

A cluster randomised controlled trial comparing the effectiveness and cost-effectiveness of a school-based cognitive-behavioural therapy programme (FRIENDS) in the reduction of anxiety and improvement in mood in children aged 9/10 years

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Scientific summary

Effectiveness of FRIENDS in reduction of anxiety and improvement in mood

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Scientific summary

Background

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 considerable, resulting in the need to improve the mental health of children being recognised as a national and global priority.

Effective psychological interventions, particularly cognitive-behavioural therapy (CBT), are available for children with anxiety disorders. However, comparatively few children with anxiety disorders are identified and referred for treatment. The limited reach and availability of traditional treatment services has led to interest in more proactive preventative approaches, with schools offering a convenient location to deliver such programmes.

Systematic reviews suggest that CBT prevention programmes can be effective, although research is methodologically poor, adequately powered implementation trials are lacking, results are inconsistent, effect sizes are highly variable and no randomised trials have been undertaken in the UK. Finally, the effect of the intervention leader (health professional vs. school professional) has been directly investigated in only one study.

The aims of this study are to investigate the clinical effectiveness and cost-effectiveness of a classroom-based anxiety prevention programme (the FRIENDS programme) universally delivered by health and school professionals in UK primary schools.

Objectives

1. Primary outcome: to evaluate the effectiveness of the FRIENDS programme in reducing symptoms of anxiety and low mood at 12 months.
2. Primary outcome: to evaluate the effectiveness of the FRIENDS programme for children with low and high anxiety at baseline in terms of symptoms of anxiety and low mood at 12 months.
3. Secondary outcomes: to examine the effectiveness of the FRIENDS programme in terms of self-esteem, worry, bullying and overall well-being at 12 months.
4. Medium term: to examine the medium-term effects of the FRIENDS programme on symptoms of anxiety and low mood at 24 months.
5. Medium term: to evaluate the medium-term effects of the FRIENDS programme for children with low and high anxiety at baseline on symptoms of anxiety and low mood at 24 months.
6. Medium term: to examine the effects of the FRIENDS programme on secondary outcomes of self-esteem, worry, bullying and overall well-being at 24 months.
7. Cost-effectiveness: to assess the cost-effectiveness of the FRIENDS programme in terms of health-related quality of life (and cost-utility) at 6 months.
8. Acceptability: to assess the acceptability of the FRIENDS programme including participant perceptions of usefulness, examples of ongoing skill usage and satisfaction (6 months).

Methods

Design

This was a pragmatic three-arm parallel cluster randomised controlled trial. School was the cluster unit for randomisation with analysis being undertaken at the individual student level. The cluster design minimised possible contamination between classes within schools. After recruitment schools were assigned by computer-generated randomisation on a 1 : 1 : 1 ratio to school-led FRIENDS, health-led FRIENDS or usual school provision. Allocation was balanced by school size; number of students, classes and mixed (multiple year group) classes; level of educational attainment; and preferred day of delivery. Interventions were universally provided to all eligible participants. Children were not blind to treatment allocation.

Interventions

Interventions were delivered in the academic year September 2011–July 2012. The FRIENDS programme is a manualised CBT intervention that has been identified as efficacious and is feasible and viable to deliver in UK schools.

The FRIENDS programme 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 enable them to identify and replace anxiety-increasing cognitions with more balanced and functional ways of thinking and to develop problem-solving skills to confront and cope with anxiety-provoking situations and events. The programme therefore teaches children skills to identify and manage their anxious feelings, develop more helpful (anxiety-reducing) ways of thinking and face and overcome fears and challenges rather than avoid them.

The intervention was delivered to whole classes of children (universal delivery) over nine 60-minute weekly sessions by either health professionals (external to the school) or school leaders. The FRIENDS programme was compared with the school's usual personal, social and health education (PSHE) curriculum delivered by the class teacher.

Participants

Participants were in Years 5 and 6 (aged 9–10 years) and attending state-funded primary schools ($n = 41$) in the south-west of England. All children attending school and taking part in the school's PSHE lessons were eligible to participate ($n = 1448$), with 1362 (94%) providing consent.

Semistructured interviews to assess children's use of health and educational resources, life events, social and recreational activities and parental mental health were undertaken with a subgroup of 308 parents.

A qualitative assessment of the acceptability and value of the FRIENDS programme was undertaken with 115 children, 20 parents and 47 school staff.

Outcome measures

Child report

Child outcomes were collected during class time at 6 and 12 months and individually in the child's home at 24 months by researchers blind to arm allocation. The primary outcome was symptoms of anxiety and depression at 12 months after baseline, as determined by the Revised Child Anxiety and Depression Scale 30-item version (RCADS-30).

Secondary outcomes assessed worry (Penn State Worry Questionnaire for Children), self-worth and acceptance (Rosenberg Self-Esteem Scale), extent of bullying (Olweus Bully/Victim Questionnaire) and life satisfaction (subjective well-being). At 24 months, children also completed the School Concerns Questionnaire (SCQ) to assess the transition to secondary school.

Parent report

All parents were sent postal questionnaires at baseline and respondents were sent these again at 6 and 12 months. All parents were then invited to take part in a further assessment at 24 months, which was undertaken with a researcher in their own home. Parents completed a behavioural screening questionnaire (Strengths and Difficulties Questionnaire, SDQ) and the parent version of the RCADS-30 (RCADS-30-P). At 24 months, they also completed the parent version of the SCQ.

Teacher report

Class teachers completed the impact rating of the SDQ for all children in their class at baseline and 6 and 12 months. This assesses the presence of an emotional or behavioural problem, chronicity, distress, social impairment and burden.

Cost-effectiveness

Cost-effectiveness was assessed during parent interview with the Client Services Receipt Inventory. Quality-adjusted life-years were assessed using the child-completed Child Health Utility 9 Dimensions (CHU-9D).

Programme acceptability

All participating children completed an end of programme evaluation. A further in-depth process evaluation was undertaken through qualitative interviews and focus groups with a sample of participating children ($n = 115$), school staff ($n = 47$) and parents ($n = 20$).

Results

In total, 45 schools were enrolled and 41 provided signed consent, with one withdrawing after randomisation. Of the remaining 40 schools, 14 were randomly assigned to health-led FRIENDS ($n = 509$), 14 to school-led FRIENDS ($n = 497$) and 12 ($n = 442$) to usual school provision. Of the 1448 eligible participants, 1362 (94%) consented to participate in the study (health-led FRIENDS, $n = 489$; school-led FRIENDS, $n = 472$; usual school provision, $n = 401$). The proportion of boys in the usual school provision group (42%) was lower than in each of the other two trial arms (health-led FRIENDS 52%; school-led FRIENDS 50%) but otherwise the arms were well balanced at baseline.

All nine sessions of the FRIENDS programme were delivered to the 49 classes in the 28 schools assigned to the health- and school-led FRIENDS arms. Intervention fidelity, assessed by recording and independently rating one session from each participating class, was good. All core tasks and home activities were delivered in the 24 health-led FRIENDS sessions. In the school-led FRIENDS sessions, 15 out 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.

Twelve-month outcomes

Primary outcome data at 12 months were collected from 1257 (92.3%) of the children who completed baseline assessments (health-led FRIENDS 91.8%; school-led FRIENDS 92.4%; usual school provision 92.7%). There was a significant difference in the adjusted mean child-reported RCADS score at 12 months between health-led FRIENDS and school-led FRIENDS [19.49, standard deviation (SD) 14.81 vs. 22.86, SD 15.24; adjusted difference -3.91 , 95% confidence interval (CI) -6.48 to -1.35 ; $p = 0.0004$] and between health-led FRIENDS and usual school provision (19.49, SD 14.81 vs. 22.48, SD 15.74; adjusted difference -2.66 , 95% CI -5.22 to -0.09 ; $p = 0.043$). Analysis of the RCADS subscales showed a difference in generalised and social anxiety but not in depression.

A predefined subgroup analysis was undertaken of the 10% of participants with the highest baseline anxiety (total RCADS score of ≥ 49) and the remaining 90% with low anxiety (total RCADS score of ≤ 48). There were significant within-group reductions for the high-risk group over time, but no between-group effects. For the low-risk group there were between-group differences in mean RCADS score at 12 months ($p = 0.006$). Adjusted mean differences showed an effect for health-led FRIENDS compared with school-led FRIENDS (-3.78 , 95% CI -6.16 to -1.40 ; $p = 0.003$) and health-led FRIENDS compared with usual school provision (-3.13 , 95% CI -5.61 to -0.65 ; $p = 0.015$). This relates to a reduction in the health-led FRIENDS group on the social ($p = 0.013$) and generalised anxiety ($p = 0.006$) subscales. 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 to 0.07) and school-led FRIENDS (Cohen's $d = 0.25$, 95% CI 0.40 to 0.11) was small.

Analysis of other child-completed secondary outcomes and parent- and teacher-completed measures identified no differences between groups.

Twenty-four-month outcomes

In total, 594 (43.6%) children completed the 24-month assessment. There were few differences in the baseline characteristics of 24-month completers and non-completers. Child-reported anxiety in all three groups had reduced by 24 months although there were no longer any between-group differences in total anxiety for the whole sample ($p = 0.182$) or for the low-anxiety ($p = 0.184$) or high-anxiety ($p = 0.773$) group. Similarly, there were no between-group differences in any of the child- or parent-reported secondary outcomes.

Cost-effectiveness

The costs of delivering health-led and school-led FRIENDS were £52.25 and £55.92 per student respectively. Health and social care usage was very low in our predominantly healthy population. The subgroup for the economic analysis differed significantly from the main trial cohort on almost every measure including our primary clinical outcome (RCADS) and the health-related quality of life measure for deriving utility (CHU-9D). Although we found no evidence that the universal provision of the FRIENDS programme was cost-effective over a 6-month period, this conclusion needs to be treated with caution.

Programme acceptability

The overall experience of the FRIENDS programme was very positive, with children enjoying the programme and teachers feeling that it provided the children with useful skills. Children and teachers liked the practical activities and group work (role play, scenarios, games, etc.) but felt that there was too much passive learning (reading, writing, listening). Teachers praised the underlying theoretical model and the logical and sequential development of new skills. Children particularly commented on the behavioural (coping step plan and problem-solving) and emotional (relaxation techniques) elements of the programme, whereas teachers were particularly positive about the cognitive ('red and green thoughts') and emotional (relaxation techniques) elements. Examples of ongoing skill usage were noted and there was evidence of vicarious effects whereby siblings, peers, parents and teachers appeared to have benefited. The major limitation related to time, with both children and teachers feeling that there was not sufficient time to cover all of the programme content.

Conclusions

The FRIENDS anxiety prevention programme is acceptable to children and school staff and can be accommodated within primary school timetables. The FRIENDS programme can be delivered with good fidelity with comparatively limited training and ongoing supervision. Short-term effectiveness depended on who delivered the programme, with health FRIENDS leaders achieving greater reductions in anxiety symptoms at 12 months than school FRIENDS leaders or usual PSHE. The finding that children with low levels of anxiety particularly benefited from health-led FRIENDS was encouraging.

However, by 24 months anxiety symptoms had reduced in all groups and there were no longer any between-group effects. Similarly, there were no between-group differences in any parent- or child-completed secondary outcomes, including depression at 12 or 24 months.

The cost of delivering the nine-session FRIENDS programme was £52–56 per child. Health and social care usage within our predominantly healthy cohort was low and it was hard to identify post-intervention changes in service usage. However, the time frame for the economic evaluation was relatively short. We captured service use over a 6-month period and with low-level service usage a longer time frame would be required to detect potential benefits.

Although we obtained service use data from > 300 parents this group was not representative of our full cohort. They differed on many measures including our primary outcome and health utility measure. We are therefore unable to draw any firm conclusions about the cost-effectiveness of the FRIENDS programme although our results suggest that it is unlikely to be cost-effective.

In terms of future research our study pinpoints a number of areas that it would be useful to investigate:

1. Identify potential moderators of school-based anxiety prevention programmes such as delivery variables (e.g. leader confidence, understanding of CBT and enthusiasm), school factors (e.g. school ethos and commitment to emotional health) and student variables (e.g. sex, motivation and disruption).
2. Identify the core 'active ingredients' of anxiety prevention programmes to maximise programme effectiveness within the limited time available in schools.
3. Given the small numbers of children in our study with high levels of anxiety it would be useful to determine the effectiveness of a universally delivered FRIENDS programme for highly anxious children.
4. Evaluate the effectiveness of the FRIENDS programme for more ethnically diverse, disadvantaged children and those with additional learning needs.
5. Assess the cost-effectiveness of the FRIENDS programme over a longer time frame and assess a wider range of costs associated with health, social and educational services and parental productivity.
6. Explore the effects of anxiety prevention programmes on academic achievement.
7. Define more clearly the content of interventions received by comparison groups to determine any differences and overlaps with active interventions.

In summary, although greater reductions in anxiety were noted at 12 months when the FRIENDS programme was delivered by health leaders, these additional benefits were not maintained at 24 months. Children improved irrespective of the intervention that they received. Our economic evaluation and 24-month assessment had significant shortcomings. However, the universal delivery of specific anxiety prevention programmes will result in additional costs, which may be beyond the finances available to most schools. Our results find limited evidence to support the universal provision of specific anxiety prevention programmes in UK primary schools.

Trial registration

The trial is registered as ISRCTN23563048.

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