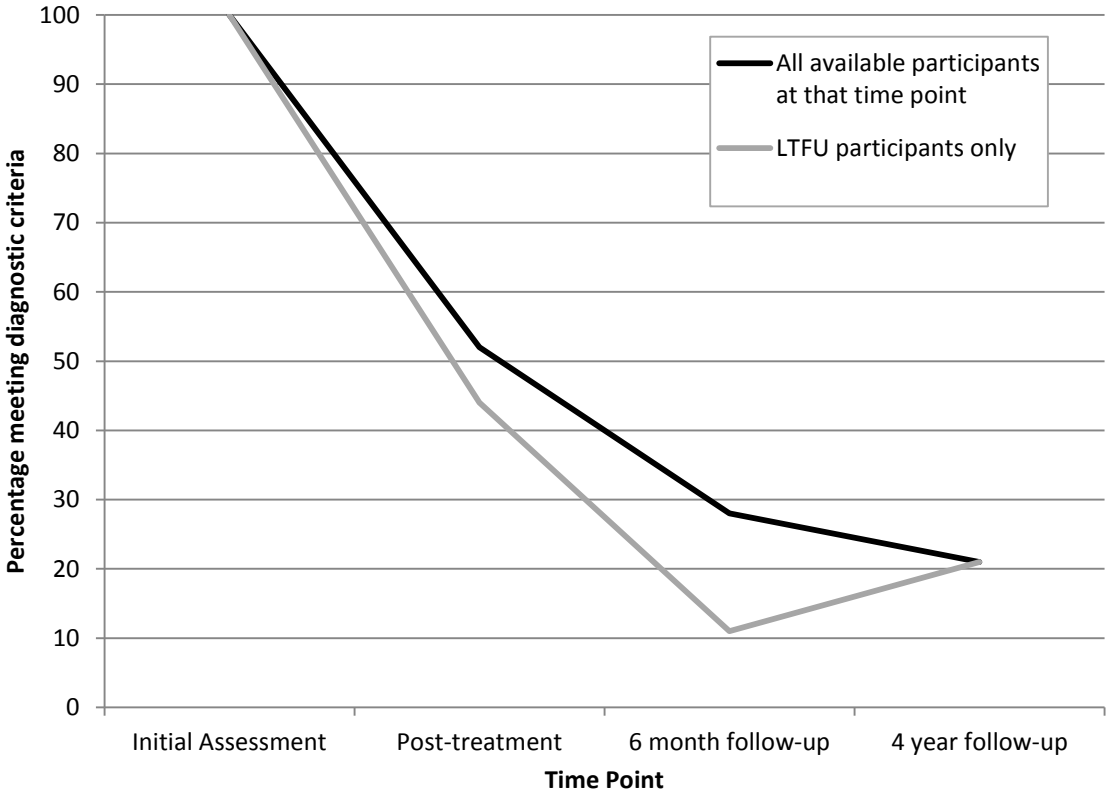

Figure 2. Percentage of participants meeting criteria for primary diagnosis at all four time points

Table 3.
Means and standard deviations of questionnaire scores at long term follow-up

Source	SCAS	CAIS	SMFQ	SDQ-C
Mother report	14.62 (11.68)	7.44 (7.78)	2.08 (3.00)	.97 (1.11)
Child self-report	24.72 (19.80)	9.40 (10.05)	3.91 (4.89)	1.65 (1.70)

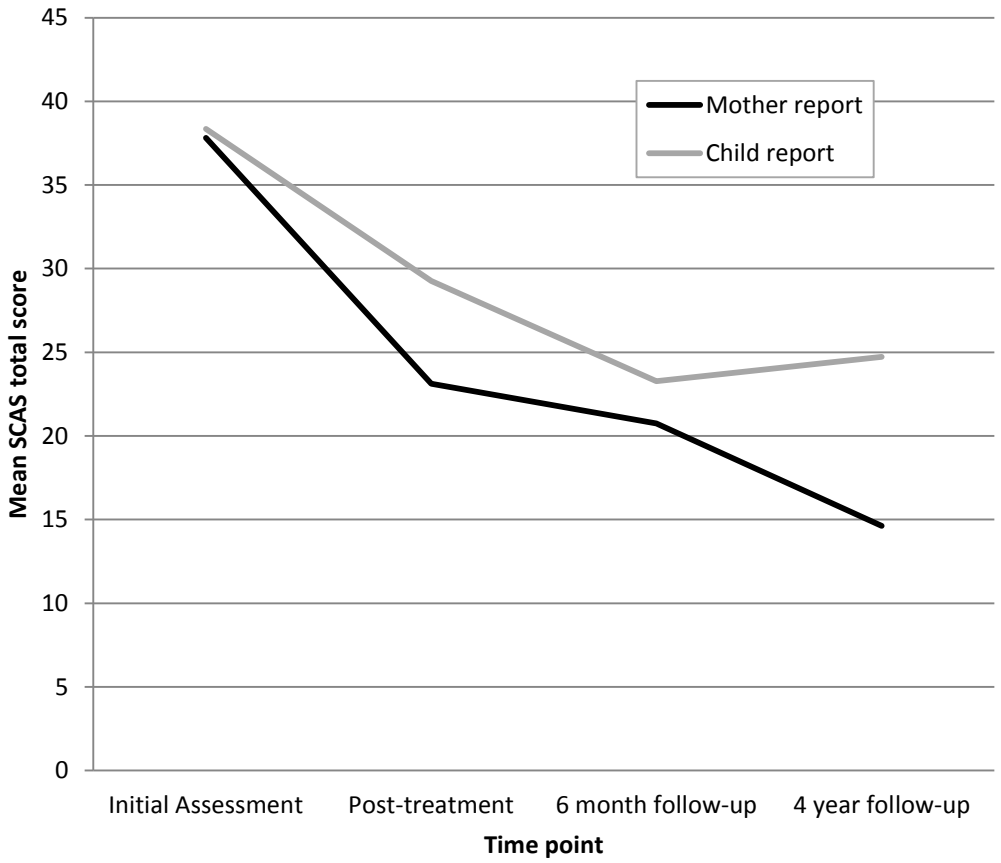

Figure 3. Mean SCAS scores at all four time points

Secondary Outcome Measures

Parent-reported SCAS, CAIS, SMFQ and SDQ-C total scores were available for 63 participants. Child self-report scores were available for 54 of these. Means and standard deviations are reported in Table 3. Neither parents nor young people reported high levels of anxiety symptoms at four year follow-up. Change in mean SCAS scores across time is shown in Figure 3. Mean scores on the SCAS and CAIS questionnaires at long term follow-up were comparable to those found in normative samples (Langley et al., 2004; Nauta et al., 2004) and scores on the SMFQ and SDQ-C fell below clinical cut-offs.

Predictor Analyses

Of the variables of interest, only initial symptom severity was found to predict whether participants met criteria for their primary anxiety diagnosis at four year follow-up. This effect was no longer significant when a more conservative .01 alpha level was used. Predictors of meeting diagnostic criteria for the child's primary diagnosis are shown in Table 4.

Table 4.

Predictors of meeting diagnostic criteria for primary diagnosis

Variable	β	*SE*	Wald	*p*	*OR*
Model 1					
Time = post-treatment	.92	.38	5.92	.02*	2.51
Time = 6 month follow-up	-.62	.44	1.97	.16	.54
Age	-.40	.56	.53	.47	.67
Time = post-treatment × age	.40	-.70	.50	.48	1.49
Time = 6 month follow-up × age	1.32	.04	4.12	.04	3.74
Model 2					
Time = post-treatment	1.95	.79	6.09	.01*	7.04
Time = 6 month follow-up	.78	.86	.82	.37	2.18
SCAS-P	.04	.02	4.96	.03*	1.04
Time = post-treatment × SCAS-P	-.02	.02	.98	.32	.98
Time = 6 month follow-up × SCAS-P	-.02	.02	.67	.41	.94
Model 3					
Time = post-treatment	1.65	.73	5.10	.02*	5.22
Time = 6 month follow-up	.31	.95	.11	.74	1.37
Comorbid Anxiety	1.26	.83	2.27	.13	3.52
Time = post-treatment × comorbid anxiety	-.41	.82	.25	.62	.66
Time = 6 month follow-up × comorbid anxiety	-.10	1.04	.01	.92	.90
Model 4					
Time = post-treatment	.82	.44	3.39	.07	2.26
Time = 6 month follow-up	-.39	.53	.54	.46	.68
SMFQ-C	-.01	.05	.08	.78	.99
Time = post-treatment × SMFQ-C	.05	.06	.85	.36	1.06
Time = 6 month follow-up × SMFQ-C	.08	.06	1.54	.21	1.08
Model 5					
Time = post-treatment	1.09	.43	6.54	.01*	6.90
Time = 6 month follow-up	.22	.50	.20	.65	3.33
SDQ-P conduct scale	.08	.14	.28	.60	1.43
Time = post-treatment × SDQ-P-Conduct	.08	.16	.24	.63	1.47
Time = 6 month follow-up × SDQ-P-Conduct	.02	.16	.02	.90	1.41

Note *df* = 1. SCAS-P = Spence Children's Anxiety Scale, parent version. SMFQ-C = Short Mood and Feelings Questionnaire, child version. SDQ-P-Conduct = Strengths and Difficulties Questionnaire, parent report, conduct problems scale.

* $p < .05$ ** $p = <.01$

Table 5

Predictors of meeting diagnostic criteria for any ADIS-IV anxiety diagnosis

Variable	β	*SE*	Wald	*p*	*OR*
Model 1					
Time = post-treatment	1.21	.41	8.70	.003**	3.37
Time = 6 month follow-up	.03	.45	.01	.94	1.04
Age	-.02	.52	.00	.96	.98
Time = post-treatment × age	-.45	.57	.62	.43	1.58
Time = 6 month follow-up × age	.43	.56	.60	.44	1.54
Model 2					
Time = post-treatment	1.45	.89	2.64	.10	4.26
Time = 6 month follow-up	1.04	.72	2.05	.15	2.82
SCAS-P	.05	.02	7.02	.008**	1.05
Time = post-treatment × SCAS-P	.01	.03	.04	.84	1.01
Time = 6 month follow-up × SCAS-P	-.02	.02	1.48	.22	.98
Model 3					
Time = post-treatment	1.75	.64	7.61	.006**	5.76
Time = 6 month follow-up	.84	.67	1.58	.21	2.32
Comorbid Anxiety	1.38	.65	4.49	.03*	3.97
Time = post-treatment × comorbid anxiety	-.28	.72	.15	.70	.76
Time = 6 month follow-up × comorbid anxiety	-.75	.74	1.03	.31	.47
Model 4					
Time = post-treatment	1.01	.46	4.80	.03*	2.74
Time = 6 month follow-up	.08	.41	.04	.84	1.09
SMFQ-C	-.03	.05	.33	.56	.97
Time = post-treatment × SMFQ-C	.06	.05	1.16	.28	1.06
Time = 6 month follow-up × SMFQ-C	.01	.05	.07	.80	1.01
Model 5					
Time = post-treatment	1.43	.40	12.69	.00**	4.19
Time = 6 month follow-up	.48	.35	1.91	.17	1.61
SDQ-P conduct scale	.18	.16	1.21	.27	1.19
Time = post-treatment × SDQ-P-Conduct	.06	.20	.08	.78	1.06
Time = 6 month follow-up × SDQ-P-Conduct	-.11	.17	.45	.50	.89

Note *df* = 1. SCAS-P = Spence Children's Anxiety Scale, parent version. SMFQ-C = Short Mood and Feelings Questionnaire, child version. SDQ-P-Conduct = Strengths and Difficulties Questionnaire, parent report, conduct problems scale.

* $p < .05$ ** $p = <.01$

Table 6

Predictors of meeting diagnostic criteria for any ADIS-IV anxiety, mood or behaviour disorder

Variable	β	*SE*	Wald	*p*	*OR*
Model 1					
Time = post-treatment	1.35	.43	9.72	.002**	3.83
Time = 6 month follow-up	.11	.46	.05	.82	1.11
Age	.21	.53	.16	.69	1.24
Time = post-treatment × age	.07	.58	.02	.90	1.08
Time = 6 month follow-up × age	.42	.56	.56	.46	1.53
Model 2					
Time = post-treatment	1.83	.85	4.66	.03*	6.25
Time = 6 month follow-up	1.39	.67	4.26	.04*	4.03
SCAS-P	.05	.02	7.11	.008**	1.05
Time = post-treatment × SCAS-P	-.10	.02	.19	.67	.99
Time = 6 month follow-up × SCAS-P	-.03	.02	3.13	.08	.97
Model 3					
Time = post-treatment	1.84	.62	8.83	.003**	6.31
Time = 6 month follow-up	.87	.65	1.79	.18	2.39
Comorbid Anxiety	1.44	.63	5.17	.02*	4.23
Time = post-treatment × comorbid anxiety	-.53	.71	.56	.46	.59
Time = 6 month follow-up × comorbid anxiety	-.72	.72	1.00	.32	.49
Model 4					
Time = post-treatment	1.21	.44	7.54	.006**	3.37
Time = 6 month follow-up	.32	.41	.62	.43	1.38
SMFQ-C	.03	.05	.40	.53	1.03
Time = post-treatment × SMFQ-C	.01	.05	.04	.84	1.01
Time = 6 month follow-up × SMFQ-C	-.02	.05	.13	.72	.98
Model 5					
Time = post-treatment	1.48	.44	11.08	.001**	4.39
Time = 6 month follow-up	.62	.42	2.19	.14	1.86
SDQ-P conduct scale	.25	.18	2.07	.15	1.29
Time = post-treatment × SDQ-P-Conduct	.08	.22	.11	.74	1.08
Time = 6 month follow-up × SDQ-P-Conduct	-.11	.18	.39	.53	.90

Note *df* = 1. SCAS-P = Spence Children's Anxiety Scale, parent version. SMFQ-C = Short Mood and Feelings Questionnaire, child version. SDQ-P-Conduct = Strengths and Difficulties Questionnaire, parent report, conduct problems scale.

* $p < .05$ ** $p = <.01$

Initial symptom severity was also found to predict whether participants met criteria for any anxiety disorder assessed by the ADIS-C/P. This effect was significant at the .01 alpha level. The presence of comorbid anxiety disorders at initial assessment predicted meeting criteria for any anxiety disorder at the .05 alpha level. Predictors of meeting diagnostic criteria for any ADIS-IV anxiety disorder are shown in Table 5. Predictors of meeting diagnostic criteria for any anxiety, mood or externalising behaviour disorder were the same as those for meeting criteria for any anxiety disorder. Predictors of meeting criteria for any overall disorder are shown in Table 6.

Change in Diagnostic Status

Diagnostic status at LTFU was then compared to diagnostic status at the last available assessment for that participant: 11 participants (19%) who had met criteria at their last assessment had since recovered, 34 (60%) had been assessed as recovered at their last assessment and remained so, seven (12%) had recovered at their last assessment and had since relapsed, and five (9%) had met criteria at their last assessment and continued to do so at LTFU. Logistic regression was used to examine possible predictors of moving to recovery during the long term follow-up period. A test of the full model against a constant only model was not significant, χ^2 (1, *N* = 52) = 9.62, *n.s.*

Clinician-rated Improvement

Clinician-rated CGI-I ratings of overall clinical improvement relative to initial assessment at post-treatment, six month follow-up and LTFU are shown in Table 7. At LTFU, the mean CGI-I rating was 1.70 (*SD* = 1.15), compared to 2.35 (*SD* = 1.20) at

post-treatment and 1.94 (*SD* = 1.27) at six month follow-up. Only initial symptom severity was found to predict CGI-I ratings. Predictors of CGI-I ratings are shown in Table 8.

Table 7.
Frequencies of Clinical Global Impression- Improvement ratings at post-treatment, six month follow- up and long term follow-up.

Clinician rating	Post-treatment (n = 141)	Six month follow-up (n = 87)	Long term follow-up (n = 57)
1- Very much improved	36 (25.5%)	45 (51.7%)	36 (63.2%)
2- Much improved	58 (41.1%)	22 (25.3%)	9 (15.8%)
3- Minimally improved	19 (13.5%)	6 (6.9%)	9 (15.8%)
4- No change	19 (13.5%)	9 (10.3%)	0 (0%)
5- Minimally worse	8 (5.7%)	4 (4.6%)	2 (3.5%)
6- Much worse	1 (0.7%)	1 (1.1%)	1 (1.8%)
7- Very much worse	0 (0%)	0 (0%)	0 (0%)

Further Mental Health Treatment

Data on receiving further treatment were available for a total of 127 participants. According to parent report, 33 participants (26%) had received further treatment for a mental health problem after taking part in the trial. Taken together with the diagnostic data on those who still met criteria for a child mental health disorder at four year follow-up, this meant that 55 (61%) of the 90 participants for whom data on diagnostic classification or further treatment were available could be classified as not recovered following parent-delivered guided bibliotherapy. Logistic regression was used to examine predictors of receiving further treatment. Initial symptom severity was found to predict further mental health treatment using a conservative alpha level. Both higher age and the presence of comorbid

anxiety predicted further mental health treatment when a .05 alpha level was used.

Results are shown in Table 9.

Table 8
Predictors of Clinical Global Impression-Improvement ratings

Variable	β	*SE*	Wald	*p*	*OR*
Model 1					
Time = post-treatment	.13	.05	6.32	.01*	1.14
Time = 6 month follow-up	.02	.05	.18	.67	1.02
Age	.01	.06	.04	.84	1.01
Time = post-treatment × age	.02	.07	.05	.82	1.02
Time = 6 month follow-up × age	.04	.07	.32	.57	1.04
Model 2					
Time = post-treatment	.19	.07	7.49	.006**	1.21
Time = 6 month follow-up	.14	.06	4.86	.027*	1.15
SCAS-P	.01	.00	8.19	.004**	1.01
Time = post-treatment × SCAS-P	-.00	.00	.83	.36	1.00
Time = 6 month follow-up × SCAS-P	-.00	.00	3.16	.08	1.00
Model 3					
Time = post-treatment	.16	.06	7.24	.007**	1.18
Time = 6 month follow-up	.06	.06	.89	.35	1.06
Comorbid Anxiety	.08	.06	1.79	.18	1.09
Time = post-treatment × comorbid anxiety	-.03	.07	.19	.66	.97
Time = 6 month follow-up × comorbid anxiety	-.02	.07	.05	.82	.98
Model 4					
Time = post-treatment	.07	.05	2.07	.15	1.07
Time = 6 month follow-up	.02	.05	.17	.68	1.02
SMFQ-C	-.00	.00	.82	.37	1.00
Time = post-treatment × SMFQ-C	.01	.01	2.43	.12	1.01
Time = 6 month follow-up × SMFQ-C	.00	.01	.08	.77	1.00
Model 5					
Time = post-treatment	.11	.05	6.16	.01*	1.12
Time = 6 month follow-up	.07	.04	2.85	.09	1.08
SDQ-P conduct scale	.02	.02	1.25	.26	1.02
Time = post-treatment × SDQ-P-Conduct	.01	.02	.42	.52	1.01
Time = 6 month follow-up × SDQ-P-Conduct	-.02	.02	.87	.35	.98

Note *df* = 1. SCAS-P = Spence Children's Anxiety Scale, parent version. SMFQ-C = Short Mood and Feelings Questionnaire, child version. SDQ-P-Conduct = Strengths and Difficulties Questionnaire, parent report, conduct problems scale.
* $p < .05$ ** $p = <.01$

Table 9.
Predictors of receiving further mental health treatment in the long term follow-up period

Variable	B	*SE*	Wald	*p*	OR
Age	.362	.179	4.075	.044*	1.436
SCAS-P	.056	.019	8.773	.003**	1.058
Comorbid anxiety	-.769	.736	1.092	.296	.464
SMFQ-C	.111	.048	5.241	.022*	1.117
SDQ-P conduct scale	-.064	.152	.179	.673	.938

Note *df* = 1. SCAS-P = Spence Children's Anxiety Scale, parent version. SMFQ-C = Short Mood and Feelings Questionnaire, child version. SDQ-P-Conduct = Strengths and Difficulties Questionnaire, parent report, conduct problems scale.
* $p < .05$ ** $p = <.01$

Discussion

This study examined whether age, symptom severity or comorbidity predicted treatment outcome among children who had received parent-delivered guided bibliotherapy for anxiety disorders an average of four years previously as part of a randomised controlled trial (Thirlwall et al., 2013). Findings suggested that among the young people who took part in follow-up assessments there was a trend for maintained or continued recovery since the end of treatment. Few of the assessed children had relapsed since their last assessment and there was an increase in the proportion of children rated as 'much improved' or 'very much improved' on a clinician rating scale. Mean scores on measures of anxiety, anxiety interference, low mood and externalising behaviour symptoms were comparable to normative populations at four year follow-up. Of the 127 young people for whom data on further mental health treatment were available, only 33 had gone on to have further input from services since participating in the trial. Of the 90 participants who either completed a follow-up assessment or provided data on further mental health treatment, 39% had recovered from all their diagnoses

without receiving any further mental health treatment, and 50% had recovered from their primary diagnosis. These findings are consistent with other studies showing treatment gains are often maintained several years later (Barrett, Duffy, Dadds & Rapee, 2001; Kendall, Safford, Flannery-Schroeder & Webb, 2004; Saavedra, Silverman, Martino-Lopez & Kurtines, 2010). Of the 194 participants who entered the initial trial, 45 (23%) were known to be in remission from their primary diagnosis at long term follow-up without having received any further treatment.

Predictor analyses showed that children who had higher scores on a parent-reported measure of anxiety symptoms at initial assessment were less likely to recover from their primary diagnosis, were more likely to still meet criteria for an anxiety disorder and were more likely to meet criteria for any anxiety, mood or externalising behaviour disorder at four year follow-up. Initial symptom severity also predicted clinician-rated improvement, which considers anxiety across all domains. The consistency of this finding suggests that symptom severity can reliably predict outcome in this type of treatment. This is in line with the findings of Liber et al. (2010), who found that severity predicted recovery following a therapist-delivered CBT for anxiety, but in the Nilsen, Eisemann and Kvernmo (2013) review of predictors of outcomes in child CBT only two of seven studies found an effect. It may be that severity is a stronger predictor of outcome in guided bibliotherapy than in therapist-delivered interventions. However, effect sizes were small, suggesting that the treatment is still effective for many children in this population who presented with severe symptoms. Children who met criteria for more than one anxiety disorder at initial assessment were more likely to meet criteria for any

anxiety disorder or to meet criteria for any anxiety, mood or externalising behaviour disorder at follow-up, although the odds ratios were small and this effect did not remain when a more conservative .01 alpha level was used. Children with more than one anxiety disorder were no less likely to have recovered from their primary diagnosis than children who only met criteria for one disorder at the initial assessment.

Self-reported symptoms of comorbid low mood and parent-reported externalising behaviour problems measured at initial assessment did not predict recovery in terms of diagnosis or clinician-rated improvement four years later. However, rates of symptoms of low mood or externalising behaviour problems were relatively low in this sample and few children had mood (4%) or behaviour (14%) problems that reached the threshold for diagnosis at initial assessment. Consequently it is unclear whether severe difficulties with low mood or externalising behaviour would have a negative impact on outcomes in this type of treatment. Age was also not found to predict treatment outcome measured by the structured diagnostic interview or clinician improvement rating.

Further support for the role of symptom severity in predicting outcomes was found when data on later mental health treatment were examined. Children with more severe symptoms at initial assessment, older children, and those with comorbid externalising behaviour problems were more likely to have gone on to receive further treatment, suggesting that parent-delivered guided bibliotherapy may not be optimal for these children. Although a minority of studies has shown that older children and those with non-anxiety comorbidity are less likely to recover

following therapist-delivered CBT, age and comorbidity are seldom found to predict outcomes (Nilsen, Eisemann & Kvernmo, 2013), and so it is possible that the effect found here is specifically due to the type of intervention used. As the number of children in the sample with externalising behaviour problems was low, it is possible that the four children who were not included in this study as they were later prescribed medication for ADHD or received a diagnosis of ASD may have disproportionately affected this finding as they are likely to have shown symptoms of externalising behaviour problems at the initial assessment.

The effect of age on further mental health treatment may suggest that older children with anxiety need more input than their younger counterparts or a different type of intervention. The lack of a similar effect of age on treatment outcome using diagnostic measures or clinician-rated improvement may reflect a lack of statistical power to detect an effect due to the smaller sample size at four year follow-up. Alternatively, this finding could suggest that older participants, who would have been in mid-to-late adolescence at the time of follow-up assessment, were more likely to be referred for further treatment than those in middle childhood and early adolescence with similar levels of psychopathology. Anxiety problems and their consequences for wider functioning could be more noticeable to clinicians, school staff or parents in older adolescents as they negotiate important and stressful life events such as puberty, exams and the end of compulsory education, or young people at this age may be more likely to seek out help themselves. Duration of untreated anxiety problems, rather than chronological age, could also be relevant to outcomes and further mental health

need. Nauta et al. (2004) found that longer duration of untreated symptoms prior to treatment predicted the presence of more symptoms following treatment. Those entering treatment at a later age may have developed difficulties early in childhood but not come to the attention of mental health services for some time, perhaps resulting in avoidant patterns of behaviour becoming more established and more difficult to change using a low-intensity treatment delivered by parents. If so, this would provide further rationale for making low-intensity interventions widely available to families so that difficulties with anxiety can be addressed soon after they develop.

This study had some notable strengths, particularly relating to the measures used. Semi-structured diagnostic interviews covering anxiety across several domains as well as mood disorders and other types of difficulties allowed for a comprehensive assessment of each young person's mental health. Consideration of diagnoses other than the primary diagnosis is important as the focus of a child's anxiety may shift as the child develops, for example a child initially presenting with separation anxiety in early to middle childhood may experience more symptoms of social anxiety in early adolescence as they become more focused on their peer group than parents. Use of diagnostic criteria to determine improvement and recovery also allowed for a conservative evaluation of treatment outcome for the included participants. The ADIS-C/P is widely used in studies of treatment for anxiety in children and adolescents, allowing these findings to be compared with other research. All of the LTFU follow-up assessments and clinician ratings were conducted by independent assessors, not involved in the original trial. Scores on

both self-reported and parent-reported symptom measures converged with clinician ratings and diagnostic data to suggest broadly positive outcomes for the participants assessed, although only parent-reported data were available for some participants, which may have reduced the validity of the assessment.

However, only tentative conclusions can be drawn from these findings due to some limitations of the study. Of the participants in the original trial, 44 (23%) were excluded from this follow-up as they had not completed at least half of the treatment sessions offered, and so outcomes following and predictors of attrition during treatment could not be examined. As this type of treatment relies heavily on the motivation and ability of families to complete CBT tasks with minimal therapist input, better understanding of risk factors and reasons given for dropout could allow therapists to provide targeted support to families who may not otherwise complete the intervention. Overall attrition from initial assessment to long term follow-up was high, with only 34% of participants who entered the original trial providing questionnaire measures or a structured interview, and so the long term outcomes for the majority of participants remain unknown. It is possible that many more children experienced ongoing symptoms of anxiety after the intervention than the findings from the long term follow-up sample suggest. Other long term follow-up studies have managed to retain larger proportions of their sample, with Saavedra et al. (2010) recruiting 63% of participants eight to 13 years post-treatment and Manassis et al. (2004) achieving 68%.

A key limitation of this study is the incomplete data on the participants who went on to seek further mental health treatment. While some frequency data were

available on the type of problem that they experienced, this relied solely upon parent report and was incomplete. It remains unknown whether the young person had recovered from their primary diagnosis then relapsed and required help for the same type of anxiety, sought help for secondary anxiety diagnoses which had not been the focus of the guided bibliotherapy treatment, or required help for a different type of problem that had developed as a consequence of their anxiety. Alternatively, subsequent mental health problems could have been unrelated to the initial anxiety problem or be triggered by a subsequent adverse life event. Manassis et al. (2004) found that 30% of the participants in their follow-up study had received further therapy or medication for anxiety since receiving CBT six to seven years previously as children, but details were not reported on whether this treatment was in relation to the initial primary diagnosis or other problems with anxiety. Kendall et al. (2004) reported that 40% of participants had received outpatient therapy, 5% had received inpatient treatment and 32% had received psychotropic medication in the long term follow-up period, but data on the type of difficulties treated were not reported. In contrast, Barrett, et al. (2001) found at six year follow-up that only one participant had received further treatment and this person was excluded from analyses. The nature of ongoing mental health needs in children who do not respond to low-intensity treatment for anxiety is an important consideration as several longitudinal studies have shown that childhood anxiety disorders can often precede other mental health difficulties in adolescence and adulthood, particularly depression (Beesdo et al., 2007; Bittner et al., 2007), and so reducing this risk of later mental health problems is a key aim of interventions for

children and young people. Early identification of young people with greater treatment needs may facilitate better outcomes in a potentially at-risk population.

Use of low-intensity treatment as first-line treatments in a stepped-care model of mental healthcare relies on treatments that act as constructive gateways into higher-intensity treatments where necessary. It would therefore be useful for further research to explore the experiences and perceptions of families who had used parent-delivered guided bibliotherapy before going on to access further mental health services. Low-intensity CBT may be experienced as a useful introduction to therapy, perhaps facilitating young people seeking further CBT of longer duration with more therapist input if they had not recovered after guided bibliotherapy. Alternatively, an unsuccessful experience of brief therapy may leave families feeling frustrated and deterred from seeking the help of mental health services again.

The sample used in the Thirlwall et al. (2013) trial was drawn from a relatively affluent, educated, predominantly white British population where most households included two parents. Furthermore, families where the main caregiving parent was currently suffering from an anxiety or mood disorder were excluded from the trial, as parental anxiety has been associated with less favourable treatment outcomes for anxious children and adolescents (Cobham, Dadds & Spence, 1998). This resulted in a sample with relatively good prognosis and perhaps optimal characteristics to make use of a low-intensity intervention using written materials, and so the effects of initial symptom severity or comorbidity on treatment outcome may be less pronounced in this population. Parents may find it

more difficult to complete a guided bibiliotherapy intervention with limited therapist input when the child has more severe symptoms or more than one problem if the family is coping with other challenges such as parental mental health difficulties.

Participants were assessed between 3.3 and 5.1 years after initial assessment, creating variability in the amount of developmental change that could occur during the follow-up period. Those who were assessed after a shorter interval may have experienced fewer key transitions and stressors which could have triggered relapse or the emergence of new difficulties. The effects of predictors such as comorbid anxiety could be more significant in adolescents who have had to negotiate significant periods of stress or change, as subclinical anxiety may be exacerbated to the extent that it becomes clinically significant.

The effect of developmental change on anxiety in children and adolescents is a key issue as much of the anxiety experienced in childhood, although distressing, is developmentally appropriate and transient. This poses challenges for clinicians who must therefore distinguish between anxieties which will run their natural course without the need for intervention and those which will persist and become disabling, increasing risk of poorer mental health and social outcomes in adolescence and adulthood, such as depression and suicidality (Costello & Angold, 1995). As this study used a sample of children with relatively good prognosis, it is possible that some of the children included would have spontaneously recovered from their diagnosis even without treatment. However, the risks associated with untreated anxiety are such that participating in a brief, low-intensity intervention

unnecessarily might be considered to be preferable if such treatments were to be made widely available.

The analytic strategy created a degree of duplication as three categories of diagnosis were used as outcome variables in addition to clinician improvement ratings; however this allowed a consistent picture to emerge regarding the relevance of initial symptom severity for long term outcomes. Given this agreement between analyses, it is notable that although an effect of comorbid anxiety disorders on the presence of any anxiety diagnosis or any overall diagnosis at follow-up was found, comorbid anxiety did not predict the need for further mental health treatment. Taken together with the finding that 37% of those assessed at long term follow-up met criteria for an anxiety disorder, this could suggest that some young people who begin treatment with more than one anxiety diagnosis continue to meet criteria for secondary diagnoses but do not necessarily seek or receive treatment for these, possibly leaving unmet mental health needs in this group. Alternatively, this may reflect a decision not to have treatment, perhaps because families felt they had the skills to manage the young person's anxiety without further professional input.

Conclusions

Findings from this study suggested that guided CBT bibliotherapy for childhood anxiety is a robust treatment which is broadly effective for many children even several years after completing the intervention. Those with more severe symptoms were less likely to have recovered at four year follow-up, but small effect sizes suggest that these children may still benefit from the intervention. Older

children, those with more severe problems and those with comorbid externalising behaviour problems were most likely to have received additional input from mental health services. Further research should focus on the experiences and ongoing mental health needs of this group to ensure that those who do not benefit from low-intensity interventions can still have their needs met.

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PART THREE: CRITICAL APPRAISAL

Introduction

This critical appraisal first provides a context for the research questions explored in this study and their relevance for clinical practice. Methodological and conceptual challenges associated with measurement, use of multiple informants and investigating mental health in children across the developmental period are then considered, with a discussion of the dilemmas posed and the decisions made in relation to them.

Background Context

The development of low-intensity interventions for common mental health problems and the shift in health policy towards making these widely available have been welcome advances for many people who suffer from anxiety and depression as psychotherapy had previously been difficult to access. However, the evidence emerging from this field and my own experiences on placement in an adult primary care psychology service suggest that, as with all psychotherapies, not everybody who begins a low-intensity treatment will recover (e.g. Cobham, 2012; Spence et al., 2011) and some may need more intensive help. As discussed in the introduction to the empirical paper, the stepped-care model of mental health services relies heavily on the decisions made by the clinician following an initial assessment regarding the treatment pathway that will be offered to the client. In this situation with clients, I have sometimes felt a tension between wanting to be able to offer an intervention quickly to someone who was keen to have help straight away but at the same time not wanting to suggest a treatment approach that was unlikely to be successful for that individual. This dilemma has created a

need for research to inform this decision making, to allow clinicians to give access to brief and readily available therapies to those who will benefit from them while also picking out those who are likely to need more input and channeling more resources towards these clients straight away. Accurate predictions at this stage about who may benefit from low-intensity therapies could allow efficient allocation of limited healthcare resources, reduce waiting times and avoid some families having potentially aversive unsuccessful experiences of brief therapy and the associated frustration and disruption this may cause.

A wide range of factors could be hypothesised to influence whether low-intensity interventions are likely to be effective, such as the therapeutic alliance, parents' expectations of the treatment, demographic factors, clinical features of the child's presentation and family factors including parental psychopathology and parental literacy. The gathering of information on demographics and clinical features such as symptom severity and comorbidity forms an integral part of an initial assessment in routine clinical practice, whereas many other relevant factors may not be explicitly measured or explored outside of research clinics. I was therefore most interested in the influence of these factors on treatment outcome, particularly in light of the mixed findings of their effects in therapist-delivered CBT for child anxiety. I was also keen to explore the effects on outcome after some time had elapsed in order to better understand which children are more likely to follow a positive developmental trajectory and which may be at risk of later psychological difficulties. However, research of this type raises a number of wider methodological and conceptual questions which required careful consideration.

Research across the developmental period

One of the major challenges in child and adolescent research is the task of understanding a young person's difficulties in the context of their development. As mental health difficulties may often relate to the way in which a child thinks and feels, developmental change in a child's cognitive and linguistic capabilities and ability to reflect upon and articulate their emotional experiences to others can confound measurement of symptom change, both from their own report and from parents' accounts. Furthermore, a child's developing coping skills and emotional resilience can complicate understanding of the effects of treatment and the effect of symptoms on functioning. When conducting follow-up assessments, I was impressed by the extent to which some young people had found ways to normalise and cope with their difficulties, such that they reported low levels of distress and good overall functioning despite ongoing fears and worries. For some, fears which had previously been disabling were still regularly present but were now talked about as a challenge that was manageable, or "just a quirk" of the young person's personality. For example, one adolescent who had sought help with a specific phobia of lifts reported at his follow-up assessment that he still felt afraid of lifts but no longer considered this a problem. As he was now in his mid-teens, he would simply take the stairs and framed this as a positive choice for his physical fitness. His fear of lifts, which had been problematic when he needed to stay with his parents and younger siblings in pushchairs, was no longer interfering in his life. While adaptive coping is considered to be a successful outcome of treatment and is often an explicit aim of CBT, this poses challenges for the measurement of

treatment effects in the context of maturation. It may be that focusing solely on the presence of symptoms misses interesting and important changes in the young person's relationship to their symptoms which have a wider meaning for their overall functioning.

Measuring symptoms

The measurement of symptoms themselves also poses challenges. While best practice in treatment trials is to use the same measures of symptoms and functioning at pre-treatment, post-treatment and follow-up in order to aid direct comparison between time points, there is a question of whether a direct comparison can truly be made between measurements at different time points in child and adolescent research. This is particularly the case when follow-up assessments have taken place several months or years later and a comparison is being made between anxiety in middle childhood and in late adolescence, as the presence of fears and worries would be expected to decrease to some extent over this time span anyway (Gullone, 2000). Many measures, such as the SCAS-C/P used in this study, have age-stratified normative comparison groups to reflect differences in the extent to which children express anxiety symptoms at different ages (Spence, 1998), which allows researchers to take this into account. It may be that t- or z-scores are therefore more useful to researchers than raw scores when child- or self-report questionnaires are used to compare symptoms across a long time interval. Structured diagnostic interviews such as the ADIS-C/P respond to this issue by asking assessors to consider the extent to which the child differs from their age-matched peers and take this into account when giving clinician severity ratings.

However, this relies upon the clinician's own experience of typical development and introduces subjectivity into the ratings, which may be particularly problematic when research assessments are conducted by assessors with limited clinical experience or knowledge of the anxieties which are typical across childhood. While this study used a structured diagnostic interview which is considered to be the 'gold standard' in this type of research and excellent inter-rater reliability was established, these limitations must be held in mind when evaluating the results of this study and findings from longer-term follow-up studies of clinical trials more generally.

Use of multiple informants

The limitations in children's ability to verbalise their symptoms and give an account of their own behaviour make the contribution of other informants essential in child and adolescent research. Parent report is typically used in addition to child self-report to assess whether children meet diagnostic criteria. However, this can create confusion when the parent and child give conflicting accounts of the difficulties experienced by the child, as agreement between children and parents is often poor (Woodruff-Borden & Leyfer, 2006). In order to ensure that problems are not missed, the ADIS-C/P includes both diagnoses if the parent and child describe two different problems, but this can result in over-reporting of difficulties in circumstances when the parent and child are conceptualizing the same underlying fear in two different ways. For example, a child who is tearful and reluctant to separate from the parent at the school gates each morning could convincingly be described as having separation anxiety by the parent, whereas the child's account

could include anxious cognitions and avoidance which appear more typical of social anxiety, triggered by attendance at school. The clinician is then required to generate overall diagnostic classifications from these accounts but it may be unclear whether one account is a more accurate depiction of the difficulties than the other or whether both disorders are in fact present.

This raises the question of whether both informants' accounts should be given equal weight when deciding diagnostic classifications, and if not, whose should be prioritised. Rapee et al. (1994) found that although inter-rater reliability on the ADIS was good, parent and child interviews often showed poor agreement and clinicians tended to rely more heavily on parent report when giving ratings in circumstances when children and parents disagreed. Again, the issue of maturation over the developmental period is highly relevant here, as it may not be appropriate to give additional weight to the same informant for the duration of a longitudinal study, especially if the research spans from early childhood well into adolescence or even early adulthood. Edelbrock et al. (1985) found that the reliability of parent reports on structured diagnostic interviews tends to decrease with increasing child age, whereas child self-report tended to become more reliable with age. Specifically using the ADIS-C/P, Silverman and Eisen (1992) found that test-retest reliability was higher amongst older children than their younger counterparts. As parents were found to still have generally good reliability when describing the symptoms of older children, this emphasises the importance of gathering data from both parents and young people wherever possible in follow-up studies. The lack of

adolescent interviews for some of the four year follow-up assessments in this study is therefore an important limitation.

Measurement of candidate predictors

Comorbidity

A related challenge in this study involved choosing which informant to use to measure the variables of interest as predictors. For the measurement of comorbid anxiety I was able to take into account both the parent and the child's perspective by using the diagnostic data gathered from the ADIS-C/P to measure the presence of a second or further anxiety disorder. However, this was not possible when measuring comorbid mood or externalising behaviour problems as very few children in the sample met diagnostic criteria for these types of disorders. I therefore decided to use the questionnaire measures of mood and behaviour symptoms in order to reflect subclinical difficulties in these areas. The SDQ is solely informant rated for children aged under 11 years, with both parent and teacher versions available. Due to a large amount of missing data from teacher reports, the parent-report version of the conduct scale was chosen. Selecting an informant for the mood questionnaire was less straightforward as I needed to consider whether parents or children were more likely to be able to give a valid account of the child's symptoms when the children ranged from seven to 12 at initial assessment. As difficulties with low mood are more common in adolescence than in childhood (Kessler et al., 2005), I was keen to ensure that any emerging difficulties among the older children were captured by the measure. I was concerned that for the 11 and 12 year olds in the sample, who had made the transition to secondary school and

were becoming adolescents, parents may not have been as fully aware of their child's internal emotional states as the parents of younger children, as these children may have started to become more emotionally independent. With regards to the younger children, Ialongo, Edelsohn and Kellam (2001) found that children's self-reported mood at the age of five or six was able to predict later mood disorders and suicidality, suggesting that even very young children are able to give an account of their mood states. In light of this I decided to use child self-report to measure the presence of comorbid low mood at initial assessment.

Severity

There were a several different ways in which I could have used the data gathered at the initial assessments to measure symptom severity. However, each of these had limitations which required careful consideration. One approach would have been to use the clinician severity rating for the child's primary diagnosis; however this would not have taken into account the full range of problems experienced by the child and would therefore have significantly underestimated the severity of the clinical presentation of the children with anxiety in more than one area. As comorbid anxiety problems were the norm in this sample, I was keen to measure severity in a way that accounted for the effect of comorbidity on total symptom severity but without simply measuring comorbidity itself.

A second option would be to sum the severity ratings of all the child's disorders to generate a composite severity score. However, this would have made the assumption that a child with two diagnoses each with a severity rating of four would have equal severity to a child with one diagnosis with a severity rating of

eight. This seemed implausible for many children, as the child would need to have severe distress and major, far-reaching impairments in functioning in order to receive a score of eight, whereas a child with two diagnoses rated at four could plausibly still function fairly well outside of the contexts when their anxiety was salient. Many of the children in the sample met criteria for more than one specific phobia and so would have received a high composite severity rating, however many of the common phobias, such as water or bees, would only be problematic in specific contexts and may be avoided for much of the time. This would therefore not result in a clinical picture with equal severity to a child with very disabling social anxiety who may not be able to attend school, family gatherings or social activities with peers and may rarely experience occasions when he or she is free of anxiety.

Following consideration of these limitations, I chose to use the anxiety questionnaire measures as the measure of symptom severity at initial assessment. This method had the advantage of capturing anxiety of all types, including subclinical anxieties, as the SCAS assesses anxiety across multiple domains and combines these into an overall score. This measure also assesses the frequency with which the difficulties occur and includes generic items such as “my child complains of feeling afraid”, which contribute to a picture of overall severity. However, I then returned to the question of which informant to use, as data from both parent reports and child self-report were available. As the mean age of participants at initial assessment was nine, and children under the age of nine have been shown to have poor reliability when reporting their own symptoms of anxiety (Edelbrock et al., 1985), I chose to use the parent-reported anxiety scale as the

measure of symptom severity. I was aware that for the children at the upper end of the age range, it was possible that parents would not be fully aware of the child's internal mental states, but this was less of a concern than for the measure of low mood as the majority of items on the SCAS-P asked parents to rate specific avoidant behaviours which could be observed by the parent. Parent report may also have been less susceptible to being confounded by age than child self-reports as parents are likely to be more able than children to evaluate the extent to which the child's anxiety is above and beyond the typical anxieties experienced by a child of that age. On reflection, it may have been advantageous to use t- or z-scores instead of raw scores to rule out any confound of age completely.

An alternative solution would have been to generate a composite score from the parent and child reports all of the anxiety questionnaires by re-scaling them into the same units then calculating a mean. This approach has been used by Rapee (2000) to assess the effect of symptom severity on outcomes in a group CBT treatment. However, this method would have given equal weight to parent and child reports, which would have been problematic for the youngest children in the sample who may not have been able to reliably report their symptoms.

Recruitment bias in follow-up studies

Recruitment is one of the biggest challenges when following up a clinical trial and was one of the largest tasks associated with this project. Making contact with parents by telephone to invite them to participate in the study raised a number of issues which led me to reflect on possible sources of recruitment bias.

The sample used in the original trial was more affluent and educated than both the general population and the population of families who usually present to mental health services, and these families had agreed to participate in a trial of a new treatment approach within a specialist research clinic, perhaps resulting in a sample of particularly motivated and self-directed parents. Furthermore, evidence from research on attrition in panel studies suggests that those who are lost to follow-up differ from retained participants in a number of ways, including socioeconomic status, ethnicity and deviant behaviour (Ribisl et al. 1996), with more disadvantaged families less likely to participate, which may have resulted in further bias towards more affluent, socially advantaged families within the sample recruited at follow-up.

When contacting families, I was pleasantly surprised by the level of enthusiasm and goodwill expressed towards the research; families were mostly interested in talking to us and keen to help when the rationale for the study was explained. I began to wonder whether those who had experienced a favourable treatment outcome might be more likely to feel motivated to support the clinic in its efforts to disseminate the intervention by participating in the study than those who were still experiencing difficulties with anxiety, creating an additional possible source of bias in the sample. Many parents whose children had recovered were keen to share their child's successes with us and so the assessment process often appeared rewarding for them, and the structured interviews were significantly less time-consuming than for those who still had substantial ongoing difficulties. If the sample included at four year follow-up were more likely to have recovered and

were more socially advantaged than those who did not participate, these findings may therefore represent a 'best case scenario' of what could be achieved with this intervention.

Conversely, parents who were concerned that their child had ongoing difficulties may have seen the follow-up assessment, and the written report of the child's difficulties that was provided afterwards by the assessor, as an opportunity to seek a new referral to services and get professional input for their child. While it was made clear that the clinic would not immediately offer treatment if difficulties emerged, some families did visit their GP after the assessment to seek a new referral to CAMHS and some of these were subsequently referred back to the research clinic. I wondered therefore if the population who were least likely to participate were those who had not made a full recovery but were not keen to have more help from the service, perhaps because they had felt that the model used was not a good fit for them or because they had not felt well supported. These families may have been underrepresented in the sample when their feedback on the treatment they had received had the potential to be the most valuable to the service. This was unlikely to be a large number of families, as many of the families who declined to participate had previously given consent for assessments then had to cancel appointments, and more still had informally stated that their child had made a good recovery but was now too busy with academic and extra-curricular activities to take part. Their views are nevertheless of great interest to researchers aiming to improve the interventions offered to children with anxiety and future

longitudinal research could benefit from ensuring that this population is adequately represented.

Conclusions

This study posed a number of challenges which gave me cause to reflect on the wider dilemmas associated with conducting child and adolescent research. The well-worn phrase "children are not just little adults" seemed relevant to me when making decisions related to measurement and conceptualising what constitutes a good recovery. Research which spans a wide time frame during childhood has to grapple with the effects of important developmental transitions, maturation and life experience and although this requires careful thought and sometimes inevitable compromises in methodology, this challenge is also an important strength for young people, as their capacity to learn, change behaviours and absorb new ideas gives them the potential to benefit enormously from the right help given at the right time.

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Appendix A:

Ethical Approval

University of Reading

Coordinator for Quality Assurance in Research
Dr Mike Proven, BSc(Hons), PhD

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Dr Kerstin Thirlwall
Winnicott Research Unit
School of Psychology and Clinical Language Sciences
University of Reading
RG6 6AL

22 February 2013

Dear Kerstin

Research Ethics Committee Project 13/08: Guided CBT Self-help for Child Anxiety: Long Term Follow Up

Thank you for your letter dated 11 February responding to my email of 4 February and addressing the points raised by the UREC Sub-committee. I can confirm that the Chair is pleased to confirm a favourable ethical opinion on the basis of the information you have supplied.

Please note that the Committee will monitor the progress of projects to which it has given favourable ethical opinion approximately one year after such agreement, and then on a regular basis until its completion.

Please also find attached Safety Note 59: Incident Reporting in Human Interventional Studies at the University of Reading, to be followed should there be an incident arising from the conduct of this research.

The University Board for Research and Innovation has also asked that recipients of favourable ethical opinions from UREC be reminded of the provisions of the University Code of Good Practice in Research. A copy is attached and further information may be obtained here: http://www.reading.ac.uk/internal/res/QualityAssuranceInResearch/reas-RSqar.aspx.

Yours sincerely

[redacted]

Dr M J Proven
Coordinator for Quality Assurance in Research (UREC Secretary)
cc: Dr John Wright (Chair); Dr Laurie Butler, Head of School

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05 March 2013

Dr Kerstin Thirlwall
MRC Clinical Research Training Fellow
University of Reading
School of Psychology and Clinical Language Sciences
Whiteknights
Reading
RG6 6AL

Dear Dr Thirlwall

Study title: **The Treatment of Child Anxiety Disorders via Guided CBT Self-Help:Long-term Follow up**
REC reference: **12/SC/0618**
IRAS project ID: **107769**

Thank you for your email of 04 March 2013. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 19 November 2012

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Covering Letter		04 March 2013
Participant Consent Form: Parents	2	03 December 2012
Participant Information Sheet: Children	2	03 December 2012
Participant Information Sheet: Parents	2	03 December 2012
Evidence of insurance or indemnity	UPDATED	

Approved documents

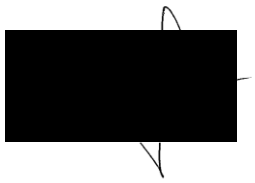
The final list of approved documentation for the study is therefore as follows:

Document	*Version*	*Date*
Covering Letter		15 October 2012
REC application		15 October 2012
Protocol	1	15 October 2012
Investigator CV		
Other: CV for Supervisor		
Other: CV for student		
Participant Consent Form: Child Consent for study	1	15 October 2012
Participant Consent Form: Parent Consent for audio recording	1	15 October 2012
Participant Consent Form: Child Consent for audio recording	1	15 October 2012
Letter from Sponsor		
Referees or other scientific critique report		
Other: ADIS Child	1	15 October 2012
Other: ADIS Parent	1	15 October 2012
Other: Parents experience	1	15 October 2012
Questionnaire: SCAS - P		
Questionnaire: CAIS - P		
Questionnaire: SCAS - C		
Questionnaire: SMFQ - C		
Other: Non NHS SSI		
Covering Letter		04 March 2013
Participant Information Sheet: Children	2	03 December 2012
Participant Information Sheet: Parents	2	03 December 2012
Participant Consent Form: Parents	2	03 December 2012
Evidence of insurance or indemnity	UPDATED	

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

12/SC/0618 **Please quote this number on all correspondence**

Yours sincerely



Mrs Maxine Knight
Committee Co-ordinator

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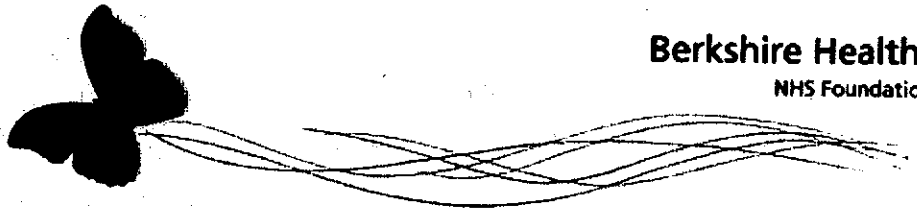
Copy to: *Dr Mike Proven,*
.



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28 January 2013

Our Ref:	2012/41		
REC Ref:	12/SC/0618		
Study title:	Guided CBT Self Help for Child Anxiety Long-Term Follow up		
Start date:	1.1.2013	End date:	1.12.2013

Dear Dr Thirlwall

Confirmation of Trust Management Approval

On behalf of Berkshire Healthcare NHS Foundation Trust, I am pleased to confirm Trust Management Approval for the above research on the basis described in the application, protocol and other supporting documents.

The Approval is conditional on you informing the R&D Department when you recruit the first patient so that we can monitor our performance against the NIHR high level metric.

If there are any changes to the study protocol, the R&D Department must be informed immediately and supplied with any amended documentation as necessary, including confirmation that the amendments have been favourably reviewed by the Sponsor and the Ethics Committee.

If the end date changes from that shown above, then please inform BHFT R&D Manager. Trust approval will cease on the end date above. Please contact the R&D Manager to discuss and request any extension.

Please note that Berkshire Healthcare NHS Foundation Trust is the site name when uploading recruitment data.

If you have any questions about the above, or you require any other assistance, then please contact the R&D Department.

I wish you every success with the study.

Yours sincerely

[redacted]

Dr Justin Wilson
Medical Director

Appendix B:

Information Sheets and Consent Forms

School of Psychology and Clinical Language Sciences
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Clinical Research Team:
Study Manager: Dr Kerstin Thirlwall(Tel: 0118 378 5534); Email: k.j.thirlwall@reading.ac.uk
Research Assistant:Ms Alex Brown (Tel: 0118 378 8926); Email:

INFORMATION SHEET FOR PARENT

Overcoming your Child's fears and Worries Follow-up Assessment

Dear

You and (INSERT CHILD'S NAME) are being invited to take part in a follow up study we are doing at Berkshire Healthcare NHS Foundation Trust and the University of Reading. Before you decide whether to take part it is important for you to understand why the study is being done and what it will involve. Please take time to read the following information carefully and discuss with others if you wish.

Why have we been approached to take part?
We are inviting all parents and children who received our guided self-help treatment; 'Overcoming you Child's Fears and Worries' to take part in a follow up study.

What is the purpose of this study?
The purpose of this study is to gain further information regarding the long term benefits of guided self-help treatments for child anxiety and to learn more about whether this form of treatment is helpful to families.

What is already known?
As you may recall, there is a standard talking treatment for anxious children called Cognitive Behaviour Therapy (CBT). Studies have shown that CBT is very helpful to lots of children. However this treatment is often not readily available within the National Health Service (NHS) as it is costly and involves highly trained staff. We developed a brief form of this treatment that parents could use with their children, with the support of a therapist.

The study you took part in showed that 55% of children who had received the 'Overcoming your Child's Fears and Worries' treatment recovered from their main difficulties by the end of treatment , and 25% no longer had any difficulties related to anxiety. Of those who had not improved by 12 weeks, approximately half showed significant improvement by 6 months.

These results were positive and suggest that this approach is a suitable alternative for families who may be waiting for a long time before they have access to standard CBT. However, we do not know what the effects of the treatment are in the longer term. We also do not know what it was like for you, as a family, to receive this type of treatment.

What does the study involve?
The study involves our team making a detailed enquiry of how (INSERT CHILD'S NAME) is currently getting on, in particular in relation to difficulties with anxiety. This will involve you completing some questionnaires (which we will send to you in the post) and a single appointment where you and (INSERT CHILD'S NAME) will be asked a standard set of questions. At the appointment we will also ask whether you would be willing to answer some additional questions about your experience of the treatment. You can choose whether you

would like the assessment appointment to take place at our clinic at The University of Reading or at your home.

If the assessment shows that (INSERT CHILD'S NAME) is currently experiencing anxiety or other problems, we will discuss options for further support with you.

Will our responses be shared with anyone?
The responses you and (INSERT CHILD'S NAME) give will be treated as entirely confidential. In fact, they will be coded and entered into a computer file with anonymity completely preserved (there will be no names on the file). We will not be sharing your responses with (INSERT CHILD'S NAME) GP or school, unless you ask us to. The only exception to this is if we learn that you or (INSERT CHILD'S NAME) is at risk of harm, in which case we will raise this with you and inform your G.P.

We would like to audio record the assessment so that we can check that we represent what you tell us correctly, however the recordings will only be heard by members of the research team and they will be destroyed at the end of the study. You can choose not to have the assessment recorded.

Who has approved this study?
The study was given a favourable ethical opinion for conduct by both the University of Reading Ethics Committee and the Berkshire Research Ethics Committee. Everyone working on this study has been through the formal Criminal Records Bureau Disclosure process and has been approved by the School of Psychology and Clinical Language Sciences of the University of Reading to work with children.

Do we have to take part?
It is up to you to decide whether or not you wish to take part. If you do decide to take part, you are also still free to withdraw from the study at any point. Whether or not you take part will not have any effect upon any current or future services you receive.

What happens next?

Someone from our research team will give you a call in two weeks time to answer any questions you may have and to find out whether you would like to be involved.
If you do not want to hear more and have decided that you do not want to take part, you can opt out of any further communication by contacting Dr Kerstin Thirlwall via e mail or telephone, (Email: k.j.thirlwall@reading.ac.uk / Telephone: 0118 378 5534)

If you have any questions or concerns about this study, now or at any time in the future, please do contact us,

Yours Sincerely

Dr Kerstin Thirlwall
Principal Investigator

School of Psychology and Clinical Language Sciences
University of Reading
Whiteknights
PO Box 238
Reading RG6 6AL

INFORMATION SHEET FOR CHILDREN

Overcoming your Child's fears and Worries Follow-up Assessment

Dear

Do you remember?

A while ago, you and your parents took part in a study where we wanted to try and help you with some problems you were having. We gave your parents a book to read and they tried to help you feel less worried and scared about things. We asked you lots of questions afterwards to see how you were doing.

We would like to meet to meet with you again

We would very much like to hear how you are doing now and we would like to meet with you again to ask you the same questions we did before. You can either come to us or we can come to see you at home, whichever you and your parents prefer.

You don't have to meet us

We would like you to help us by taking part in our study. However, you do not have to meet with us. If you and your parents decide not to talk to us, that is fine. Also, if you do decide to take part and then change your mind, this won't matter at all.

What you say is important

We want to find this out so that we know whether or not the book we gave your parents and the appointments they had with us were useful or not and whether we should do this again when other families who come to us for help.

We would like to record what you say so we can make sure we don't miss anything. We will delete the recording at the end of the study. You can tell us if you don't want us to record anything.

We won't tell anyone

Everything you tell us will be treated as a secret; nobody other than us will ever know what you have told us. The only time we would not be able to keep a secret is if you told us that you or someone else was in danger. If this happened, we would have to tell another adult- like your mum or family doctor.

If we write anything you have said when we are reporting our study, we will make sure nobody can tell that it was you who said it (we would not use your name).

We were told it was ok to contact you

Before we contacted you, our study had to be checked by a group of people called an Ethics Committee. They make sure that this study is ok to do. This study has been checked by the Reading University Committee and the Berkshire NHS Committee and both of them were happy for it to go ahead.

Let us know if you have any questions

If you have any questions about this, either now or later, please do ask us. You have a right to know everything and we will be happy to tell you everything. Your parents have my email address and telephone number if you want to ask me anything.

Best wishes,

Dr Kerstin Thirlwall

Chief Investigator

PARENT CONSENT FORM

Overcoming your Child's fears and Worries Follow-up Assessment

	Please initial box to show agreement.
1. I confirm that I have read and understand the information sheet dated for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I understand that my and my child's participation is voluntary and that we are free to withdraw at any time, without giving a reason, without my medical care or legal rights being affected.	
3. I understand that any data collected during the study, may be looked at by responsible individuals from The University of Reading where it is relevant to our taking part in this research. I give permission for these individuals to have access to my records.	
4. I agree to audio recordings being made during the course of the assessment interview. I understand that the audio will be heard and seen only by members of the research team; and they will be destroyed at the end of the research study.	
5. I agree to anonymised quotations being used in research reports.	
6. I agree to take part in the study.	
7. I agree to answer questions about my child's anxiety	
8. I agree to answer questions about my experience of the treatment	

Name of child: _____

Name of parent/guardian: _____

Parent/guardian signature: _____

Date: _____

Name of person taking consent: _____

Date: _____

Signature: _____

CONSENT FORM FOR CHILDREN
(To be completed by the child and his/her guardian)

Overcoming your Child's fears and Worries Follow-up Assessment

Please circle all you agree with:

Have you read (or had read to you) the information about this study?
YES/ NO

Has somebody else explained this study to you?
YES/ NO

Do you understand what this study is about?
YES/ NO

Have you asked all the questions you want?
YES/ NO

Have you had your questions answered in a way you understand?
YES/ NO

Do you understand it's OK to stop taking part at any time?
YES/ NO

Are you happy to take part?
YES/ NO

If any answers are 'no' or you **don't** want to take part, **don't** sign your name!

If you **do** want to take part, please write your name and today's date
Your name _____
Date _____

Your parent or guardian must write his/her name here too if s/he is happy for you to do the project
Print name _____
Sign _____
Date _____

The person who explained this project to you needs to sign too:
Print name _____
Sign _____
Date _____