



Classroom-based cognitive behaviour therapy (FRIENDS): a cluster randomised controlled trial to Prevent Anxiety in Children through Education in Schools (PACES)

Paul Stallard, Elena Skryabina, Gordon Taylor, Rhiannon Phillips, Harry Daniels, Rob Anderson, Neil Simpson

Summary

Background Anxiety in children is common, impairs everyday functioning, and increases the risk of severe mental health disorders in adulthood. We investigated the effect of a classroom-based cognitive behaviour therapy prevention programme (FRIENDS) on anxiety symptoms in children.

Methods Preventing Anxiety in Children through Education in Schools (PACES) is a three-group parallel cluster randomised controlled trial. Interventions were given between September, 2011, and July, 2012, with schools as the unit of allocation and individual participants as the unit of analysis. We enrolled state-funded junior schools in southwest England. We sent information to all eligible schools (state-funded junior schools in southwest England) inviting them to enrol in the study. School year groups were assigned by computer-generated randomisation (1:1:1) to receive either school-led FRIENDS (led by teacher or school staff member), health-led FRIENDS (led by two trained health facilitators), or usual school provision. Children were not masked to treatment allocation. The allocated programme was given to all students (aged 9–10 years) in the school year (ie, universal delivery) as part of the school curriculum as nine, 60 min weekly sessions. Outcomes were collected by self-completed questionnaire administered by researchers masked to allocation. Primary outcome was symptoms of anxiety and low mood at 12 months assessed by the Revised Child Anxiety and Depression Scale (RCADS 30). Analyses were intention to treat and accounted for the clustered nature of the design. The study is registered, number ISRCTN23563048.

Findings 45 schools were enrolled: 14 (n=497 children) were randomly assigned to school-led FRIENDS, 14 (n=509) to health-led FRIENDS, and 12 (n=442) to usual school provision. 1257 (92%) children completed 12 month assessments (449 in health-led FRIENDS, 436 in school-led FRIENDS, and 372 in usual school provision). We recorded a difference at 12 months in adjusted mean child-reported RCADS scores for health-led versus school-led FRIENDS (19·49 [SD 14·81] vs 22·86 [15·24]; adjusted difference -3·91, 95% CI -6·48 to -1·35; p=0·0004) and health-led FRIENDS versus usual school provision (19·49 [14·81] vs 22·48 [15·74]; -2·66, -5·22 to -0·09; p=0·043). We noted no differences in parent or teacher ratings. Training teachers to deliver mental health programmes was not as effective as delivery by health professionals.

Interpretation Universally delivered anxiety prevention programmes can be effective when used in schools. However, programme effectiveness varies depending on who delivers them.

Funding National Institute for Health Research Public Health Research Programme.

Introduction

Anxiety disorders affect 10% of children by the age of 16 years.¹ They significantly impair everyday functioning, often persist into adulthood, and increase the risk of other psychiatric disorders in adolescence and young adulthood.^{2–5} The associated health-related burden, and economic and societal costs are large, and the need to improve the mental health of children is being increasingly recognised as a global priority.^{6–8}

Effective psychological interventions, especially cognitive behaviour therapy (CBT), are available for children with anxiety disorders.^{9,10} However, comparatively few children with anxiety disorders are identified and referred for treatment.^{11,12} The poor reach and availability of traditional treatment services has led to interest in more proactive preventive approaches with schools offering a convenient and natural location to deliver such programmes.^{13,14}

Findings of systematic reviews show that universal and targeted anxiety prevention programmes are often based on cognitive behaviour therapy.¹⁵ Data from reviews^{15,16} suggest that cognitive behaviour therapy prevention programmes can be effective, although research methods are poor, adequately powered implementation trials are scarce, results are inconsistent, and effect sizes vary greatly. Most studies report overall changes in symptoms, and the preventive benefits for less symptomatic participants have seldom been reported.

Prevention programmes can be universally provided to all of an identified population, or targeted towards those at risk of developing a disorder or showing early signs of a disorder, or a combination of both approaches.¹⁷ Universal programmes have good reach, avoid the need for screening, are less stigmatising, and offer the potential to enhance mental health and reduce present symptoms.

Lancet Psychiatry 2014;

1: 185–92

Published Online

July 16, 2014

[http://dx.doi.org/10.1016/S2215-0366\(14\)70244-5](http://dx.doi.org/10.1016/S2215-0366(14)70244-5)

See [Comment](#) page 164

Department for Health,

University of Bath, Bath, UK

(Prof P Stallard PhD,

E Skryabina PhD, G Taylor PhD);

Institute of Primary Care and

Public Health, Cardiff

University, Cardiff, UK

(R Phillips PhD); Department of

Education, University of

Oxford, Oxford, UK

(Prof H Daniels PhD); University

of Exeter Medical School,

University of Exeter, Exeter, UK

(Prof R Anderson PhD); and

Sirona Care and Health, Bath,

UK (N Simpson MBBS)

Correspondence to:

Paul Stallard, Child and

Adolescent Mental Health

Research Group, Department of

Health, University of Bath,

Bath BA2 7AY, UK

p.stallard@bath.ac.uk

Targeted programmes focus scarce resources on individuals with greatest needs, and usually achieve larger treatment effects.^{18,19}

The effect of the intervention leader (health vs school professional) has important implications for the method of delivery and sustainability of an intervention but has been directly investigated in only one study.²⁰ Barrett and Turner noted that a universal anxiety prevention programme (FRIENDS; panel 1) was equally effective in the reduction of symptoms of anxiety in children aged 10–12 years when given by a psychologist or teacher. However, systematic reviews have reached different conclusions about who is most effective at delivering these programmes.^{15,16}

Before anxiety prevention programmes can be endorsed and widely provided, independent implementation trials

are needed to measure effectiveness and cost-effectiveness when provided under real-life conditions and to establish the effect of the intervention leader on outcome.

We undertook a pragmatic assessment of the effectiveness of a classroom-based anxiety prevention programme (FRIENDS²¹) universally delivered by health and school professionals to school years 4 and 5 (children aged 9–10 years) in UK junior schools.

Methods

Study design and participants

We did this three-group parallel cluster randomised controlled trial between September, 2011, and July, 2012, with school as the unit of allocation and individual participants as the unit of analysis.²² A project information sheet and trial enrolment form was sent to all primary schools in Bath and northeast Somerset, Swindon Borough, and Wiltshire within a 50 mile radius of the University of Bath, UK (n=268). Eligible schools were state-funded junior schools in three Local Education Authorities in southwest England. Such junior schools are mainstream government-funded schools that are attended by 94.5% of children aged 5–10 years in the UK. All children aged 9–10 years (years 4 and 5) in participating schools were eligible, unless they were not attending school (eg, because of long-term sickness or excluded from school) or did not participate in Personal Social and Health Education (PSHE) lessons for religious or other reasons. The allocated intervention was given to all participants in the school year (ie, universal delivery) as part of the PSHE curriculum. The trial protocol is online.

Participation required written consent from the school head teacher, parents' not opting their child out of the study, and signed assent from the child. The study was approved by the University of Bath, Department for Health Research Ethics Committee.

Randomisation and masking

Once all schools had been enrolled, we randomly assigned year groups (1:1:1) to school-led FRIENDS, health-led FRIENDS, or usual school provision. Randomisation was undertaken at school and not the class level to avoid possible contamination within schools. Trial groups were balanced with respect to key characteristics by calculating an imbalance statistic for a large random sample of possible allocation sequences.²³ Children were not masked to treatment allocation. Outcomes were collected by self-completed questionnaire administered by researchers masked to allocation. Group allocation was kept in a separate password-protected database. Researchers who analysed data were also masked to allocation—trial groups were numerically coded and data analysis undertaken masked to which code related to each trial group. The variables used for balancing were school size, number of students and classes, number of mixed classes, level of educational attainment, and preferred timetabling. A statistician with no other involvement in

For more on the trial protocol see <http://www.trialsjournal.com/content/13/1/227/abstract>

Panel 1: Acronym for the FRIENDS process

- F Feelings
- R Remember to relax
- I I can do it. I can try my best
- E Explore solutions and coping step plans
- N Now reward yourself. You've done your best
- D Don't forget practice
- S Smile. Stay calm for life

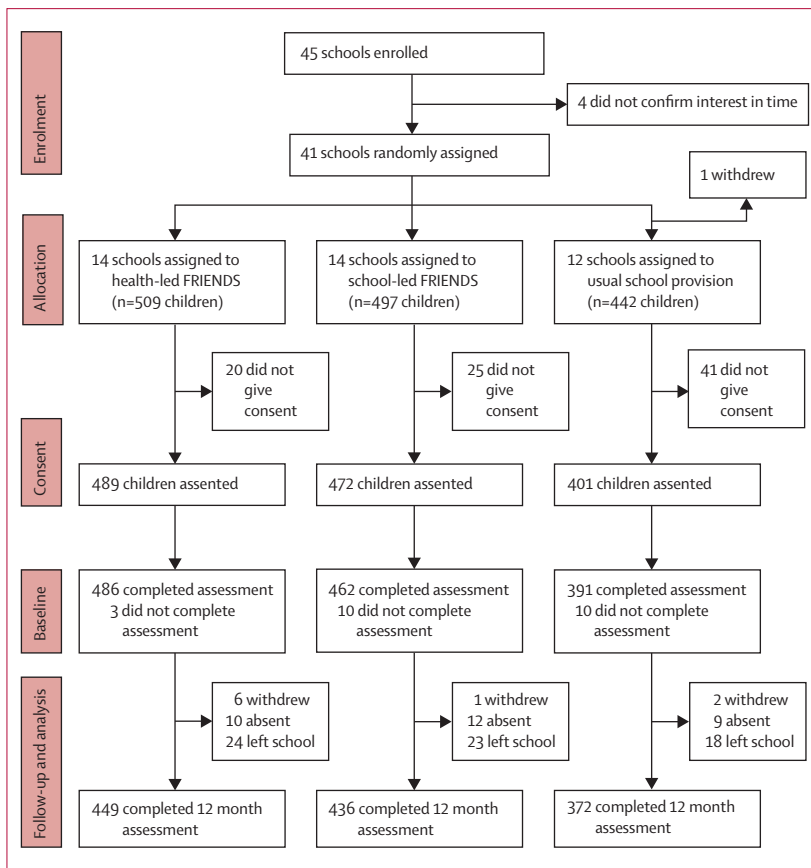


Figure: Trial profile

the study randomly selected one sequence from a subset with the most desirable balance properties.

Procedures

Interventions were delivered in the academic year September, 2011, to July, 2012. The anxiety prevention programme we assessed (FRIENDS) is a manualised cognitive behaviour therapy intervention that has been identified as effective.^{16,24} The programme was developed to be delivered in schools and provided to whole classes of children. FRIENDS is based on the principles of CBT and develops skills to counter the cognitive, emotional, and behavioural aspects of anxiety. Children develop emotional awareness and regulation skills, to identify and replace cognitions that increase anxiety with more balanced and functional ways of thinking and to develop problem-solving skills to confront and cope with situations and events that provoke anxiety. The intervention trialled in this study consisted of nine, 60 min weekly sessions delivered to whole classes of children. Children had their own workbook and group leaders had a detailed session plan that specified key learning points, objectives, and core activities for each session. The feasibility and viability of delivering FRIENDS in UK schools has previously been established.^{25,26}

In the health-led FRIENDS programme, each session was led by two trained health facilitators working alongside the class teacher. All facilitators had at least an undergraduate university degree in a relevant discipline (eg, social science or education), appropriate professional backgrounds (eg, psychology, nursing, or education), or experience of working with children or young people. Initial 2 day training and supervision every 2 weeks were provided by accredited FRIENDS trainers. Supervision was in a group format and consisted of review of session plans, the underlying cognitive model, class and behaviour management skills, and any interpersonal difficulties or communication problems with the class teacher.

In the school-led FRIENDS programme, sessions were led by a teacher or member of the school staff (eg, teaching assistant) who were trained in delivery of the programme and were supported by two facilitators. School staff attended the same 2 day initial training and were offered ongoing supervision. We assessed treatment fidelity by randomly assessing audiotape recordings of 10% of FRIENDS sessions.

In the usual school provision programme, children participated in the usual PSHE sessions provided by the school. All schools were following a UK National Curriculum programme designed to develop self-awareness, management of feelings, motivation, empathy, and social skills.²⁷ The sessions were planned and provided solely by the teacher and did not include any external input from the research team.

Outcomes

Child outcomes were collected during class time with self-completed questionnaires administered by researchers at

baseline, 6 months, and 12 months. As described in the trial protocol,²⁰ the primary outcome was symptoms of anxiety and low mood 12 months after baseline as established by the Revised Child Anxiety and Depression scale (RCADS 30).^{28,29} Secondary outcomes assessed worry (with the Penn State Worry Questionnaire for Children),³⁰ self-worth and acceptance (with the Rosenberg Self-Esteem Scale),³¹ extent of bullying (with the Olweus Bully/Victim Questionnaire), and life satisfaction (with a subjective wellbeing assessment).

	Health-led FRIENDS (N=489)	School-led FRIENDS (N=472)	Usual PSHE (N=401)
Number of schools	14	14	12
Number of schools with ≥two classes	6	7	5
Class size	19.56 (6.56)	18.15 (7.68)	20.05 (8.29)
Missing baseline assessment	3 (0.6%)	10 (2.1%)	10 (2.5%)
Sex			
Boys	255 (52.1%)	237 (50.2%)	170 (42.4%)
Girls	234 (47.9%)	235 (49.8%)	231 (57.6%)
Ethnic origin			
British white	455 (94.2%)	439 (95.2%)	359 (92.1%)
Non-white	28 (5.8%)	22 (4.8%)	31 (7.9%)
Living situation			
Mother and father	347 (71.4%)	315 (68.2%)	268 (68.5%)
Parent and partner	43 (8.8%)	55 (11.9%)	37 (9.4%)
Single parent	67 (13.8%)	68 (14.8%)	58 (14.8%)
Other	29 (6.0%)	24 (5.2%)	28 (7.2%)
Number of siblings			
0	49 (10.1%)	30 (6.5%)	32 (8.2%)
1	221 (45.5%)	214 (46.5%)	184 (47.1%)
2	129 (26.5%)	134 (29.1%)	92 (23.5%)
3 or more	87 (17.9%)	82 (17.8%)	83 (21.2%)
Family affluence			
Low (0–2)	6 (1.5)	11 (2.4)	13 (3.3)
Medium (3–5)	142 (29.4)	139 (30.1)	128 (32.9)
High (6–8)	331 (69.1)	311 (67.5)	249 (63.8)
Child-completed assessments			
Child total RCADS	26.24 (15.56)	24.91 (14.32)	26.78 (16.32)
Penn Worry Scale	10.63 (8.14)	10.99 (8.24)	10.46 (8.35)
Self-esteem	18.94 (5.34)	19.43 (5.39)	19.57 (5.98)
Total life satisfaction	14.21 (6.77)	13.32 (5.71)	13.76 (6.82)
Been bullied			
Bullied ≥two to three times per month	142 (29.3%)	124 (26.8%)	112 (28.6%)
Not bullied or only once or twice	343 (70.7%)	338 (73.2%)	279 (71.4%)
Parent-completed assessments	217 (44.4%)	201 (42.6%)	153 (38.2%)
Total RCADS	12.55 (8.81)	10.99 (8.60)	12.52 (9.34)
Total SDQ	9.09 (6.32)	8.31 (6.28)	9.00 (6.24)
Teacher-reported assessment	487 (99.6%)	466 (98.7%)	396 (98.8%)
Teacher SDQ impact			
Difficulty	119 (24.4)	125 (26.8)	109 (27.5)

Data are mean (SD) or number (%) unless otherwise indicated. Family affluence assessed by the Family Affluence Scale. PSHE=personal social and health education. RCADS=Revised Child Anxiety and Depression Scale. SDQ=Strength and Difficulties Questionnaire.

Table 1: Baseline characteristics

	Health-led FRIENDS		Adjusted difference (95% CI) at 12 months: health-led FRIENDS vs usual school provision	Adjusted difference (95% CI) at 12 months: health-led FRIENDS vs school-led FRIENDS	School-led FRIENDS		Adjusted difference (95% CI) at 12 months: school-led FRIENDS vs usual school provision	Usual school provision		p value overall group effect*
	Baseline n=489	12 months n=449			Baseline n=472	12 months n=436		Baseline n=401	12 months n=372	
Depression	4.04 (2.60)	3.15 (2.53)	-0.36 (-0.76 to 0.04)	-0.34 (-0.82 to 0.14)	3.68 (2.34)	3.34 (2.51)	-0.02 (-0.43 to 0.38)	3.85 (2.77)	3.47 (2.72)	0.120
Social anxiety	5.28 (3.28)	4.39(3.32)	-0.41 (-0.94 to 0.12)	-0.79 (-1.42 to -0.16)	5.05 (3.23)	5.04 (3.43)	0.38 (-0.16 to 0.91)	5.13 (3.26)	4.68 (3.37)	0.013
Separation anxiety	3.81 (3.34)	2.48 (2.94)	-0.42 (-0.97 to 0.12)	-0.42 (-1.07 to -0.23)	3.68 (3.14)	2.89 (2.96)	0.00 (-0.54 to 0.55)	4.23 (3.45)	3.07 (3.14)	0.190
Generalised anxiety	5.79 (3.80)	4.43 (3.56)	-0.77 (-1.40 to -0.14)	-0.89 (-1.64 to -0.14)	5.64 (3.54)	5.19 (3.64)	0.12 (-0.52 to 0.75)	5.97 (3.94)	5.15 (3.70)	0.011
Panic	2.85 (2.87)	2.03 (2.56)	-0.34 (-0.78, 0.09)	-0.37 (-0.89 to 0.15)	2.68 (2.79)	2.33 (2.74)	0.03 (-0.41 to 0.47)	2.97 (3.11)	2.42 (3.00)	0.157
OCD	4.56 (3.31)	3.43 (3.10)	-1.99 (-0.71 to 0.31)	-0.51 (-1.12 to 0.10)	4.45 (3.12)	3.99 (3.20)	0.31 (-0.21 to 0.83)	4.61 (3.22)	3.79 (3.20)	0.124
Total RCADS	26.24 (15.56)	19.49 (14.81)	-2.66 (-5.22 to -0.09)	-3.91 (-6.48 to -1.35)	24.91 (14.32)	22.86 (15.24)	1.28 (-1.30 to 3.87)	26.78(16.32)	22.48 (15.74)	0.009

Data are mean (SD) unless otherwise stated. PSHE=personal social and health education. RCADS=Revised Child Anxiety and Depression Scale. OCD=obsessive compulsive disorder. *RCADS adjusted for sex, school, and baseline RCADS.

Table 2: Analysis of primary outcome (child-completed RCADS) for all children at 12 months for health-led FRIENDS and school-led FRIENDS vs PSHE

	Health-led FRIENDS		School-led FRIENDS		Usual school provision		p value overall group effect*
	Baseline	12 months	Baseline	12 months	Baseline	12 months	
Child reported							
N	489	449	472	436	401	372	..
Penn Worry Scale	10.63 (8.14)	8.19 (7.93)	10.99 (8.24)	9.62 (8.30)	10.46 (8.35)	9.03 (8.52)	0.136
Self-esteem	18.94 (5.34)	20.90 (6.22)	19.43 (5.39)	20.77 (5.82)	19.57 (5.98)	20.87 (5.95)	0.639
Total life satisfaction	14.21 (6.77)	13.87 (6.00)	13.32 (5.71)	13.73 (6.08)	13.76 (6.82)	13.95 (5.88)	0.770
Bullied more ≥2-3 times per month	142 (29.3%)	74 (16.5%)	124 (26.8%)	98 (22.5%)	112 (28.6%)	86 (23.2%)	0.156
Not bullied or once or twice	343 (70.7)	374 (83.5)	338 (73.2)	337 (77.5)	279 (71.4)	285 (76.8)	
Parent reported							
N	217	173	198	159	152	119	..
Total RCADS	12.55 (8.81)	10.76 (8.90)	10.99 (8.60)	9.82 (7.13)	12.52 (9.34)	10.03 (7.31)	0.816
Total SDQ	9.09 (6.32)	7.06 (6.00)	8.31 (6.28)	6.67 (5.62)	9.00 (6.24)	7.32 (9.95)	0.767
Total SDQ threshold ≥17	22 (10.5%)	15 (9.3%)	25 (13.0%)	11 (7.3%)	21 (14.4%)	9 (7.9%)	0.333
Teacher reported							
N	487 (99.6%)	454 (92.8%)	466 (98.7%)	445 (94.3%)	396 (98.8%)	375 (93.5%)	..
Teacher SDQ impact	119 (24.4)	131 (28.9)	125 (26.8)	143 (32.1)	109 (27.5)	117 (31.2)	0.538

Data are mean (SD) scores or n (%). PSHE=personal social and health education. RCADS=Revised Child Anxiety and Depression Scale. SDQ=Strength and Difficulties Questionnaire *Between group differences at 12 months adjusted for baseline, sex, and school level effects.

Table 3: Analysis of secondary outcomes for all children at 12 months for health-led FRIENDS, school-led FRIENDS and usual school provision (PSHE)

Parents completed a behavioural screening questionnaire (Strength and Difficulties Questionnaire [SDQ])³² and the parent version of the Revised Child Anxiety and Depression Scale (RCADS-30-P)³³ at baseline, 6 months, and 12 months.

Class teachers completed the impact rating of the Strengths and Difficulties Questionnaire (SDQ) for all children in their class at all three assessment points to assess the presence of an emotional or behavioural problem, chronicity, distress, social impairment, and burden.

Statistical analysis

We powered the study to detect a difference of 3.6 points in mean RCADS total scores between FRIENDS and usual PSHE. On the basis of an SD of 12 points and an intracluster correlation coefficient of 0.02, 28 pupils per class, 90% consent and 80% retention, effect sizes between 0.28 and 0.30, SDs are detectable with 80% power and 5% two-sided α with 1134–1360 assenting pupils.

We used descriptive statistics to assess balance between the trial groups at baseline. The primary outcome was assessed by intention to treat without imputation. To take

appropriate account of the hierarchical nature of the data, we used multivariable mixed effects models to compare mean RCADS at 12 months for health-led FRIENDS with school-led FRIENDS and usual school provision, with adjustment for baseline RCADS, sex, and school effects. We repeated these analyses for secondary outcomes. For RCADS we undertook a further planned analysis. We used repeated-measures mixed-effects analysis of variance models to investigate convergence and divergence between trial groups over time. We did preplanned subgroup analyses with interaction terms in the regression models between the randomised group and the baseline variable (low anxiety RCADS 0–48, high anxiety ≥ 49).

We did sensitivity analyses to assess the potential effect of missing data. Completion rates for all groups at 12 months were high (91.8–92.7%), although non-completers tended to be more symptomatic on our primary outcome measure (RCADS) at baseline (data not shown). With multiple imputation methods, we created 20 datasets and showed that imputation for missing data made no material difference to the overall results.³⁴ Therefore, the data we present are based on recorded data only.

The study is registered, number ISRCTN23563048.

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, interpretation of data, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Between September, 2011, and July, 2012, 45 schools were enrolled. 41 consented to participate and were randomly assigned: 14 (n=497 children) to school-led FRIENDS, 14 (n=509) to health-led FRIENDS, and 12 (n=442) to usual school provision. One school from usual school provision withdrew before baseline assessments were undertaken (figure). The remaining 40 schools were representative of the UK in terms of academic attainment according to Department of Education performance tables (ie, the percentage of children achieving key stage 2 level 4 in maths and English; data not shown). However, more children had special educational needs (23.2% vs 17.1%), pupil absence rates were lower (4.4% vs 5.1%), and eligibility for free school meals was lower (12.4% vs 18.2%) in the cohort than the national average.

Of the 1448 eligible participants, 1362 (94%) consented to participate in the study, of whom 1339 (98%) completed baseline assessments. The proportion of boys in the usual school provision group (42%) was lower than in each of the other two trial groups, but otherwise the groups were well balanced (table 1).

All nine FRIENDS sessions were delivered to classes assigned to both the health-led and school-led conditions. To assess intervention fidelity, we recorded and independently rated 49 sessions (one from each class in the

	Health-led FRIENDS	School-led FRIENDS	Usual school provision	p value overall group effect*
High anxiety†				
N	36	31	32	..
Baseline	57.59 (8.18)	55.66 (7.16)	57.57 (7.90)	0.288
12 months	35.31 (19.24)	40.65 (21.40)	33.97 (21.15)	0.368
Low anxiety‡				
N	374 (91.2%)	360 (92.1%)	295 (90.2%)	..
Baseline	22.78 (11.86)	22.01 (11.05)	22.51 (12.03)	0.623
12 months	17.68 (13.40)	21.06 (13.42)	20.74 (14.12)	0.006

Data are n (%) or mean (SD) unless otherwise indicated. RCADS=Revised Child Anxiety and Depression Scale. *Adjusted for sex, school, and baseline RCADS. †A total baseline RCADS score of 49 or more. ‡A total baseline RCADS score of 48 or less.

Table 4: Subgroup analysis of primary outcome (child-completed total RCADS) for children with high and low anxiety

28 schools delivering FRIENDS). All specified core tasks and home activities were delivered in the 24 health-led sessions. In the school-led sessions, 15 of 25 (60%) delivered all core tasks and the home activity, eight (32%) delivered all except the home activity, and two (8%) did not deliver one core task and the home activity. Session attendance was not recorded although average school absence rates were very low (4.2% in the health-led group and 4.4% in the school-led group).

We collected primary outcome data at 12 months from 1257 (92%) of the children who completed baseline assessments (449 [92%] in the health-led group, 436 [92%] in school-led group, and 372 [93%] in the usual school provision). We recorded a significant difference in adjusted mean RCADS at 12 months for health-led FRIENDS compared with school-led FRIENDS (interaction coefficient -3.91 , 95% CI -6.48 to -1.35 ; $p < 0.0004$) and usual school provision (-2.66 , -5.22 to -0.09 , $p = 0.043$). The 95% CIs include our predefined clinically important difference of 3.6 points on the RCADS. Analysis of the RCADS subscales showed difference in generalised and social anxiety, but not depression (table 2).

Analysis of other secondary outcomes and parent and teacher completed measures identified no differences between treatment groups at 12 months (table 3).

As specified in the protocol, we did separate subgroup analysis in children with the highest 10% of baseline RCADS scores (high anxiety ≥ 49) and the remaining 90% (low anxiety ≤ 48 ; table 4).²²

We recorded significant within-group reductions for the high-risk group at 12 months but no effects between groups. For the low-risk group, we noted between-group differences in mean RCADS at 12 months (table 4). Adjusted mean differences showed an effect for health-led FRIENDS versus school-led FRIENDS (adjusted difference -3.78 , 95% CI -6.16 to -1.40 ; $p = 0.003$) and health-led FRIENDS versus usual school provision (-3.13 , -5.61 to -0.65 ; $p = 0.015$). This effect relates to a reduction in the health-led FRIENDS group on the social and generalised anxiety subscales (table 2).

For Department of Education performance tables see <http://www.education.gov.uk/schools/performance/archive/index.shtml>

In the low anxiety group, the standardised effect size of health-led FRIENDS compared with usual school provision (Cohen's $d=0.22$, 95% CI 0.38–0.07) and school-led FRIENDS (0.25, 0.40–0.11) was small. The economic evaluation will be published separately.

Discussion

This is the first large pragmatic randomised trial comparing a universally provided classroom-based cognitive behaviour therapy anxiety prevention programme led by health and school staff with usual school provision. When we transferred health-led FRIENDS to everyday settings, the programme was more effective in the reduction of child-reported symptoms of anxiety than was school-led FRIENDS or usual school provision (panel 2). Although intervention leaders received the same initial training, our data suggest that a manualised programme might result in different outcomes depending on who delivers it. Although training teachers to deliver mental health programmes offers a potentially convenient low-cost sustainable option, our results show that this approach is not as effective as delivery by health professionals.

Further exploration identified two potentially important differences between health and school leaders. First, although treatment fidelity was high, the

home assignment was not undertaken in 40% of the school-led sessions that were assessed. Continuing practice of newly acquired skills is an integral part of cognitive behaviour therapy programmes and the absence of such practice might have compromised effectiveness. However, this possibility needs to be balanced against the increased opportunities for class teachers to integrate and consolidate programme skills more intensively through their daily contact with children. Second, although both groups had the same initial training, comparatively few teachers attended continuing supervision. Although teachers will be competent in some of the areas addressed in supervision (eg, classroom management and engaging children of differing abilities), they will be less familiar with the underlying cognitive model. Therefore, scarce opportunities to consolidate the theoretical model might have compromised programme delivery.

Children with high and low anxiety showed significant reductions in anxiety symptoms over time. The number of children with high anxiety was small and our study was not powered to compare between-group differences within this subgroup. Therefore, the absence of between-group differences might be a power issue or might show regression to the mean. This issue needs to be clarified in further suitably powered studies of highly anxious children. However, our cohort provided sufficient power to detect differences within the low anxiety group in which we found a marked reduction between groups in favour of the health-led FRIENDS group. Universally delivered prevention programmes offer the potential to reduce present symptoms, enhance emotional wellbeing, and potentially shift population means over time. Our findings support this theory and show that children in the low-anxiety health-led FRIENDS group showed markedly lower anxiety symptoms at 12 months than did those in the usual school provision group. Because fears, anxiety, and stress are common in children, anxiety prevention programmes might be especially suited to universal delivery.¹⁶ Further research is needed to establish whether improvements are sustained in the medium term, and to detail the cost-effectiveness of such universal interventions delivered by health professionals.

We recorded no differences between groups for any secondary outcomes, suggesting that the intervention effects were specific to anxiety. The FRIENDS programme is designed as an anxiety prevention programme and specifically develops skills known to reduce anxiety. Therefore, the specific effect that we identified is consistent with the underlying theoretical model and programme focus, although in view of the comorbidity between anxiety and depressive disorders and the shared elements of many cognitive behaviour programmes, this result is disappointing.³⁵ Our findings show that although anxiety prevention programmes can have a positive effect on anxiety symptoms, they cannot be assumed to enhance the general emotional wellbeing of children.

Panel 2: Research in context

Systematic review

Findings of systematic reviews of school-based anxiety prevention programmes show that universally (ie, whole class) provided programmes based on cognitive behavioural therapy can be effective.^{15,16,24} However, research methods are poor, adequately powered implementation trials are scarce, results are inconsistent, few medium term follow-ups exist, and direct comparison of school versus health-led delivery have seldom been undertaken.

We aimed to undertake a suitably powered implementation trial of a school-based cognitive behaviour therapy anxiety prevention programme (FRIENDS) for children aged 9–10 years. Programme delivery by health and school professionals was compared with treatment as usual at 12 months.

Interpretation

Our results are consistent with those from systematic reviews that show that school-based anxiety prevention programmes informed by cognitive behaviour therapy are effective in the reduction of anxiety in children. The programme leader is important because the programme we assessed was only effective when delivered by health staff. Our finding that children with low symptoms also benefited from the programme supports the use of universal approaches. This study supports the implementation of a universal anxiety prevention programme delivered by health professionals in regular schools in everyday settings.

The effect was also specific to child report because although parent and teacher ratings reduced over time, these changes were not significant. This finding might suggest that although children are feeling better, adults have not noticed any improvement in functioning or reduction in distress. However, only 42% of parents returned baseline questionnaires and as such these findings might not be representative of the total cohort. Similarly, the teacher assessment was global and might be insensitive to specific changes in anxiety symptoms. Alternatively, the absence of a parent and teacher effect might show the difficulty of assessment of changes in internal emotional symptoms and cognitions that are not directly observable.

The results of our study are consistent with those of reviews in which the intervention leader affected programme effectiveness,¹⁶ and with other implementation trials in which teacher-led FRIENDS was not effective.^{36,37} Our findings differ to those of the study by Barrett and Turner,²⁰ which directly compared teacher and psychologist delivery of FRIENDS, although their study lacked statistical power. Overall, our study supports the growing evidence base for the use of the FRIENDS programme as an effective school-based anxiety prevention programme.^{16,24}

The intervention that we assessed was based on cognitive behaviour therapy, which is typically used to treat mental health disorders. However, for school-based universal emotional health programmes, most children will be healthy and will not need treatment. Furthermore, provision of individual treatment in a classroom context would not be appropriate. Therefore, it is important to emphasise that we did not provide treatment but used the cognitive behaviour therapy framework to help children to develop emotional, cognitive, and behavioural skills. Provision of life skills development within the school context fits with the growing recognition that schools are not just concerned with the development of academic skills, but also have an important role in the enhancement of emotional development in children.

Our study has many strengths. We used a manualised anxiety prevention programme that has been shown to be effective in schools and has been piloted in UK schools.^{16,25,26} Recruitment and retention were high, absenteeism was low, and programme fidelity was good. In terms of limitations, we relied on self-report measures and did not undertake any diagnostic interviews. Although anxiety symptoms were reduced in the health-led FRIENDS group, whether this reduction was indicative of changes in diagnostic status or impairment is unclear. Second, although our regional cohort included a representative sample of UK schools on several key dimensions, our group was less socially disadvantaged and had more white British participants than did the average UK state school. Therefore, whether similar results would be obtained with a more disadvantaged or ethnically diverse population is

unclear. Similarly, although our schools were well matched across trial groups and our exploratory qualitative analysis identified few differences in school culture and ethos, these differences could have affected outcomes. Third, although the health-led and school-led FRIENDS facilitators had the same initial training and treatment fidelity was good, we did not directly assess how the intervention was delivered. Therefore, the differences between these groups might be indicative of differences in leader enthusiasm, confidence, and ability to engage and motivate students, which are skills that could be developed in school staff with additional training and supervision.¹⁶ Finally, although we reported symptoms at 12 months, we were unable to establish whether the improvements reported would be sustained over time. This point is especially important for prevention programmes in which the full extent of the preventive effects might take several years to emerge.

In summary, our results are encouraging and show that anxiety prevention programmes delivered in schools to children aged 9–10 years do reduce anxiety symptoms at 12 months. The finding that children with low symptoms benefited from the programme supports a universal approach, which also fits well with school timetables and organisational structures.¹⁸ However, our data suggest that the same programme can result in different effects depending on who delivers it. Further research is needed to explore the longer term effect, and the potential mediators and moderators of anxiety prevention programmes, to assess cost-effectiveness, and to establish whether anxiety prevention programmes are effective with more diverse and disadvantaged groups.

Contributors

PS, GT, RP, HD, RA, and NS conceived and designed the study. ES managed the trial and supervised data collection. GT undertook the statistical analysis. All authors had access to all study data and participated in interpretation of the findings, contributed core ideas and were involved in critically revising the paper for important intellectual content. All authors read and approved the final manuscript. PS was principal investigator and will act as guarantor for the paper.

Declaration of interests

We declare no competing interests.

Acknowledgments

This study was funded by the National Institute for Health Research Public Health Research Programme (09/3000/03). The views and opinions expressed therein are those of the authors and do not necessarily reflect those of the Department of Health. We thank the schools and students who participated in this project and the facilitators who helped with intervention delivery; and the research team including Lucy Georgiou, Ellen Cook, Dr Esther Mugweni, Sarah Rook, Danielle Byrne, Joanna Morris, Sarah Sedman, Nicola Harkin, and Karen Spillard. We acknowledge the support and guidance of the Trial Steering Committee and Data Monitoring and Ethic Committee and in particular their respective chairs, Alan Emond and Tamsin Ford.

References

- 1 Costello EJ, Mustillo S, Erkanl A, Keeler G, Angold A. Prevalence and Development of Psychiatric Disorders in childhood and adolescence. *Arch Gen Psychiatry* 2003; **60**: 837–44.
- 2 Langley AK, Bergman RL, McCracken J, Piacentini JC. Impairment in childhood anxiety disorders: Preliminary examination of the child anxiety impact scale—parent version. *J Child Adolesc Psychopharmacol* 2004; **14**: 105–14.

- 3 Kim-Cohen J, Caspi A, Moffitt TE, Harrington H, Milne BJ, Poulton R. Prior juvenile diagnoses in adults with mental disorder: developmental follow-back of a prospective-longitudinal cohort. *Arch Gen Psychiatry* 2003; **60**: 709–17.
- 4 Bittner A, Egger HL, Erkanli A, Costello EJ, Foley DL, Angold A. What do childhood anxiety disorders predict? *J Child Psychol Psychiatry* 2007; **48**: 1174–83.
- 5 Woodward LJ, Fergusson DM. Life course outcomes of young people with anxiety disorders in adolescence. *J Am Acad Child Adolesc Psychiatry* 2001; **40**: 1086–93.
- 6 Kieling C, Baker-Henningham H, Belfer M, et al. Child and adolescent mental health worldwide: evidence for action. *Lancet* 2011; **378**: 1515–25.
- 7 Collins PY, Patel V, Joestl SS, March D, Insel TR, Daar AS. Grand challenges in global mental health. *Nature* 2011; **475**: 27–30.
- 8 Snell T, Knapp M, Healey A, et al. Economic impact of childhood psychiatric disorder on public sector services in Britain: estimates from national survey data. *J Child Psychol Psychiatry* 2013; **54**: 977–85.
- 9 James AC, James G, Cowdrey FA, Soler A, Choke A. Cognitive behavioural therapy for anxiety disorders in children and adolescents (Review). *Cochrane Database Syst Rev* 2013; **6**: CD004690.
- 10 Reynolds S, Wilson C, Austin J, Hooper L. Effects of psychotherapy for anxiety in children and adolescents: a meta-analytic review. *Clin Psychol Rev* 2012; **32**: 251–62.
- 11 Ford T, Goodman R, Meltzer M. Service use over 18 months among a nationally representative sample of British children with psychiatric disorder. *Clin Child Psychol Psychiatry* 2003; **8**: 37–51.
- 12 Merikangas KR, He JP, Brody D, Fisher PW, Bourdon K, Koretz DS. Prevalence and treatment of mental disorders among US children in the 2001–2004 NHANES. *Pediatrics* 2010; **125**: 75–81.
- 13 Davies SC, Lerner C, Strelitz J, Weil L. Our children deserve better: prevention pays. *Lancet* 2013; **382**: 1383–84.
- 14 Shepherd J, Pickett K, Dewhurst S, et al. Training teachers for the public health workforce: systematic mapping and synthesis of effectiveness and process. *Lancet* 2013; **382**: 590.
- 15 Neil AL, Christensen H. Efficacy and effectiveness of school-based prevention and early intervention programs for anxiety. *Clin Psychol Rev* 2009; **29**: 208–15.
- 16 Fisak BJ, Richard D, Mann A. The prevention of child and adolescent anxiety: a meta-analytic review. *Prev Sci* 2011; **12**: 255–68.
- 17 Mrazek PJ, Haggerty RJ. Reducing risks for mental disorders: frontiers for preventive intervention research. Washington DC: National Academy Press, 1994.
- 18 Giesen F, Searle A, Sawyer M. Identifying and implementing prevention programmes for childhood mental health problems. *J Paediatr Child Health* 2007; **43**: 785–89.
- 19 Stallard P. School-based interventions for depression and anxiety in children and adolescents. *Evid Based Ment Health* 2013; **16**: 60–61.
- 20 Barrett P, Turner C. Prevention of anxiety symptoms in primary school children: Preliminary results from a universal school-based trial. *Br J Clin Psychol* 2001; **40**: 399–410.
- 21 Barrett P. Friends for life: group leaders manual for children. Bowen Hills: Australian Academic Press, 2004.
- 22 Stallard P, Taylor G, Anderson R, et al. School-based intervention to reduce anxiety in children: study protocol for a randomized controlled trial (PACES). *Trials* 2012; **13**: 227.
- 23 Raab GM, Butcher I. Balance in cluster randomized trial. *Stat Med* 2001; **20**: 351–65.
- 24 WHO. Prevention of mental disorders: effective interventions and policy options summary report. Geneva: Department of mental health and substance abuse, 2004.
- 25 Stallard P, Simpson N, Anderson S, Carter T, Osborn C, Bush S. An evaluation of the FRIENDS programme: a cognitive behaviour therapy intervention to promote emotional resilience. *Arch Dis Child* 2005; **90**: 1016–19.
- 26 Stallard P, Simpson N, Anderson S, Goddard M. The FRIENDS emotional health prevention programme: 12 month follow-up of a universal UK school based trial. *Eur Child Adolesc Psychiatry* 2008; **17**: 283–89.
- 27 Department for Education and Skills. Excellence and Enjoyment: social and emotional aspects of learning. Guidance. May, 2005. <http://webarchive.nationalarchives.gov.uk/20130401151715/https://www.education.gov.uk/publications/eOrderingDownload/SEAL%20Guidance%202005.pdf> (accessed May 13, 2014).
- 28 Chorpita BF, Moffitt CE, Gray J. Psychometric properties of the revised child anxiety and depression scale in a clinical sample. *Behav Res Ther* 2005; **43**: 309–22.
- 29 Sandin B, Chorot P, Valiente RM, Chorpita BF. Development of a 30 item version of the revised child anxiety and depression scale. *Revista de Psicopatología y Psicología Clínica* 2010; **15**: 165–78.
- 30 Chorpita BF, Tracey SA, Brown TA, Collica TJ, Barlow DH. Assessment of worry in children and adolescents: an adaptation of the Penn State Worry Questionnaire. *Behav Res Ther* 1997; **35**: 569–81.
- 31 Rosenberg M. Society and the adolescent self-image. Princeton, NJ: Princeton University Press, 1965.
- 32 Goodman R. The strengths and difficulties questionnaire: a research note. *J Child Psychol Psychiatry* 1997; **38**: 581–86.
- 33 Ebesutani C, Chorpita BF, Higa-McMillan CK, Nakamura BJ, Regan J, Lynch RE. A psychometric analysis of the revised child anxiety and depression scales – parent version in a school sample. *J Abnorm Child Psychol* 2011; **39**: 173–85.
- 34 Sterne JA, White IR, Carlin JB, et al. Multiple imputation for missing data in epidemiological and clinical research: potential and pitfalls. *BMJ* 2009; **338**: 2393.
- 35 Garber J, Weersing VR. Comorbidity of anxiety and depression in youth: implications for treatment and prevention. *Clin Psychol (New York)* 2010; **17**: 293–306.
- 36 Miller LD, Laye-Gindhu A, Liu Y, March JS, Thordarson DS, Garland EJ. Evaluation of a preventive intervention for child anxiety in two randomized attention-control school trials. *Behav Res Ther* 2011; **49**: 315–23.
- 37 Miller LD, Laye-Gindhu A, Bennett JL, et al. An effectiveness study of a culturally enriched school-based CBT anxiety prevention program. *J Clin Child Adolesc Psychol* 2011; **40**: 618–29.