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.

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Introduction

Anxiety disorders affect 10% of children by the age of 16 years. They significantly impair everyday functioning, often persist into adulthood, and increase the risk of other psychiatric disorders in adolescence and young adulthood. 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. Effective psychological interventions, especially cognitive behaviour therapy (CBT), are available for children with anxiety disorders. However, comparatively few children with anxiety disorders are identified and referred for treatment. 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.

Findings of systematic reviews show that universal and targeted anxiety prevention programmes are often based on cognitive behaviour therapy. Data from reviews 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. 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.
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

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### Figure: Trial profile

### Panel 1: Acronym for the FRIENDS process

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

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**Articles**

449 completed 12 month assessment

436 completed 12 month assessment

372 completed 12 month assessment

41 schools randomly assigned

14 schools assigned to school-led FRIENDS (n=497 children)

14 schools assigned to health-led FRIENDS (n=509 children)

12 schools assigned to usual school provision (n=442 children)

462 completed assessment

456 completed assessment

391 completed assessment

41 did not give consent

20 did not give consent

25 did not give consent

4 did not confirm interest in time

1 withdrew

2 withdrew

1 withdrew

9 absent

2 withdrew

12 absent

23 left school

9 withdrew

24 left school

12 withdrew

10 absent

6 withdrew

4189 children assented

472 children assented

401 children assented

486 completed assessment

3 did not complete assessment

462 completed assessment

10 did not complete assessment

391 completed assessment

10 did not complete assessment

Follow-up and analysis

449 completed 12 month assessment

436 completed 12 month assessment

372 completed 12 month assessment

41 schools assigned to school-led FRIENDS (n=497 children)

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41 schools randomly assigned

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NHS

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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. 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 that consisted of session plans, the underlying cognitive model, class and behaviour management, and any interpersonal difficulties or communication problems with the class teacher.

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. 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, 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). Secondary outcomes assessed worry (with the Penn State Worry Questionnaire for Children), self-worth and acceptance (with the Rosenberg Self-Esteem Scale), extent of bullying (with the Olweus Bully/Victim Questionnaire), and life satisfaction (with a subjective wellbeing assessment).

<table>
<thead>
<tr>
<th>Number of schools</th>
<th>14</th>
<th>14</th>
<th>12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of schools with at least two classes</td>
<td>6</td>
<td>7</td>
<td>5</td>
</tr>
<tr>
<td>Class size</td>
<td>19.56 (6.56)</td>
<td>18.15 (7.68)</td>
<td>20.05 (8.29)</td>
</tr>
<tr>
<td>Missing baseline assessment</td>
<td>3 (0.6%)</td>
<td>10 (2.1%)</td>
<td>10 (2.5%)</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boys</td>
<td>255 (52.1%)</td>
<td>237 (50.2%)</td>
<td>170 (42.4%)</td>
</tr>
<tr>
<td>Girls</td>
<td>234 (47.9%)</td>
<td>235 (49.8%)</td>
<td>231 (57.6%)</td>
</tr>
<tr>
<td>Ethnic origin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>British white</td>
<td>455 (94.2%)</td>
<td>439 (95.2%)</td>
<td>359 (92.3%)</td>
</tr>
<tr>
<td>Non-white</td>
<td>28 (5.8%)</td>
<td>22 (4.8%)</td>
<td>31 (7.9%)</td>
</tr>
<tr>
<td>Living situation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mother and father</td>
<td>347 (71.4%)</td>
<td>315 (68.2%)</td>
<td>268 (68.5%)</td>
</tr>
<tr>
<td>Parent and partner</td>
<td>43 (8.8%)</td>
<td>55 (11.9%)</td>
<td>37 (9.4%)</td>
</tr>
<tr>
<td>Single parent</td>
<td>67 (13.8%)</td>
<td>68 (14.8%)</td>
<td>58 (14.8%)</td>
</tr>
<tr>
<td>Other</td>
<td>29 (6.0%)</td>
<td>24 (5.2%)</td>
<td>28 (7.2%)</td>
</tr>
<tr>
<td>Number of siblings</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>49 (10.1%)</td>
<td>30 (6.5%)</td>
<td>27 (8.2%)</td>
</tr>
<tr>
<td>1</td>
<td>221 (45.5%)</td>
<td>214 (46.5%)</td>
<td>184 (47.1%)</td>
</tr>
<tr>
<td>2</td>
<td>129 (26.5%)</td>
<td>134 (29.1%)</td>
<td>92 (23.5%)</td>
</tr>
<tr>
<td>3 or more</td>
<td>87 (17.9%)</td>
<td>82 (17.8%)</td>
<td>83 (21.2%)</td>
</tr>
<tr>
<td>Family affluence</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low (0–2)</td>
<td>6 (1.5%)</td>
<td>11 (2.4%)</td>
<td>13 (3.3%)</td>
</tr>
<tr>
<td>Medium (3–5)</td>
<td>142 (29.4%)</td>
<td>139 (30.1%)</td>
<td>128 (32.9%)</td>
</tr>
<tr>
<td>High (6–8)</td>
<td>331 (69.1%)</td>
<td>311 (67.5%)</td>
<td>249 (63.8%)</td>
</tr>
<tr>
<td>Child total RCADS</td>
<td>26.24 (15.56)</td>
<td>24.91 (14.32)</td>
<td>26.78 (16.32)</td>
</tr>
<tr>
<td>Penn Worry Scale</td>
<td>10.63 (8.14)</td>
<td>10.99 (8.24)</td>
<td>10.46 (8.35)</td>
</tr>
<tr>
<td>Self-esteem</td>
<td>18.94 (5.34)</td>
<td>19.43 (5.39)</td>
<td>19.57 (5.98)</td>
</tr>
<tr>
<td>Total life satisfaction</td>
<td>14.21 (6.77)</td>
<td>13.32 (5.71)</td>
<td>13.76 (6.82)</td>
</tr>
<tr>
<td>Been bullied</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bullied at least twice per month</td>
<td>142 (29.3%)</td>
<td>124 (26.8%)</td>
<td>112 (28.6%)</td>
</tr>
<tr>
<td>Not bullied or only once or twice</td>
<td>343 (70.7%)</td>
<td>338 (73.2%)</td>
<td>279 (71.4%)</td>
</tr>
<tr>
<td>Parent-completed assessments</td>
<td>217 (44.4%)</td>
<td>201 (42.6%)</td>
<td>152 (38.2%)</td>
</tr>
<tr>
<td>Total RCADS</td>
<td>12.55 (8.81)</td>
<td>10.99 (8.60)</td>
<td>12.52 (9.34)</td>
</tr>
<tr>
<td>Total SDQ</td>
<td>9.09 (6.32)</td>
<td>8.31 (6.28)</td>
<td>9.00 (6.24)</td>
</tr>
<tr>
<td>Teacher-reported assessment</td>
<td>487 (99.6%)</td>
<td>466 (98.7%)</td>
<td>396 (98.8%)</td>
</tr>
<tr>
<td>Teacher SDQ impact</td>
<td>119 (24.4%)</td>
<td>125 (26.8%)</td>
<td>109 (27.5%)</td>
</tr>
</tbody>
</table>

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.
Parents completed a behavioural screening questionnaire (Strength and Difficulties Questionnaire [SDQ]) and the parent version of the Revised Child Anxiety and Depression Scale (RCADS-30-P) 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 intraclass 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

### 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

<table>
<thead>
<tr>
<th>Health-led FRIENDS</th>
<th>Adjusted difference (95% CI) at 12 months: health-led FRIENDS vs usual school provision</th>
<th>School-led FRIENDS</th>
<th>Adjusted difference (95% CI) at 12 months: school-led FRIENDS vs usual school provision</th>
<th>Usual school provision</th>
<th>p value overall group effect*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Baseline</strong></td>
<td>n=489</td>
<td>n=449</td>
<td>n=472</td>
<td>n=436</td>
<td>n=401</td>
</tr>
<tr>
<td>Depression</td>
<td>4.04 (2.60)</td>
<td>3.15 (2.53)</td>
<td>-0.36 (-0.76 to 0.04)</td>
<td>-0.34 (-0.82 to 0.14)</td>
<td>3.68 (2.34)</td>
</tr>
<tr>
<td>Social anxiety</td>
<td>5.28 (3.28)</td>
<td>4.39 (3.32)</td>
<td>-0.41 (-0.94 to 0.12)</td>
<td>-0.79 (-1.42 to -0.16)</td>
<td>5.05 (3.23)</td>
</tr>
<tr>
<td>Separation anxiety</td>
<td>3.81 (3.34)</td>
<td>2.48 (2.94)</td>
<td>-0.42 (-0.97 to 0.12)</td>
<td>-0.42 (-1.07 to -0.23)</td>
<td>3.68 (3.14)</td>
</tr>
<tr>
<td>Generalised anxiety</td>
<td>5.79 (3.80)</td>
<td>4.43 (3.56)</td>
<td>-0.77 (-1.40 to -0.14)</td>
<td>-0.89 (-1.64 to -0.14)</td>
<td>5.64 (3.54)</td>
</tr>
<tr>
<td>Panic</td>
<td>2.85 (2.87)</td>
<td>2.03 (2.56)</td>
<td>-0.34 (-0.78, 0.09)</td>
<td>-0.37 (-0.89 to 0.15)</td>
<td>2.68 (2.79)</td>
</tr>
<tr>
<td>OCD</td>
<td>4.56 (3.31)</td>
<td>3.43 (3.10)</td>
<td>-1.99 (-0.71 to 0.31)</td>
<td>-0.51 (-1.12 to 0.10)</td>
<td>4.45 (3.12)</td>
</tr>
<tr>
<td>Total RCADS</td>
<td>26.24 (15.56)</td>
<td>19.49 (14.81)</td>
<td>-6.66 (-5.12 to -1.48)</td>
<td>-7.91 (-6.48 to -3.35)</td>
<td>24.91 (14.32)</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Health-led FRIENDS</th>
<th>School-led FRIENDS</th>
<th>Usual school provision</th>
<th>p value overall group effect*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Baseline</strong></td>
<td><strong>12 months</strong></td>
<td><strong>Baseline</strong></td>
<td><strong>12 months</strong></td>
</tr>
<tr>
<td>N</td>
<td>489</td>
<td>449</td>
<td>472</td>
</tr>
<tr>
<td>Penn Worry Scale</td>
<td>10.63 (8.14)</td>
<td>8.19 (7.93)</td>
<td>10.99 (8.24)</td>
</tr>
<tr>
<td>Self-esteem</td>
<td>18.94 (5.34)</td>
<td>20.90 (6.22)</td>
<td>19.43 (5.39)</td>
</tr>
<tr>
<td>Total life satisfaction</td>
<td>14.21 (6.77)</td>
<td>13.87 (6.00)</td>
<td>13.32 (5.71)</td>
</tr>
<tr>
<td>Bullied more ≥2-3 times per month</td>
<td>142 (29.3)</td>
<td>74 (16.5)</td>
<td>124 (26.8)</td>
</tr>
<tr>
<td>Not bullied or once or twice</td>
<td>343 (70.7)</td>
<td>374 (83.5)</td>
<td>338 (73.2)</td>
</tr>
</tbody>
</table>

Parent reported

| N                  | 217               | 172                    | 198                         | 159                        | 152                         | 119                            |                                |
| Total RCADS        | 12.55 (8.81)      | 10.76 (8.90)           | 10.99 (8.60)                | 9.82 (7.12)                | 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 (5.95)                     | 0.767                          |
| Total SDQ threshold ≥2 | 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 | 4.87 (2.4)        | 2.03 (2.5)             | 2.85 (2.87)                 | 2.33 (2.74)                | 2.97 (3.11)                 | 2.42 (3.00)                     | 0.157                          |

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.
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. 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%), and pupil absence rates were lower (4·4% vs 17·1%), 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. Therefore, the data we present are based on recorded data only.

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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%), and pupil absence rates were lower (4·4% vs 17·1%), 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 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 FRENDS (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). 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).

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

<table>
<thead>
<tr>
<th>Group</th>
<th>Health-led FRIENDS</th>
<th>School-led FRIENDS</th>
<th>Usual school provision</th>
<th>p value overall group effect*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>High anxiety</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>36</td>
<td>31</td>
<td>32</td>
<td>−</td>
</tr>
<tr>
<td>Baseline</td>
<td>57/59 (8/18)</td>
<td>55/66 (7/16)</td>
<td>57/57 (7/10)</td>
<td>0.288</td>
</tr>
<tr>
<td>12 months</td>
<td>35/31 (19/24)</td>
<td>40/65 (21/40)</td>
<td>33/97 (21/15)</td>
<td>0.368</td>
</tr>
<tr>
<td><strong>Low anxiety</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>374 (91·2%)</td>
<td>360 (92·1%)</td>
<td>295 (90·2%)</td>
<td>−</td>
</tr>
<tr>
<td>Baseline</td>
<td>22/78 (11/86)</td>
<td>22/01 (11/05)</td>
<td>22/51 (12/03)</td>
<td>0·623</td>
</tr>
<tr>
<td>12 months</td>
<td>17/68 (13/40)</td>
<td>21/06 (13/42)</td>
<td>20/74 (14/12)</td>
<td>0·006</td>
</tr>
</tbody>
</table>

Data are n (%) or mean (SD) unless otherwise indicated. RCADS=Revised Child Anxiety and Depression Scale. *Adjusted for sex, school, and baseline RCADS. 1A total baseline RCADS score of ≥49 or more. 1A total baseline RCADS score of ≥48 or less.
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) 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 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.

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. 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. 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, and with other implementation trials in which teacher-led FRIENDS was not effective. Our findings differ to those of the study by Barrett and Turner, 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.

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. 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 data suggest that anxiety prevention programmes are effective with more diverse and disadvantaged groups. 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 in more disadvantaged or ethnically diverse populations.


