



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

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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.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.

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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

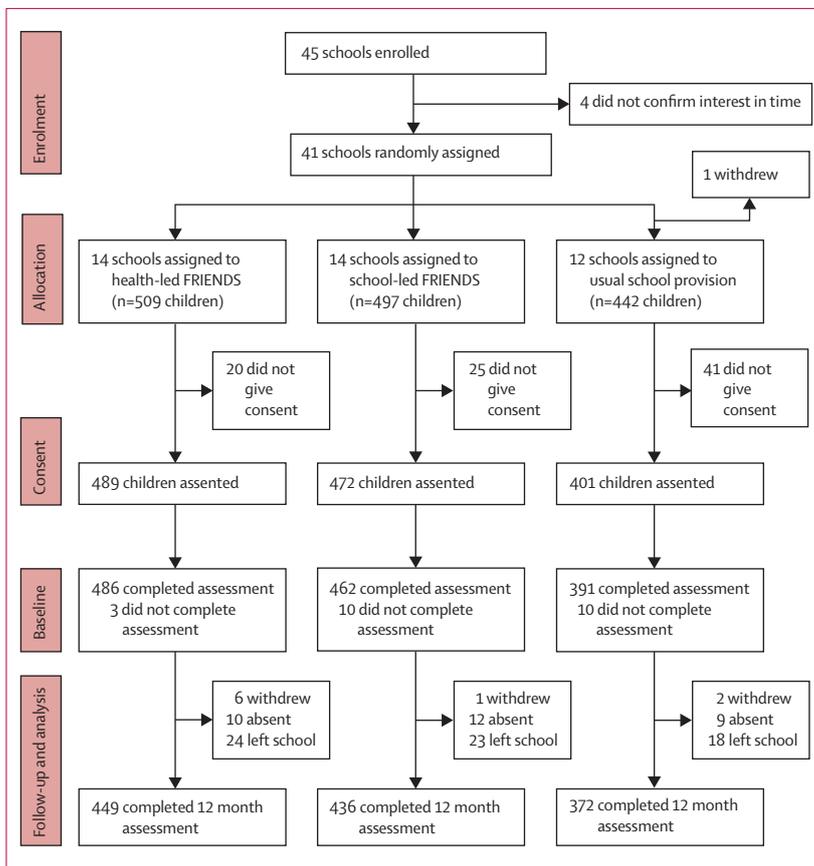


Figure: Trial profile

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