

British Journal of Clinical Psychology (2018), 57, 351–366 © 2018 The British Psychological Society



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Preventing family transmission of anxiety: Feasibility RCT of a brief intervention for parents

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Objectives. Children of anxious parents are at high risk of anxiety disorders themselves. The evidence suggests that this is due to environmental rather than genetic factors. However, we currently do little to reduce this risk of transmission. There is evidence that supporting parenting in those with mental health difficulties can ameliorate this risk. Therefore, the objective of this study was to test the feasibility of a new onesession, group-based, preventive parenting intervention for parents with anxiety disorders.

Design. Feasibility Randomized Controlled Trial.

Methods. A total of 100 parents with anxiety disorders, recruited from adult mental health services in England (and child aged 3–9 years), were randomized to receive the new intervention (a I-day, group workshop), or to treatment as usual. Children's anxiety disorder and anxiety symptoms were assessed to 12 months by outcome assessors who were blind to group allocation. Exploratory analyses were conducted on an intention to treat basis, as far as possible.

Results. A total of 51 participants were randomized to the intervention condition and 49 to the control condition (82% and 80% followed to 12 months, respectively). The attendance rate was 59%, and the intervention was highly acceptable to parents who received it. The RCT was feasible, and 12-month follow-up attrition rates were low. Children whose parents were in the control condition were 16.5% more likely to have an anxiety disorder at follow-up than those in the intervention group. No adverse events were reported.

Conclusions. An inexpensive, light-touch, psycho-educational intervention may be useful in breaking the intergenerational cycle of transmission of anxiety disorders. A substantive trial is warranted.

Practitioner points

 Anxiety disorders run in families, but we currently do little to help anxious parents to raise confident children. A brief group workshop was highly acceptable to such parents and was very inexpensive to run.

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- Children of parents who took part in the brief intervention were 16.5% less likely to have an anxiety disorder, I year later, than children whose parents were in the control group.
- This was a feasibility study, and while it showed that both the intervention and the research were feasible, the study needs replicating with a much larger sample.
- Many parents faced barriers to attending the workshop, and future efforts should focus on widening
 accessibility.
- We were unable to obtain sufficient self-report data from children, so the outcomes are based on parent report only.

We know that mental health problems run in families, but we do almost nothing to prevent this from happening. In this study, we describe a brief inexpensive intervention, targeted at anxious parents, to help them to raise less anxious children.

Anxiety disorders are prevalent and may be the most common psychological disorder of childhood (Cartwright-Hatton, McNicol, & Doubleday, 2006; Somers, Goldner, Waraocj, & Hsu, 2006). With onset typically before adolescence (Kessler, Berglund, Demler, Jin, & Walters, 2005), many of those living with anxiety will be young adults with children of their own. Anxiety disorders also run in families: In one study, offspring of clinically anxious parents were seven times more likely to meet diagnostic criteria than controls (Turner, Beidel, & Costello, 1987). In another, over one-third of children with a clinically anxious parent had an anxiety disorder. This rose to two-thirds where both parents were clinically anxious, compared to around one-fifth where no parent was anxious (Merikangas, Avenevoli, Dierker, & Grillon, 1999).

Moreover, much of this intergenerational transmission of anxiety disorders is attributable to environmental rather than genetic processes. In a recent 'Children of Twins' study, exploring genetic and environmental factors in the intergenerational transmission of adolescent anxiety, Eley and colleagues concluded that: 'For both anxiety and neuroticism, the models provide support for significant direct environmental transmission from parents to their adolescent offspring. In contrast, there was no evidence of significant genetic transmission' (Eley *et al.*, 2015). The degree to which environmental processes seem to be responsible for intergenerational transmission of anxiety presents us with an opportunity for prevention work with anxious parents.

Anxiety disorders in childhood present a number of risks: a large proportion of sufferers have anxiety difficulties into adulthood (Last, Hansen, & Franco, 1997) and experience problems with education (Wood, 2006), relationships (Pine, 1997), and reduced quality of life (Mendlowicz & Stein, 2000). Children with anxiety disorders are at risk of developing other diagnoses, particularly mood disorders (Kashani, Orvaschel, Rosenberg, & Reid, 1989), and substance misuse (Kushner, Sher, & Beitman, 1990). Societally, childhood anxiety disorders are costly: A Dutch Study found societal costs for anxious children that were 21 times higher than for typical children (Bodden, Dirksen, & Bögels, 2008). Moreover, there is evidence that childhood anxiety disorders are increasing (Twenge, 2000).

Recent British policy documents (e.g., 'Think Family' and 'Future in Mind'; Department-for-Children-Schools-and-Families, 2008; Department of Health, 2015) urge adult services to give attention to the needs of clients' families. But despite the personal and societal costs that are associated with the intergenerational transmission of anxiety, we currently do very little. There are a number of reasons for this inaction, including commissioning arrangements that silo adult and child mental health services, leading to neither being in the position to offer intergenerational support. However, a key factor is that the evidence base for suitable interventions is very small: There are currently no

interventions that are likely to be suitable for widespread use in the British health care context.

This study set about developing such an intervention for anxious parents. A number of approaches were considered: Adult services might prioritize treatment of anxiety for adults who have children: However, treatment is not always available or wanted, and there is no guarantee of success; we also have no evidence that this would improve outcomes for children. Another might be to target the 'at-risk' children themselves: However, given the pragmatic and ethical difficulties in delivering clinical interventions to non-referred (often asymptomatic) children, we chose to devise an intervention that did not directly involve children. Therefore, a preventive/early intervention targeted at anxious parents, but which did not depend on parents' recovery, was favoured. Because the evidence suggests that anxiety is transmitted in large part via environmental processes, an intervention that targeted anxiogenic parenting processes seemed likely to have benefit. There is now a small body of evidence suggesting that we can work very effectively on these parenting processes, to reduce anxiety in children. For example, Cartwright-Hatton and colleagues (Cartwright-Hatton, 2010; Cartwright-Hatton et al., 2011) developed a purely parenting-based intervention (From Timid to Tiger) for young children with anxiety disorders. After a 10-week (20-hr) course, children in the active condition were significantly more likely to be anxiety-free than a control group. Other studies have also reported substantial impacts on child anxiety, after working with parents alone (Thirlwall et al., 2013; Waters, Ford, Wharton, & Cobham, 2009).

According to a recent systematic review of the area (Lawrence, Rooke, & Creswell, 2017), just one existing intervention for preventing anxiety in the offspring of anxious parents has been evaluated (Ginsburg, Drake, Tein, Teetsel, & Riddle, 2015). This US-based, 11-session cognitive-behaviourally based programme demonstrated a medium-to-large effect size (0.81 at 6 months, 0.57 at 12 months) in preventing anxiety in children of anxious parents. However, we wanted the intervention to be short and inexpensive, to maximize engagement from potential service-users, and from cost-conscious UK-based service-providers. Therefore, a very brief, group-based intervention, delivered in 1 day (5 hrs, including breaks), was devised.

There is evidence that good, general, parenting skills, focusing on behaviour management, are effective in reducing internalizing symptoms in young children (Cartwright-Hatton, McNally, White, & Verduyn, 2005) but that these skills are less likely to be used by anxious parents (Laskey & Cartwright-Hatton, 2009; Robinson & Cartwright-Hatton, 2008). Therefore, the first half of the session was focused on general parenting techniques, such as child-centred play, praise and reward, effective limit setting, and consequences. The second half focused on parenting issues that are particularly pertinent to parents who live with anxiety, in particular, overprotection, perfectionism, transmission of fears/worries, and opportunities that may be denied to the child of an anxious parent (e.g., varied social encounters). Parents were helped to devise strategies for minimizing the impact of these factors. For example, parents with fears and phobias were helped to identify an adult close to the child who might spend time with the child, providing positive exposure experiences to stimuli of which the parent was afraid. The second part concluded with guidance on constructing fear hierarchies to manage mild to moderate fears, and information on further sources of support.

Aims

The study was intended as a feasibility study and was not powered to detect group differences. We hypothesized that the group workshops would be acceptable to participants and that sufficient recruitment and retention would be feasible. In addition, we aimed to produce a preliminary estimate of the effectiveness of the intervention.

Method

Design

This was a Feasibility Randomized Controlled Trial. All parents were referred from Mental Health Services or Primary Care Services. The trial took place at NHS/University sites across England.

This study was approved by East London NHS Research Ethics Committee (11/LO/0759). It is registered as ISRCTN57199411. The full protocol is available from the first author.

Participants

See CONSORT Diagram (Figure 1).

We recruited 100 parents (15 male) aged 26–66 years (mean 37.1, SD=6.92) and their 100 children (59 male) aged 3–9 years (mean 5.5 years; SD=1.99) from a range of adult mental health services in England. Parents identified their ethnicity as: 'White' (British, Irish, Other) = 85%; 'Black' (British African, British Caribbean, Other) = 5%; 'Asian' (British Indian, British Pakistani, Other) = 4%; 'Other' = 4%; 2% no information. Parents described their financial status as 'comfortable' (21%); 'managing' (50%); 'struggling' (25%); no information (4%). Parents described their educational qualifications as 'postgraduate' (15%); 'degree or equivalent' (38%); 'A' Level or equivalent' (passed exams at 18 years – 23%); 'GCSE or equivalent' (passed examinations at previous minimum school leaving age of 16-16%); 'some secondary' (5%); no information (3%). The evidence strongly favoured the groups being equivalent on all measures (see Data S1).

Inclusion and exclusion criteria

Both child and parent had no major developmental or intellectual disability; parent had good English.

Parents had any anxiety disorder, as verified by a diagnostic interview (Anxiety Disorders Interview Schedule – ADIS; Brown, DiNardo, & Barlow, 1994) with a trained Clinical Research Coordinator.

The study was designed to have few exclusion criteria, because the intervention was intended for pragmatic use in services, with as wide a range of clients as possible. Therefore, referrers were asked to exclude only participants who, in their opinion, lacked the capacity to consent to participation, or whose needs were inappropriate for a group-based intervention (e.g., current active psychosis, severe depression; current manic state; certain Axis II conditions). These criteria were intended to produce a pool of participants that reflected those who might participate in the intervention if it were eventually rolled out to adult mental health services.

Parents' anxiety diagnoses are reported in Table 1.

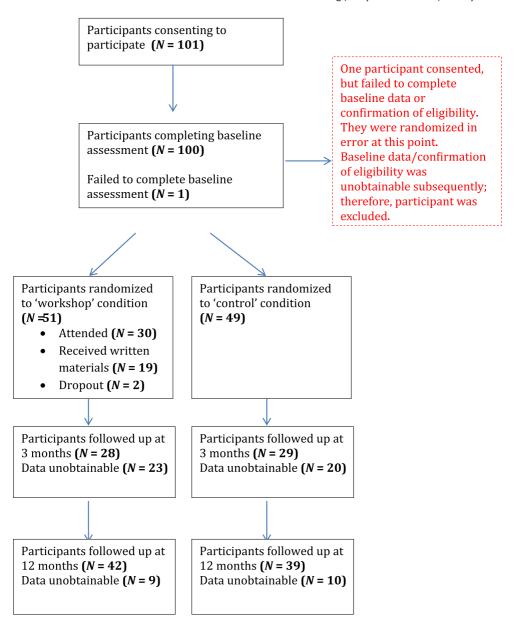


Figure 1. Consort diagram. [Colour figure can be viewed at wileyonlinelibrary.com]

Randomization and masking

Participants were randomized to the new intervention, or to control group. Email randomization (with concealed allocation) was conducted by an independent agency who generated the sequence, and assigned to groups, but had no further involvement in the trial. Participants were randomized (after consenting and completing baseline assessments) in a ratio 1:1 using the method of minimization, balancing for child gender (M/F), with an 80% probability. Subsequently, all assessments were conducted by assessors who were blind to allocation. However, participants and workshop leader were

Table 1. Parental anxiety diagnoses

Diagnosis	Number of parents (%)
Agoraphobia	40 (40)
Panic disorder	49 (49)
Social anxiety disorder	55 (55)
Generalized anxiety disorder	74 (74)
Obsessive-compulsive disorder	26 (26)
Posttraumatic stress disorder	16 (16)
Specific phobia	35 (35)
Health anxiety	7 (7)

aware of allocation. One participant was randomized (in error) before any baseline measures and eligibility checks were completed and none could subsequently be obtained; therefore, this participant was excluded.

Procedure

Initially, participants were identified by their treating clinician. Subsequently, they were offered an eligibility/consenting interview, where they were further assessed against inclusion/exclusion criteria by a clinical research coordinator, the study was explained in detail and written consent was taken. At this session, one index child was identified for participation. Where parents had more than one child who met criteria, one child was selected for participation using a remote, Internet-based random selector. Children aged five and over, and who were present at this interview, were invited to complete outcome measure themselves, and where they agreed, written consent was taken.

Subsequently, parents completed the adult ADIS and the self-report questionnaires measuring child anxiety, as described above. Note that to run a highly efficient trial (mindful of very large sample size likely to be needed in any substantive trial), we did not complete the child ADIS at this baseline assessment. Participants were reimbursed £25 against expenses.

Three months after completion of the workshop (or 3 months after the next workshop that would have been available to them, for those in the control group), participants completed a 3-month follow-up assessment online. This was identical to the pre-participation assessment except that the adult ADIS was not completed.

Twelve months after completion of the workshop (or 12 months after the next workshop that would have been available to them, for those in the control group), participants completed a 12-month follow-up assessment by telephone with a research assistant (ADIS) and online (self-report measures). Parents completed the child ADIS and self-report anxiety questionnaires (FSSC and SCAS) on behalf of their child, and children aged five or over were invited to complete the FSSC and SCAS.

All participants were invited to provide 3- and 12-month follow-up data, regardless of whether they had attended the intervention or not.

Interventions

One-day workshop

The workshops ran from approximately 9.30 am to 3.00 pm, with breaks.

Table 2. Workshop programme

Introduction: Sharing names Getting to know each other Ground rules Format of the day Format of the day All about anxiety: Fight/Flight response A basic CBT understanding of what happens in anxiety, as a foundation for later discussions Thinking in anxiety (The Seven Confident Thoughts) How dangerous is the world?: Risk statistics National statistics are shared to illustrate the very low risk • Child death rates of serious harm that British children face Violent crime rates Child cancer • Child murder Child injury Parental attention General behaviour management: A brief overview of parenting skills, with a focus on Child-centred play behaviour management skills, to be used to encourage Praise good and confident behaviour Reward Planned ignoring Giving commands Consequences Parenting for anxious parents: Overprotection Issues in parenting that are particularly pertinent to Perfectionism parents living with anxiety Transmitting fears and worries Missed experiences Managing early signs of anxiety: Fear hierarchies How to manage early signs of anxiety in children Where to go for further help

The intervention was intended to be non-blaming and non-stigmatizing, and to be highly engaging. Much use was made of role-plays, humour and games, and it was highly interactive throughout.

Children did not attend the session, which were delivered by a single clinical child psychologist. Up to six parents attended each course. Table 2 provides an overview of the material. Participants were given access to further telephone and email support for 1 month after the intervention, but only one participant made (very brief) use of this resource. Participants were reimbursed £15 towards travel expenses for attendance (as courses were often run at some distance from where they would normally attend for their care).

Control condition

Parents in the control condition did not receive any intervention as part of this study. However, they continued with the treatment that they were receiving for their own anxiety. For ethical reasons, they were sent a booklet of information about child anxiety. This booklet contained brief information on the causes and symptoms of childhood anxiety, and the treatment options (medical and psychological) that are available. Overlap with content from the intervention arm was avoided.

Measures

As this was a feasibility trial, a range of measures were employed, with none being identified a priori as primary or secondary. To maximize efficiency, after face-to-face baseline assessments, all outcome measures were collected via the Internet (self-report instruments – NB one participant completed by post), or telephone (ADIS).

Eligibility Measure

Parental anxiety diagnoses – The ADIS (Brown et al., 1994). This was completed by a trained Clinical Research Coordinator, with parents, to confirm their anxiety diagnosis. The following sections were used: panic disorder, agoraphobia, social phobia, generalized anxiety disorder, obsessive-compulsive disorder, specific phobia, posttraumatic stress disorder, health anxiety. Interviews were audio-recorded and a random 20% re-rated by blind research assistants, yielding 95% reliability; therefore, initial ratings were retained.

Outcome Measures

Children's Anxiety Diagnoses (ADIS-PV; Silverman & Albano, 1996). Parents were interviewed using the Anxiety Disorders Interview Schedule for Children and Parents-IV (parent version). This assesses for DSM-IV childhood anxiety diagnoses and screens for other common diagnoses. It is designed for use by trained research assistants and is highly reliable and valid. Interviews were conducted by research assistants (trained by a clinical child psychologist) and blind to group allocation. Diagnoses were assigned only if significant interference was reported. Interviews were audio-recorded, and an independent researcher re-rated a random 20%, yielding good reliability on the presence of anxiety disorder (95%); therefore, the first raters' diagnoses were retained.

Parent report questionnaires: Parents completed the Fear Survey Schedule for Children-II, plus either the Spence Children's Anxiety Scale (children aged five and over) or the Spence Pre-school Anxiety Scale (children aged below 5 years).

Spence Children's Anxiety Scale – Parent Report (SCAS-P; Spence, 1998). The SCAS-P is a parent-reported assessment of child anxiety, which includes symptoms of panic and agoraphobia, separation anxiety, physical injury fears, social phobia, obsessivecompulsive disorder, and generalized anxiety disorder. The SCAS-P has 38 items, rated on a 4-point scale with scores of 0-3 representing 'never', 'sometimes', 'often', and 'always', respectively. This scale has good properties of internal consistency and validity (Nauta et al., 2004).

Spence Pre-school Anxiety Scale - Parent Report (SCAS-Pre; Spence, Rapee, McDonald, & Ingram, 2001). This is an adaptation of the SCAS for pre-school children. The 28-item measure has five subscales (generalized anxiety, social anxiety, obsessivecompulsive disorder, physical injury fears and separation anxiety), rated on a 5-point scale, scored 0-4 ('Not at all', 'Seldom true', 'Sometimes true', 'Quite often true', 'Very often true'). The scale has good properties of reliability and validity (Edwards, Rapee, Kennedy, & Spence, 2010).

Fear Survey Schedule for Children - II-Parent Version (FSSC-II-PV; Bouldin & Pratt, 1998). The FSSC-II-PV is a parent-rated measure of children's fears across 94 items (eight factors) on a 4-point scale ('not scared', 'scared', 'very scared', 'not applicable'). Two items were adapted to meet the needs of a British sample (i.e., 'dingoes' altered to 'dogs'; 'bees' altered to 'bees and wasps'). The scale has good properties of reliability and validity (Bouldin & Pratt, 1998).

Workshop satisfaction. At the end of the workshop, participants who attended completed a five-item satisfaction questionnaire. Four of these were rated on a 5-point scale ('Not at all' to 'Very'): (1) 'How much have you enjoyed coming to the workshop?'; (2) 'How easy was it to understand what was talked about in the workshop?'; (3) 'How much do you think coming today will help you to prevent your child developing anxiety?'; (4) 'To what extent were you already familiar with the information in the workshop?' and one item with a yes/no response format: 'Would you recommend the workshop to an anxious friend with children?'. Note that participants who failed to attend and who, instead, received workshop materials by post, did not complete the satisfaction questionnaire.

Child report: Spence Children's Anxiety Scale (Spence, 1998). This instrument (administered only to children aged five and over) measures general self-report child anxiety symptoms. It comprises 44 items (six fillers) measuring symptoms of panic/agoraphobia, separation anxiety disorder, generalized anxiety disorder, social phobia, obsessive-compulsive disorder, and physical injury fears, rated on a 4-point scale ('never' to 'always'). Good properties of reliability and validity have been reported (Spence, 1998).

The Fear Survey Schedule for Children – Revised (FSSC-R; Ollendick, 1983). This instrument (administered only to children aged five and over) measures children's self-reported fears across 80 items, on a 3-point response scale ('none', 'some', 'a lot'). Good properties of reliability and validity have been reported (Ollendick, 1983).

Statistical analyses

In line with accepted practice for feasibility studies, no power analysis was conducted and all analyses were exploratory only.

Results

Recruitment took place over 13 months and stopped once the target number of participants was reached.

At baseline, some questionnaires had missing values for some items. Where the number of missing items was <10% on a given measure, missing values were imputed using the *mice* package in R (van Buuren & Groothuis-Oudshoorn, 2011) before scale totals were calculated.

At both follow-up points (3 and 12 months), as all measures were administered online, outcome measures were always either completed in full or not completed at all. Where scale totals were missing at 3- and 12-month follow-up, the last available score was carried forward, in line with an intention to treat approach.

Some parents completed the SCAS and others the SCAS pre-school, which have a different number of items (38 and 28, respectively). Because *T*-scores are not available for the SCAS pre-school, scores on each scale were converted to *z*-scores to make them comparable.

Baseline characteristics of the two conditions are reported in Table 3.

Acceptability of the intervention

Attendance

Of those randomized to receive the intervention, 59% attended a workshop. The remainder (except two participants who dropped out early) were sent comprehensive

Table 3. Baseline and demographic information by condition

		Intervention group	Control group	Classical test	Bayes factor (%)
Child age	Years (SD)	5.53 (2.03)	5.45 (1.96)	t_{Yuen} (53.84) = 0.30, p = .76	0.21 ± 0.03
Parent	Female	41	44	χ^2 (I) = 1.07, p = .30	0.76 ± 0
gender	Male	10	5		
Child gender	Female	22	19	$\chi^2(1) = 0.06, p = .81$	0.27 ± 0
-	Male	29	30		
Financial	Comfortable	10	11	χ^2 (2) = 0.49, p = .78	0.11 \pm 0
status	Managing	24	26		
	Struggling	14	11		
Child	'White'	42	34	χ^2 (I) = 1.65, p = .20	0.87 ± 0
ethnicity	'Other'	9	15		
Parent	'White'	45	40	$\chi^2(1) = 0.42, p = .52$	0.50 ± 0
ethnicity	'Other'	6	9		
Parent education	Educated to minimum school leaving age (MSLA)	10	П	$\chi^{2}(1) = 0.01, p = .92$	0.31 ± 0
	Educated beyond MSLA	41	38		

Notes. T-test is a robust variant proposed by Yuen and implemented using the functions by Wilcox (2012); Bayes factors computed with the BayesFactor package in R (Morey & Rouder, 2014) using the default priors. A Bayes Factor = I represents equal evidence for the null and alternative hypotheses; values below I (as in this table) suggest more evidence for the null than for the alternative hypothesis.

Table 4. Parents' responses to satisfaction questionnaire

Question	Mean (SD) Range
How much have you enjoyed the workshop?	3.65 (0.61) 2–4
How easy was it to understand what we talked about in this workshop?	3.82 (0.43) 2–4
How much do you think that coming today will help you to prevent your child developing anxiety?	3.1 (0.89) I-4

Note. The scale ran from 0 ('not at all') to 4 ('very much').

workshop materials. This low uptake rate was largely driven by sites where just one or two workshops were offered, limiting accessibility of the intervention. In the local area, where there was more choice of workshop dates, attendance was 69%.

The end-of-workshop questionnaire showed excellent acceptability and satisfaction. See Table 4.

All but one parent agreed that they would recommend the workshop to another anxious parent (this was a missing response).

Feasibility

Parent data. An encouraging 85% of parents participated in at least one post-intervention outcome assessment.

However, at 3-month follow-up, only 57% of parents participated. Although this was a relatively low response rate, this is not unusual for Internet-based outcome data collection (Mathieu, McGeechan, Barratt, & Herbert, 2013).

With some adjustments to the process, participation increased to 81% at 12 months – in particular, we encouraged parents to complete their outcome measures even if they could not persuade their child to do theirs.

There did not appear to be any substantial differential attrition by condition (18% in intervention condition, 20% in control, at 12 months).

Child-report data. Receipt of data from children was very low at both baseline and at follow-ups. This was not unexpected and was driven by three key factors: (1) children not attending intake session with parents or refusing to participate (13%); (2) children aged below five were not asked to provide self-reports (38%); and (3) our dependence on parents for children's engagement at follow-up – in many cases, parents provided data using our Internet form, but their children did not. At both 3- and 12-month follow-up, only 20% of children (32% of those eligible) returned data.

It appears that adequate data collection from children in this context is not feasible.

Cost. An estimate of the cost of this intervention (using Unit Costs of Health and Social Care, 2015; Curtis & Burns, 2015) and assuming five consecutive sessions of an IAPT professional's time comes to £525 per workshop. The workshop was run with up to six participants (and could be run with around 10), giving a cost per parent of under £90, and considerably less per child, if we assume that many parents will have more than one child.

Outcomes

Scores for outcome variables by the condition are reproduced in Table 5. NB:

(1). Parents completed either the SCAS *or* the SCAS pre-school (according to child's age), which have different items. Therefore, scores were converted to *z*-scores to make them comparable (assuming configural measurement invariance).

Table 5. Outcomes by condition

	Baseline (SE)	3 Months (SE)	12 Months (SE)			
Spence Child Anxiety Scale – Parent Report (z-scores) (lower score = fewer symptoms)						
Intervention	-0.0751 (0.141)	-0.254 (0.112)	-0.241 (0.120)			
Control	0.0689 (0.152)	0.138 (0.160)	0.213 (0.166)			
Fear Survey Schedule for Children – Parent Report						
Intervention	138 (4.20)	132 (3.92)	130 (3.54)			
Control	138 (3.84)	136 (4.25)	132 (4.19)			
Proportion with anxiety diagnosis						
Intervention	, -		51.5%			
Control			60.5%			

- (2). Given the very low return rate from children, we do not report their self-report data.
- (3). The study was not designed to test the efficacy of the intervention and, therefore, not powered *a priori* for significance tests.

Table 5 shows that children's symptom scores fell from baseline, and this reduction appears to be greater for the intervention group. There were also 16.5% more diagnoses at 12 months in the control group than in the intervention group.

The study was not powered to test differences between groups using classical statistical models; however, Bayesian models were fit to ascertain plausible values of the effect of the intervention and are reported in Data S1.

There were no reports of adverse events.

Discussion

This study showed that an RCT of a brief group-based, parenting intervention aimed at reducing risk of anxiety in children of parents with anxiety disorders was feasible. Early signs of effectiveness were found.

For those who attended the workshop, satisfaction with the intervention was excellent. The vast majority of participants enjoyed the intervention, found the material easy to understand, and thought that it would help them prevent anxiety in their children. All but one participant stated that they would recommend the workshop to an anxious friend (the participant did not complete this item). However, attendance levels were modest: Overall, 59% of those randomized to attend a workshop did so. This was higher in the local area (69%), which had the greatest choice of workshop dates. For many external trust participants, and those recruited at the end of the study, there was very limited choice of workshop dates, and this impacted on uptake. However, it should be noted that all non-attenders were sent comprehensive written materials (handouts from the workshop) and these may have had a positive impact for those families. Reasons given for non-attendance were almost exclusively pragmatic (lack of childcare, unable to take time off work). However, it is possible that anxiety prevented attendance by many. This attendance rate is not as high as we had hoped for (although typical for community-based interventions), and in future, efforts should be made to address the barriers to access that clearly face many parents. Potential solutions that we are considering for future iterations of the workshop include as follows: running the workshop at a range of different days and times of day; running a crèche alongside the workshop; and developing an online version of the intervention, to allow parents to access the material in their own time and without having to be part of a group.

We wanted to find out whether we could keep loss to follow-up at an acceptable level after an intervention that was light touch, and preventative (many parents had no concerns about their children at baseline). Eighty-five per cent of parents participated in at least one follow-up assessment. However, the return of outcome data at 3-month follow-up was modest – 57% of parents completed measures. Although not unusual for studies using online outcome data collection (Mathieu *et al.*, 2013), we were disappointed with this response rate. In response, changes were made to procedures at 12-month follow-up: We made more strenuous efforts to contact participants and encouraged parents to provide data themselves even if their children did not wish to do so themselves. These changes boosted response rates at 12 months to 81%. We would recommend that any future trial considers dropping the 3-month follow-up and concentrating efforts on the 12-month assessment. Given the 12-month results, and a fast-evolving methodology for

collecting data online (e.g., Bailey *et al.*, 2013), we believe that excellent follow-up (of parents) to 12 months is feasible. Critically, there was no evidence of differential attrition by condition.

We wanted to test the feasibility of capturing not just parents' ratings of children's anxiety, but children's ratings too. However, this did not prove to be feasible. Children under 5 years were excluded from these measurements for practical reasons (38% were ineligible for this reason), which reduced the potential pool. Second, children were not always present at baseline assessment (13%). As a result, baseline data were available for little over half of all participants, a rate that fell to just 20% at each subsequent assessment. Therefore, these data are not reported, and we recommend that future studies focus efforts on collecting reports on children from parents only, as is usual in trials of parenting interventions for this age group. Alternatively, studies could attempt to gather a full set of much less detailed data (e.g., a single short anxiety questionnaire) from children.

This study was not powered to detect statistically significant differences between groups. However, for all of the outcome measures, the results were in the predicted direction. That is, children's mean anxiety symptoms and anxiety diagnoses were lower at 12 months in the intervention group than in the control group. Notably, for children whose parents were in the intervention group, 51.5% were found to have an anxiety disorder at follow-up. This figure was 60% for those whose parents had been in the intervention condition, representing 16.5% more diagnoses in the control group than in the intervention group. However, it should be noted that sample sizes were small and there is therefore imprecision in these estimates (see Data S1 for Bayesian estimates of the plausible effect sizes of the intervention for each outcome measure).

This study is the first attempt to prevent anxiety in the children of parents with anxiety disorders using a light-touch approach. This approach appears to be inexpensive, easy to administer, and highly palatable to clients.

The study has a number of strengths, including good retention at 12 months, and no differential attrition. However, it has a number of limitations. Most of these arose in an effort to keep resource use to a manageable level, mindful that any substantive trial of this intervention is likely to need a very large sample size. Therefore, we did not conduct a children's diagnostic interview at baseline, relying instead on questionnaire data to determine that our groups were similar at intake. As expected, the groups were very similar at baseline on these measures, and it is likely therefore that children will have entered the study with similar levels of anxiety diagnoses. However, without baseline diagnostic interviews, we cannot be absolutely sure of this. As a result of not measuring diagnoses at baseline, it was also not possible to use a 'last observation carried forward' approach to managing missing diagnostic data (as was used for the questionnaire data), and, therefore, the results presented for diagnoses cannot be 'Intention to Treat'.

As discussed above, we experienced a high level of missing data at the 3-month time point. However, this was resolved very successfully at 12 months and we now have confidence that any subsequent substantive study could collect sufficient data for valid analysis.

It should be noted that the intervention was delivered by a single clinical child psychologist who specializes in anxiety of childhood. However, the material is relatively simple to deliver and it is anticipated that it could be delivered by most mental health professionals with a modest amount of training. A manual, to allow delivery by other professionals, is in preparation.

Finally, we attempted to collect data from children, to reduce the dependence on parents who may have reporting biases. In event, too little data were collected from children to analyse meaningfully. Similar difficulties have been reported in related studies of young children (Cartwright-Hatton et al., 2011), and indeed, studies of parenting interventions for this age group typically do not attempt to gather child self-reports. We do not think that it is feasible, or cost-effective, to collect this in any future, larger study.

In conclusion, we have shown that it is feasible, with some modification, to run and to evaluate a brief, parenting-based, preventative intervention for parents with anxiety disorders. The intervention was appealing to parents and appears to have some impact on children's anxiety symptoms and diagnoses. A much larger, longer-term study is now required, to thoroughly evaluate the effectiveness and cost-effectiveness of this intervention.

Acknowledgements

This report is independent research arising from an NIHR Career Development Award supported by the National Institute for Health Research. The views expressed in this publication are those of the authors and not necessarily those of the NHS, the National Institute for Health Research or the Department of Health. This study was supported by the United Kingdom Clinical Research Collaboration-registered King's Clinical Trials Unit at King's Health Partners, which is part-funded by the NIHR Biomedical Research Centre for Mental Health at South London and Maudsley NHS Foundation Trust and King's College London and the NIHR Evaluation, Trials and Studies Coordinating Centre.

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Received 30 October 2017; revised version received 19 January 2018

Supporting Information

The following supporting information may be found in the online edition of the article:

Data S1. Statistical models.