DETAILED PROJECT DESCRIPTION

1. Project Title

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

2. Background

2.1. Existing Research

2.1.1. Importance of good mental health in children

Emotional problems in children are common with community surveys in the USA and UK indicating that 4-8% of children aged 5-16 will fulfil DSM diagnostic criteria for a severe disorder with accompanying significant impairment (Costello et al, 2003; Meltzer et al, 2003). In addition, many more children experience severe anxiety or depressive symptoms which fall below (i.e. sub-threshold) criteria required for a formal diagnosis but are nonetheless significant. Studies suggest that during childhood approximately 1 in 5 children will experience incapacitating anxiety or depression (Costello et al, 1996: Essau, Conradt & Petermann 2000; Ferguson, Horwood, Ridder & Beautrais, 2005).

Emotional problems have a persistent and unremitting course. Childhood depression causes significant impairment, impacts on developmental trajectories, interferes with educational attainment and increases the risk of attempted and completed suicide as well as major depressive disorder in adulthood (Birhamer et al 1996; Harrington, Fudge, Rutter, Pickles & Jill 1990). In terms of anxiety, Kim-Cohen et al (2003) found that 85% of adults with anxiety disorders had a prior diagnosis in childhood. Similarly, childhood anxiety disorders, if left untreated, increase the risk in young adulthood of other problems including depression, illicit drug dependence and educational underachievement (Kim-Cohen et al 2003; Woodward & Fergusson 2001). The economic burden associated with childhood emotional disorders is not known although it is expected to be considerable (NICE, 2005).

Improving the emotional health of children is an important public health issue which has become a major tenet of Governmental policy (National Service Framework, DoH 2004: Every Child Matters, DfES 2004: Social and Emotional Aspects of Learning (SEAL), DfES 2005).

2.1.2. The need for prevention

Effective psychological treatments are available for children with mental health disorders although few children receive these. The UK National Mental Health Survey found that over an 18 month period only 22% of those with significant mental health disorders received treatment from specialist child and adolescent mental health services (Ford, Goodman & Meltzer 2003). In particular, those with emotional disorders were least likely to have contact with specialist services. The limited reach and availability of specialist treatment services alongside a policy shift towards early intervention has led to a growing interest in preventative approaches and a move from clinical to community settings.

In the UK, almost eight million children and young people attend primary and secondary schools (Adi et al 2007). As such, schools provide an important environment for public health initiatives offering the potential for delivering both primary prevention (i.e. promoting well being and reducing the occurrence of new

problems) and secondary prevention (i.e. stopping mild or moderate problems from worsening). Schools are a familiar and natural environment, reaching a high percentage of children. Their central role in promoting emotional wellbeing has been emphasised in the national Social and Emotional Aspects of Learning (SEAL) initiative (Department of Education and Skills 2005).

2.1.3. School based mental health programmes

The effectiveness of school based emotional health prevention programmes for primary school children has been the subject of two recent NICE reviews (Adi et al 2007; Shucksmith, Summerbell, Jones, Whitaker 2007). Adi et al (2007) systematically reviewed 31 studies which adopted a universal approach (i.e. interventions were provided to all children regardless of need). A total of 31 studies were identified with only one being undertaken in the UK. The other focused upon targeted/indicated approaches, where interventions were provided to children at high risk or those already displaying mild or moderate problems (Shucksmith, et al 2007). Ten studies which focused upon internalising problems (anxiety and mood) were identified and none were from the UK.

Both reviews found evidence that universal and targeted/indicated mental health programmes could have an effect upon mental health. In terms of content, multi-component programmes (i.e. teaching different skills such as relaxation, problem solving, and cognitive awareness) based upon a clear theoretical framework, particularly Cognitive Behaviour Therapy (CBT), and which included some parent input (e.g. training/information) had the strongest evidence. This conclusion is also endorsed in a recent review of twenty seven randomised controlled anxiety prevention trials (Neil & Christensen, 2009). The results indicate that most universal, selective and indicated prevention programmes were effective in reducing anxiety symptoms. Although not formally tested, the authors note that the effects of CBT programmes were marginally larger than non-CBT interventions, with the median effect size for CBT programmes of 0.57 indicating a moderate effect. However, there was considerable variation in effect size between studies suggesting that whilst the content is important, mediating variables such as adherence to programme fidelity, leader rapport, levels of participation and audience appeal are also important factors that will influence effectiveness.

The reviews also note a number of important methodological limitations including small sample sizes, use of non-standardised mental health outcome measures and an absence of follow-up assessments. In addition, the comparative effectiveness of teacher versus mental health delivered interventions is unclear. Further robust research is required to determine the effectiveness of school based prevention programmes delivered under everyday conditions in the UK upon the mental health of children. This is particularly timely since the recent evaluation of the DfES initiative, SEAL, has produced mixed results. Although the evaluation found a positive, albeit limited, impact on psychological wellbeing, the effect upon mental health was limited (Humphrey, 2008). Anxiety and mood were not specifically assessed although mental health was investigated through the use a widely used questionnaire, the Strength and Difficulties Questionnaire (SDQ). Parent and teacher ratings showed little evidence of any significant post intervention change in child mental health and none of the interventions had any effect upon the emotional sub-scale (i.e. anxiety and depression) of the SDQ (Humphrey et al 2008). Factors associated with better outcomes included allocating sufficient time to deliver the intervention, good leader rapport, engendering a sense of fun and enjoyment, better programme fidelity, and the intervention having a good profile within the school. The authors also noted that the interventions may not be sufficient (6-8 sessions of 40

mins) to bring about change and that standardised training in the interventions to ensure fidelity would be advisable.

2.1.4. The FRIENDS CBT prevention programme

Of the school based CBT preventive programmes that have been developed, the FRIENDS programme is one of the better evaluated and more consistently effective (Neil & Christensen 2009). This was also noted by the World Health Organisation, who identified FRIENDS as having strong evidence of being effective as a school based intervention for anxiety (WHO 2004). The programme addresses a number of the issues identified in the previous reviews. It has a clear theoretical model; sufficient sessions; age appropriate materials; enjoyable and fun activities; structured leader manual with detailed session plans; standardised leader training; on-going supervision to ensure fidelity; a parent session, and weekly parent contact sheets.

In an initial randomised controlled trial (RCT) involving 489 children aged 10-12, significant post intervention reductions in anxiety were reported following FRIENDS (Barrett & Turner 2001). These results were replicated in a subsequent study involving 594 children aged 10-13 and were found to be maintained at 12 months (Lowry-Webster, Barrett & Dadds 2001; Lowry-Webster, Barrett & Lock 2003). FRIENDS also had a positive effect upon mood in the high anxiety group. In terms of those with more significant problems, 85% of those in the FRIENDS group who initially scored above the clinical cut-off for anxiety and low mood were diagnosis free at 12 months compared with 31% in the comparison group. In the most recent study involving 692 children the FRIENDS group demonstrated that significant reductions in anxiety were evident 3 years after FRIENDS (Barrett, Farrell, Ollendick & Dadds, 2006). In addition, comparison between children aged 9/10 and those aged 14/16 showed that although both age groups benefited from FRIENDS, the younger group demonstrated the greatest changes in anxiety symptoms (Lock & Barrett, 2003). Although these results are promising, no RCTs of FRIENDS have been undertaken in the UK.

2.2. Risks and Benefits

The risks of participating in this study are small. At worse, the proposed interventions may not result in any additional lasting benefits. However, in view of the significant and long term consequences of childhood anxiety and low mood the benefits of intervening outweigh any risks of not pursuing such a course of action.

2.3. Rationale for Current Study

The systematic reviews summarised above indicate that school based programmes can have benefits both in terms of secondary (post-intervention reductions in symptoms) and primary (preventing the development of significant symptoms) prevention. Programmes with a clear theoretical model based upon CBT appear the most effective for anxiety and mood disorders. In addition, multi-component programmes teaching children skills in different areas and which involve parents (e.g. relationship building/skill enhancing) appear particularly promising.

Of the programmes fulfilling these criteria, the FRIENDS programme has a strong evidence base. Pilot work involving small scale cohort studies of FRIENDS have been undertaken in the UK and demonstrate the feasibility of delivering the programme within the UK educational system. These studies have found encouraging post intervention results with gains being maintained 1 year after the programme (Stallard et al 2005; Stallard et al 2007). Similarly a recent small scale evaluation has found preliminary evidence to suggest that FRIENDS may also have a primary preventative effect (Stallard et al 2008).

This trial will compare the relative effectiveness of FRIENDS delivered by trained school and health staff compared to usual school lessons (Personal, Social and Health Education – PSHE). The study will address methodological concerns identified above and includes adequate power to detect predicted differences; assessment of treatment fidelity; a 12 month follow-up; analysis of primary and secondary preventive effects and an evaluation of cost effectiveness. If found to be effective, FRIENDS could be made widely available in the UK. It could be integrated within the school PSHE curriculum and would compliment and build upon other SEAL initiatives.

3. Research Objectives

This proposal is for a cluster randomised controlled intervention trial involving three treatment arms; health professional led CBT (FRIENDS programme) vs. school led CBT vs. a treatment as usual control group. The study evaluates a complex intervention and has 9 objectives;

1.) Primary Outcome (all children): To evaluate the effectiveness of FRIENDS in reducing symptoms of anxiety and low mood at 6 & 12 months.
2.) Primary Outcome (high and low anxiety children): To evaluate the effectiveness of FRIENDS for children with low and high anxiety at baseline on symptoms of anxiety and low mood at 12 months.
3.) Secondary outcomes: Examine the effectiveness of FRIENDS on self-esteem, worry, bullying and overall wellbeing at 6 & 12 months.
4.) Medium term (primary outcomes, all children): To examine the longer term effects of FRIENDS on symptoms of anxiety and low mood at 24 months
5.) Medium term (primary outcomes, high and low anxiety children):To evaluate the effects of FRIENDS for children with low and high anxiety at baseline on symptoms of anxiety and low mood at 24 months
6.) Medium term (secondary outcomes): To examine the effects of FRIENDS for all children and low and high anxiety children on secondary outcomes of self-esteem, worry, bullying and overall wellbeing at 24 months
7.) Delivery method: To undertake an exploratory analysis to compare the relative effectiveness of FRIENDS delivered by health professionals and school staff at 6, 12 and 24 months.
8.) Cost Effectiveness: Assess the cost-effectiveness of FRIENDS in terms of health-related quality of life (and cost-utility) at 6 and 24 months.
9.) Acceptability: To assess acceptability of the intervention including participant perception of usefulness, examples of on-going skill usage, and satisfaction (6 months).

4. Research Design

4.1. Design

A randomised controlled cluster trial comparing health professional vs. school led FRIENDS vs. treatment as usual for the reduction and prevention of anxiety symptoms and low mood (i.e. reduced symptoms of depression) in children aged 9/10. The three arms are summarised in Table 1 below.

Table 1: Arms of the FRIENDS Randomised Controlled Trial

Study Arm	**Content**	**Delivery**
Treatment as usual	Normal curriculum	School staff
School led FRIENDS	Structured CBT programme	School staff

Health led FRIENDS	Structured CBT programme	Health professional

4.2. Setting
41 junior schools in Bath and North East Somerset and Wiltshire.

4.3. Method of Randomisation
Individual randomisation is not practical and would create insurmountable timetabling and organisational difficulties for schools. The intervention will be delivered as part of the PSHE curriculum and as such it is important that it fits within the existing school structures. The cluster unit will therefore be schools, which will minimise potential contamination between study arms. In order to minimise potential baseline bias, the cohort will be stratified according to school size, number of children in year 5 classes, number of year 5 classes, single/mixed year classes, preferred term and day of intervention delivery, and level of educational attainment on standardised assessment tests of Mathematics and English.

Allocation of schools will take place once all schools have been recruited. Balance between trial arms with respect to key characteristics (numbers of students, number of classes, preferred term, % of mixed classes and level of educational attainment) will be achieved by calculating an imbalance statistic for a large random sample of possible allocation sequences (Raab & Butcher 2004). A statistician with no other involvement in the study will then randomly select one sequence from a subset with the most desirable balance properties. Generation of possible allocation sequences and selection of one sequence will be conducted using computer-generated random numbers.

5. Study Population

5.1. Inclusion
Interventions will be provided during the school day as part of the school PSHE curriculum. All children in participating classes, i.e. year 4/5 (9-10 years old), will therefore be expected to participate in the PSHE sessions.

5.2. Exclusion
None. There will be some occasions when children do not participate in PSHE for religious or other reasons. These will be respected but it is expected that these will be limited.

6. Planned Interventions

6.1. The FRIENDS Programme
FRIENDS is a manualised cognitive behaviour therapy (CBT) programme designed to improve children's mental health. Each child has their own workbook and group leaders have a comprehensive manual specifying key learning points, objectives, and activities for each session. FRIENDS involves nine, 60-minute weekly sessions delivered to whole classes of 9/10 year old children as part of the school PSHE programme. Through a range of age appropriate fun activities including stories, quizzes, role plays and games, children learn practical skills to identify their feelings; to learn to relax; to identify unhelpful thoughts and to replace them with more helpful thoughts; and how to face and overcome their problems and challenges. Written work is kept to a minimum and each session uses a variety of different materials and activities to engage and maintain the interest of the children. Initial training and regular supervision of leaders will be provided by an accredited FRIENDS trainer. Detailed content for each of the sessions is summarised below.

Session 1:	Introduction to FRIENDS
Session 2:	Introduction to feelings
Session 3:	The relationship between thoughts and feelings
Session 4:	Emotional recognition, relaxation and how to feel good
Session 5:	Developing positive self-talk
Session 6:	Challenging negative/unhelpful thoughts
Session 7:	Developing problem solving skills
Session 8:	Creating step plans and praising self for success
Session 9:	Learning to cope with worries; practice using FRIENDS

An additional session for parents/carers is provided at the start of the FRIENDS programme to provide parents with an overview of the programme, the CBT rationale, and the skills the children will learn. In addition, parents receive a summary sheet at the end of each session, detailing the key learning points and the ideas their child will be practicing so that they can reinforce and encourage their use at home.

6.2. Study Arms

Schools will be randomised to one of the three conditions; school led FRIENDS, health led FRIENDS or treatment as usual (control). In most schools there will be one eligible class. However, if there are more, then all classes will be invited to participate and all will be assigned to the condition that the school has been allocated.

In order to describe the pedagogic orientation of each school a coding scheme will be developed from legacy materials, developed by Daniels (2008). Specific attention will directed to pedagogic relations of control and the extent to which PSHE is separated from the rest of the curriculum. This coding scheme will be used in all schools and analysis will explore relations between pedagogic modalities and outcome and degree of implementation of FRIENDS.

6.2.1. School led FRIENDS

Each participating school will be asked to identify staff (class teachers, special educational needs co-ordinators and/or teaching assistants) who will deliver FRIENDS. They will attend a two day training event to familiarise them with the nature, extent and presentation of anxiety and depression in children and the CBT model. They will work though each of the FRIENDS sessions and have opportunities to practice the exercises and familiarise themselves with the materials and key learning points. During delivery of the programme, fortnightly supervision groups will be established specifically for school staff designed to address any problems with implementation.

6.2.2. Health led FRIENDS

This condition will be delivered by health professionals (Band 6, e.g. school nurses, psychology assistants) external to the school. These are not mental health specialists but are at a lower level of training/expertise. There is a plentiful supply of people wishing to obtain these posts. They will receive the same initial training as specified above and will attend a fortnightly supervision group.

6.2.3. Treatment as usual

In this group, children will participate in the usual PSHE sessions provided by the school. These sessions will be planned and led by the class teacher. A standardised record sheet will be used to summarise the content of each session so that any

potential overlap with the active intervention can be determined. A random sample of 10% of sessions will be observed by researchers to independently check session content and to rate the extent to which the session focused upon anxiety or mood and possible overlap with the active conditions.

In order to more specifically define PSHE within each school the head and class teacher will complete a standardised checklist. This will assess whether the school is following the national SEAL curriculum; what additional interventions might be running in the school and their content; the PSHE topics covered by the 9/10 year old children during the study period; the way it is addressed (dedicated sessions, integration, circle time, etc) the length of time devoted to the PSHE curriculum and the number of adults (e.g. teachers, assistants, volunteers, trainees) in the classroom. In addition class teachers will rate the degree to which they felt children had engaged and benefited from PSHE and the degree to which it may have helped with anxiety or mood problems.

6.3. Treatment Fidelity

A random sample of 10% of FRIENDS sessions will be audio-taped and rated by project researchers. A standardised checklist will be completed detailing whether session objectives had been achieved, key learning points covered and the session exercises/materials covered.

6.4. Attrition

An attendance register will be kept to monitor attendance and absenteeism. Similarly attrition during the course of the study will be monitored.

6.5. Participation and Loss at Follow-up

Local pilot work in 30 junior schools indicates that less than 1% of children opt out of FRIENDS and that approximately 90% complete baseline and follow-up assessments. Our predictions for this study are therefore conservative. We predict 90% of the eligible population will participate and of these 80% will complete the follow-up assessments. The 12 month follow-up will be maximised by completion of assessments before they disperse and transfer to secondary school.

7. Outcome Measures

The following standardised assessments of child mental health will be used.

7.1. Psychological Functioning – Child Completed

7.1.2. Primary outcome measures

- The Revised Child Anxiety and Depression Scale (RCDAS: Chorpita et al 2000). This is a recent modification of the Spence Children's Anxiety Scale (Spence 1997) which was revised to correspond more closely to DSM-IV criteria for anxiety and depression (Chorpita, Moffit & Gray 2005). The 30 item scale assess anxiety in the areas of social phobia, separation anxiety, obsessive compulsive disorder, panic disorder and generalised anxiety disorder. The RCDAS does not include the fear of physical injury subscale but has an additional subscale that assesses major depressive disorder. The 30 and 25 item versions of the RCADS have good internal consistency, test-re-test stability and good convergent and divergent validity (Muris, Meesters & Schouten 2002; Sandin et al 2010). The RCDAS-30 will be the primary outcome measure.

7.1.3. Secondary outcome measures

- *Self-esteem:* The Rosenberg Self-Esteem Scale (Rosenberg, 1965) is a 10-item self-completed questionnaire, related to overall feelings of self-worth or self-acceptance. The items are answered on a four-point scale, ranging from strongly agree to strongly disagree. The Rosenberg Self-Esteem Scale has demonstrated good reliability and validity across a large number of different sample groups, including young children aged 7-12, and is one of the most commonly used and best known measuring tool for self-esteem.
- *Bullying:* The Olweus Bully/Victim Questionnaire is the most widely used questionnaire to assess the nature and extent of bullying amongst school children. The two global items assessing the frequency of self reported bullying and being the victim of bullying will be used.
- *Wellbeing:* Subjective well-being and satisfaction with six aspects of life (school, appearance, family, home, friendships, health) and overall life satisfaction are assessed via a 7 point scale. These were selected from the 12 domains identified as contributing to the subjective well-being of children (Rees, Goswami & Bradshaw 2010)
- *Worry:* Penn State Worry Questionnaire for Children (PSWQ-C) is a self-report questionnaire that measures the tendency of children to engage in excessive, generalised and uncontrollable worry (Chorpita et al 1997). The 11 item version has improved psychometric properties when used with children aged 8-12 and (Muris, Meester & Gobel 2001).

7.2. Psychological Functioning

7.2.1. Parent Completed

- Strength and Difficulties Questionnaire (SDQ): The SDQ is a brief, widely used behavioural screening questionnaire about 3-16 year olds completed by parents and teachers. It asks about 25 attributes, some positive and others negative. These 25 items cover emotional symptoms, conduct problems, hyperactivity/inattention, peer relationship problems and prosocial behaviour which added together generate a total difficulties score (see Goodman, 1997; Goodman and Scott, 1999).
- Revised Child Anxiety and Depression Scale – Parent completed (RCADS-30-P). This is a 30 item parent version of the primary outcome measure completed by children. The RCADS - P has high internal consistency, test-re-test reliability and good convergent and divergent validity (Ebesutani et al 2011).

7.2.2. Teacher Completed

Class teachers will be asked to complete the impact rating of the Strengths and Difficulties Questionnaire (SDQ) for all children in their class. This assesses the teacher perception of whether a child has a problem, and if so, enquires about chronicity, distress, social impairment and burden.

7.3. Parental/Carer Interviews

7.3.1. Quantitative Data: For the economic evaluation, structured interviews will be conducted with a sample of carers/parents of 300 children, 100 from each of the three conditions. All parents will be invited to participate and they will be offered £20 to cover the cost of their time. They will complete a structured interview, the Client Receipt of Services Questionnaire, about their child's use of services (described in more detail in 10.2) over the past 6 months. In addition, demographic details, a screen of parental health and mental health, assessment of life events and a survey of child leisure activity will be undertaken.

7.3.2. Qualitative Data: Qualitative interviews will be undertaken with 10% of the above parents/carers (7.3.1.) whose children received either of the FRIENDS interventions. This will provide n= 20 qualitative interviews which will be used to explore "how" and "why" the intervention might benefit children. A range of topics will be covered including parent views of their child's mood, anxiety and general behaviour; friendships; family relationships; educational progress and engagement in out of school social and recreational activities. We expect that 20 interviews will be sufficient to reach theoretical saturation, however, if necessary additional interviews will be undertaken.

7.4. Contextual Data

Data on a number of socio-economic indices which might be related to outcome will be collected for each participating school. These include number of free school meals; number of children in care; number of children with educational statements; level of educational attainment on standardised assessment tests; class size, and number of teaching assistants in study classes. In addition, the dominant pedagogic orientation of the school will be profiled and analyzed.

7.4.1 Socioeconomic status

The socioeconomic status of individual children will be assessed by the Family Affluence Scale (Andersen et al 2008). This short questionnaire asks children to rate the following 4 items relating to family affluence: family ownership of a car; child has own bedroom; number of family holidays in past year and how many computers the family own.

7.5. Intervention Delivery

7.5.1. FRIENDS leader ratings: At the end of each FRIENDS session leaders will rate a range of possible mediating variables including; child engagement, participation & contributions, school support, personal confidence in delivering FRIENDS; personal enjoyment of the group and their perception of group benefit.

7.5.2. Class & Head teacher ratings: At the end of each FRIENDS programme the class and head teacher will complete a structured questionnaire summarizing their views about the programme. They will be asked whether they had noticed any particular benefits, identified any problems in terms of delivery, materials, integration within the school curriculum and whether they felt the programme was sustainable.

7.6. Child Acceptability

7.6.1. Quantitative data: All children participating in FRIENDS will be asked to rate the programme on 10 dimensions including enjoyment, acquisition and use of new skills, and degree to which they felt safe talking about themselves.

7.6.2. Qualitative data: Interviews will be undertaken with 10% of children in the FRIENDS groups (approximately 60-80 interviews in total). The purpose of this is to provide a fuller understanding of the intervention i.e. had they learned anything new, used any new skills, what aspects of the programme were most helpful or could be improved. Areas of satisfaction and dissatisfaction will be assessed and views about the materials, activities and specific sessions obtained.

8. Assessment and follow-up

Assessments will take place at 4 different time points: Time 1 - baseline (pre FRIENDS); Time 2 - 6 months (post FRIENDS); Time 3 - 12 months follow-up; Time

4- 24 month follow-up. Timings are calculated from the start of the study i.e. 6, 12, 24 months since completing the baseline assessments.

8.1. Content of Assessments

- ***Time 1 Baseline:*** In school, all consenting children will complete the RCADS (30-item version), Penn State Worry Questionnaire for Children (PSWQ-C), Rosenberg Self-Esteem Scale, Bully/Victim items and Well-being questionnaire (described in 7.1) and CHU-9D questionnaire. The Strength and Difficulties Questionnaire (SDQ) and Parent version of The Revised Child Anxiety and Depression Scale (RCADS-P) will be sent to parents and the SDQ impact rating will be completed by the class teacher.

- Interviews will be conducted with parents about health service use over the preceding 6 months. A brief screen of parental health (SF-8) mental health (PHQ-9: GAD-7: IAPT Phobia Scales); the Penn State Worry Questionnaire and items relating to demographic characteristics, life events and child leisure activity will be assessed.

- ***Time 2*****:** 6 Month Follow-up: All the above child completed assessments will be repeated. Children participating in FRIENDS, FRIENDS leaders and class and head teachers will provide information relating to programme satisfaction and experience of delivery (described 7.5 & 7.6). The Strength and Difficulties Questionnaire and the RCADS-P will be sent to parents and the impact rating completed by class teachers. Structured interviews with 300 parents for the economic evaluation will be repeated and all assessments described in 7.3.1.will be repeated. Qualitative interviews undertaken with a sample (n=20) of those parents whose children participated in FRIENDS (described 7.3.2.)

- ***Time 3:*** 12 Month follow-up: The child, parent and teacher assessment described at baseline (described 7.1 & 7.2) will be repeated.

- ***Time 4:*** 24 Month follow-up: The child will complete the same questionnaires completed at baseline, 6 & 12 months. These will be completed at home and include the RCADS, Penn State Worry Questionnaire for Children, Rosenberg Self-Esteem Scale, Bully/Victim items and Well-being questionnaire and CHU-9D questionnaire. By this stage children will have transitioned to secondary school and they will also complete the 20-item School Concerns Questionnaire assessing worries about starting at secondary school (Rice et al 2010). Parents will complete the Strength and Difficulties Questionnaire (SDQ) and Parent version of The Revised Child Anxiety and Depression Scale (RCADS-P) and the School Concerns Questionnaire (SCQ).

  In addition, the sub-group of parents who were interviewed at baseline and 6 months and who opt to participate in the 24 month assessment will be asked to complete the assessments detailed at 7.3.1. They will complete the Client Receipt of Services Questionnaire, a screen of parental health and mental health and an assessment of life events.

8.2. Assessment of Efficacy and Effectiveness

- The secondary preventive effect (reduction in symptoms) will be assessed by comparing the primary outcome measures within and between the three groups from Time 1 (baseline) to: Time 2 (6 months),Time 3 (12 months) and Time 4 (24 months).

- The primary preventive effect will be assessed in two ways. Firstly, a comparison between Time 1 (baseline) and Time 3 (12 month) and Time 4 (24 month) scores on the RCADS of all children will be undertaken to detect any overall reductions in average scores within and between the three groups. Secondly, on the basis of baseline scores on the RCADS, the top 10% of high scoring children will be identified. This, more symptomatic group will be classified as "high anxiety" and the remaining 90% as "low anxiety". An analysis of the low anxiety group will be undertaken to explore how many in each condition continue to remain "low risk" at 12 and 24 months and how many have developed elevated symptoms.

- An economic evaluation (described more fully in 10.2) will be undertaken by comparing data from the structured parent interview on service usage at baseline, 6 and 24 month assessments.

8.3. Assessment of Harms

Possible harms arising from this study are expected to be minimal but will be monitored as follows:

- An independent Data Monitoring and Ethics Committee (DMEC) will be established. Schools will be taken on over three terms. At the follow-up assessment of the first wave of schools anxiety and mood symptoms will be monitored by the DMEC to check that they are not significantly higher in the intervention compared to the control group.
- An adverse events log will be established to record complaints from pupils, parents or staff and any significant distress/behavioural problems during/relating directly to the intervention. The log will be monitored by the DMEC and the independent Ethics Committee.
- A protocol for dealing with adverse events and concerns about individual children will be developed. Concerns will initially be discussed within the school and a plan agreed. This could include monitoring of the child at school; withdraw from FRIENDS if found to be distressing; follow-up discussion with their carers; referral/discussion with the school nurse; referral to the child mental health services or to social services. Immediate help/advice for distressed children will be co-ordinated via the lead applicant and could include contact with the school nurse, child mental health services, or a referral to social services.

9. Proposed Sample Size

The power calculation is based upon our primary outcomes, i.e. reduced levels of anxiety and improved mood. The study is primarily designed to assess whether FRIENDS is more effective than usual PSHE. The predicted effect size of 0.3 is therefore based on the comparison between no intervention and FRIENDS (whether school or health care led).

An estimate of the intra-cluster correlation coefficient (ICC) is not available in this setting or with this age group for our primary outcome. However ICCs of 0.02 or less have been observed for school based universal anxiety studies involving adolescents in Australia and the UK and in English schools for measures of self-esteem.

Results from studies in Australia suggest a (standardised) treatment effect size on continuous measures of anxiety and depression of 0.4. Our local evaluation suggests slightly lower values of 0.28 for anxiety and 0.32 for self-esteem. A standardised treatment effect size of 0.3 is equivalent to an estimated difference on the Revised

Child Anxiety and Depression Scale (RCADS 30) of 3.6 points, based on a SD of 12. This would both be considered as a worthwhile change over 6 months.

Assuming 28 pupils per class, 90% recruitment, 80% retention (20 completing pupils per class), homogeneous cluster sizes and a Bonferroni correction of the P value to allow for the comparison between Nothing (treatment as usual) versus CBT (health or school led), a total of 15 - 18 schools per arm would yield adequate power to detect effect sizes of this magnitude at the primary 12 month endpoint (see Table 2).

Table 2: Detectable effect sizes with different numbers of schools and students recruited

Number of schools recruited (per arm)	15	16	17	18
Number of pupils (per arm)	300	320	340	360
Detectable effect size (SDs)*				
80% power	0.30	0.29	0.28	0.28
90% power	0.34	0.33	0.32	0.31

*Two sided P value of 0.025. Adjusted for multiple comparisons.

10. Statistical Analysis

10.1. Quantitative Data

Analysis and presentation of data will be in accordance with CONSORT guidelines and in particular the extension to cluster randomised trials (BMJ 2004; 328; 702-708). The primary comparative analyses will be conducted on an intention-to-treat (ITT) basis with due emphasis placed on confidence intervals for the between-arm comparisons. Descriptive student- and class-level statistics will be used to ascertain any marked imbalance between the arms at baseline. The primary analysis will employ a mixed effect linear regression model to compare the active CBT interventions versus treatment as usual adjusting for stratification variables and baseline score, and taking appropriate account of the hierarchical nature of the data (repeated measures, students, classes and schools). Sensitivity analyses making different assumptions will be conducted to investigate the potential effects of missing data.

The extent of missing data will be reported and baseline factors will be compared for completers and non-completers to asses the extent of any bias that may result. Analysis will be undertaken using intention to treat (ITT), with missing values being replaced with the last valid response and therefore providing a conservative “no change” assumption. Depending on the extent of any missing data and the potential for any resulting bias, a further analysis may be undertaken of those participants with complete data (as described in the protocol) compared to the intention to treat results.

Secondary analyses will include: 1) repeating the primary analysis adjusting for any variables exhibiting marked imbalance at baseline to examine whether this influences the findings; 2) comparison of children who score high and low on anxiety and mood questionnaires at baseline to examine who most benefits form these interventions; 3) similar analyses for other secondary outcomes (using appropriate multi-level models and adjusting p-values for multiple testing); 4) investigation of process measures such as number of sessions attended; 5) investigation of possible treatment moderators (e.g. gender) and mediators (e.g. pedagogic orientation)

10.2. Economic Evaluation.

10.2.1. Cost effectiveness: An analysis comparing the two versions of FRIENDS and treatment as usual will be undertaken. The cost-effectiveness analysis will be

based on the primary outcome measures (i.e. cost per extra point reduction per child on the psychological measures of anxiety and mood). Both the cost analysis and the cost-effectiveness analysis will be from the joint perspective of the health (NHS) and education/social services sector (e.g. capturing children's within-trial contacts with mental health services, as well as those opportunity costs incurred by schools in order to participate). It will encompass resources needed to provide the intervention (teacher and health professional time, training time and materials, recruitment of schools), and any estimated resource impacts of altered outcomes (e.g. mental health service consultations and treatments and social care use). The research will identify, measure, and value the resource consequences of each alternative (applying opportunity cost as the main principle for valuation), including the separate identification of those costs/resources associated with the provision and evaluation of the interventions within the context of a research trial (i.e. those costs which would probably not be incurred should the programme be more widely implemented).

We will collect individual-level data on: use of extra educational support; use of mental or other health services; absence from school; use of social work/care services; use of voluntary/advice services and informal care. Resource use data will be collected directly from 300 parents/carers (100 in each trial arm) at baseline and again at 6 and 24 month follow-up (described in 7.3.1). An adapted Client Service Receipt Inventory questionnaire (Beecham & Knapp, 2001) will provide quantitative data about the frequency, duration of use of health, education and social care services and informal care. Resources will be valued using national unit cost information, such as the PSSRU's Unit Costs for Health and Social Care, or local unit costs from the four study areas where national costs are unavailable. For the trial-based analysis no discounting will be used.

In the base case analysis we will compare the whole cost of the intervention(s) with outcomes for all recruited children. Cost-effectiveness in relation to baseline high-risk and low-risk status will be explored in a sub-group analysis. Uncertainty will primarily be expressed through the calculation of confidence intervals for the incremental cost-effectiveness ratios (using non-parametric Bootstrapping). If appropriate, the trial-based cost-effectiveness results will also be extended beyond 6 months and key uncertainties further explored using a simple decision model.

10.2.2. Cost Utility: In order to assess cost-utility, we will ask children to complete the CHU-9D (licensed by the University of Sheffield, Stevens 2008). The CHU-9D, a validated measure of health related quality of life, is short (9 items) and has been specifically developed for use with children aged 7 to 11 years of age. The use of the CHU-9D will allow us to assess how improvements in mental health (anxiety and depression) translate into changes in overall health related quality of life. Children from all three conditions will complete the CHU-9D at baseline, 6, 12 and 24 months.

11. Ethical Arrangements

11.1. Ethical Approval

An application will be made to the local NHS Research Ethics committee for review and approval. If the committee feels that this study falls outside their remit, then an application will be made to the Ethical Committee at the University of Bath.

11.2. Ethical Issues

This study raises few ethical concerns. The key ethical issues are;

- The active intervention (FRIENDS) will be provided as part of the standard school curriculum, but parents/carers can opt their child out of FRIENDS. Local experience with over 3000 children indicates that this has only happened once.
- Only those parents/carers and children who consent/assent will complete the assessments.
- We will have a no treatment group because we do not know whether FRIENDS is better or worse than other programmes that schools are already providing. The no treatment group will be offered training in the FRIENDS programme after the one year follow-up is completed.
- We do not expect FRIENDS to have any detrimental effects upon the children. At worst it will not be effective.
- A mental health expert who is part of the local child services will be identified as the link for each local school to discuss and offer advice about any additional help that may be required for those children identified with significant mental health problems or who become upset/distressed in sessions.
- There is a risk that children may disclose information during sessions that indicates possible abuse or harm. In all cases the local child protection arrangements will be followed.

11.3. Consent/Assent

11.3.1. Baseline, 6 & 12 month assessments

Interventions will be provided during the school day as part of the school PSHE curriculum. Children will therefore participate in whatever is provided by the school However, we will offer parents/carers the opportunity to opt their child out of the programme and/or completing the assessments. The consent/assent process in this study has three levels.

Firstly, eligible schools (i.e. within the geographical area of BaNES and Wiltshire) are required to opt in to the study. This will require the approval of the Head Teacher, participating class teachers, and other relevant parties (e.g. members of the Senior Management Team and the Board of Governors).

Secondly, all eligible parents (i.e. of 9/10 year old children) will be provided with a project information sheet informing them about the study. Although all children will be expected to participate in the PSHE sessions that the school provides, only those children who provide signed consent/assent will complete the assessments. The letter will therefore inform carers that they can opt out of the assessments if they do not wish their child to complete the questionnaires.

Finally, the children themselves will be required to opt in and provide signed assent to complete the assessments. The project information sheet will be read to the children and child assent obtained before completing the questionnaire. Dual carer/child consent/assent will be required for assessment completion.

11.3.2. Medium term 24 month assessment

The PACES cohort will transition to secondary school in September 2013 and so assessments can no longer be undertaken at school. The cohort will therefore be contacted and invited to opt-in to the 24 month assessment. Our recruitment strategy will draw upon suggestions from systematic reviews designed to maximize recruitment to trials (Edwards et al 2002).

Firstly, opt-in reply slips and a project information sheet with the University and PACES logo will be sent via schools to parents of all children who participated in the PACES study. Secondly, playground recruitment visits will be undertaken at the end of the day when parents collect their children. These will allow informal discussions about the project and an opportunity for parents to opt-in to the study. Thirdly, a range of PACES publicity materials with the project contact details (e.g. pencils, fridge magnets, stress balls and message bugs) will be handed out to children during these visits. Fourthly, a PACES Facebook page will be established as a way of allowing parents to contact the study team and opt in to the study. Finally a £30 financial incentive will be offered to compensate parents and children for their time in completing the assessments.

12. Research Governance

12.1. Sponsor

The study will be sponsored by Oxford Health NHS Trust.

12.2. Research Governance

The study will comply and be conducted in accordance with NHS Trust Research Governance requirements. This will include storage & retention of confidential research data. There will be three main management committees:

1) Trial Steering Committee (TSC). This will provide overall supervision of the trial. It will meet at least once a year and its role will be to monitor and supervise the progress of the trial towards achieving its goals; to advise the investigators in general scientific and management issues; and to ensure that there are no major deviations from the trial protocol. The lead applicant will inform the Chair of the TSC who may call additional meetings when there are matters arising from the conduct or management of the trial that might require their advice.

2**) Data Monitoring and Ethics Committee (DMEC).** This will monitor data and advise the TSC on whether there are any ethical or safety reasons why the trial should not continue. The DMEC will meet at least annually.

3) Trial Management Group: A Trial Management Group will be established to oversee the operational running and progress of the project. This will be chaired by the Lead Applicant and will include the trial manager and researchers, and other co-applicants as appropriate. The group will meet monthly or as required.

13. Project Timetable and Milestones

- Months 1-2: Recruitment and induction of project staff; establishment of project infra-structure.
- Months 3-6: Submit ethics application; school recruitment; recruitment of health FRIENDS leaders.
- Months 7-8: School randomisation; detailed planning with schools; prepare assessment packs & FRIENDS resources.
- Month 9: FRIENDS training; consent letters and project information sheet posted to parents.
- Months 10-12: Complete baseline assessments; start delivery of interventions.
- Months 13-15: Deliver interventions; baseline data entry, cleaning and checking.
- Months 16-18: Complete baseline analysis; complete 6 month assessments.
- Months 19-21: 6 month data entry, cleaning and checking.

- Months 22-24: Complete 6 month analysis; start 12 month follow-up.
- Months 25-27: 12 month data entry, cleaning and checking.
- Months 28-30: Complete 12 month analysis.
- Months 31-36: Project summary and papers written and submitted.
- Months 30-33: Complete 24 month recruitment.
- Months 33- 45: Complete 24 month follow-up. Data entry and cleaning.
- Months 45-48: Complete 24 month analysis and disseminate findings.

14. Expertise

Professor Paul Stallard is a National expert on the use of CBT with children and young people. He has led and evaluated previous school based emotional health interventions and undertaken RCTs including a national project evaluating a school based depression prevention programme. He will provide leadership for the project and specific training and supervision of the CBT based intervention. **Dr Neil Simpson** has considerable experience in parent and school liaison and has been involved in implementing and co-ordinating school based emotional health programmes across 30 schools. He will lead school and parent liaison and contribute to the cost and cost effectiveness analysis. **Dr Rob Anderson**, a health economist based in the Peninsula Technology Assessment Group, Universities of Exeter & Plymouth, will lead the cost and cost effectiveness analysis and has previously evaluated the cost-effectiveness of school-based screening programmes. **Dr Gordon Taylor** is a senior lecturer (medical statistician) at the University of Bath and has experience of undertaking cluster RCTs and analysis of complex interventions. He will provide advice about study design and lead the statistical analysis. **Professor Harry Daniels,** an educationalist, will support engagement with schools through the networks that have been established in a long series of DCSF/ DFEE, DFE, DFES studies concerned with mental health and emotional and behavioural difficulty. His analysis of the relation between the cultures of schooling and pupil well being will inform the development of the project and the interpretation of results. **Sue Anderson** has been involved in delivering and co-ordinating mental health interventions across a number of schools and has established good relationships with target schools. She will co-ordinate the health input. **Dr Rhiannon Buck** is a Clinical Trial Manager currently leading a school based depression prevention RCT. Dr Buck will provide advice about clinical trial management.

15. Members of the Public

FRIENDS is an established manualised programme which has been used in Bath with over 3000 children. Feedback from children about the programme is routinely collected and has been used to inform programme delivery.

We intend to involve children and parents in this project in three key ways. Firstly, we will establish four focus groups of children aged 9/10 to discuss the project methodology. In particular, the groups will advise on content, wording and presentation of project information sheets and consent forms for the study. Secondly we will work with a children's group hosted by a local voluntary group, Off the Record. The group can be used to discuss and advise on issues that emerge during the trial and on the preparation and dissemination of the findings for children and parents. Thirdly, we will recruit two parents to become members of the Trial Steering Committee. They will be active partners in the management of the project including monitoring progress and potential difficulties, interpretation of findings, summarising conclusions & identifying key lessons.

16. Justification of Support Required

17. References

Adi Y, Killoran A, Janmohamed K, Stewart-Brown, S. Systematic review of the effectiveness of interventions to promote mental wellbeing in children in primary education. Report 1: universal approaches (non-violence related outcomes). London: National Institute for Health and Clinical Excellence. 2007.

Andersen, A., Krolner, R., Dallago, L., Due, P., Richter, M., Orkenyi, A. & Holstein, B.E. High agreement of family affluence between children's and parent's reports: international study of 11-year old children. Journal of Epidemiology and Community Health, 2008, 62, 1092-1094.

Barrett, P.M., Farrell, L.J., Ollendick, T.H. & Dadds, M. Long-term outcomes of an Australian universal prevention trial of anxiety and depression symptoms in children and youth: an evaluation of the FRIENDS programme. Journal of Clinical Child and Adolescent Psychology. 2006; 35, 3, 403-411.

Barrett, P. & Turner, C. Prevention of anxiety symptoms in primary school children: Preliminary results from a universal school-based trial. British Journal of Clinical Psychology. 2001; 40, 399-410.

Beecham J & Knapp M. Costing psychiatric interventions. In: Measuring Mental Health Needs (ed. G Thorncroft). London. Gaskell. 2001

Birhamer B, Ryan ND, Williamson DE, Brent DA, Kaufman J, Dahl RE, Perel J & Nelson B. Childhood and adolescent depression: a review of the past 10 years. Part 1. Journal of the American Academy of Child & Adolescent Psychiatry. 1996; 35, 1, 427-439.

Costello, E., Angold, A., Burns, B.J., Stangl, D.K., Tweed, D.L. Erkanli, A. & Worthman, C.M. The Great Smoky Mountains Study of Youth: goals, deigns, methods and prevalence of DSM-iii-R disorders. Archives of General Psychiatry. 1996; 53, 1129-1136.

Chorpita BF, Moffitt CE, Gray J. Psychometric properties of the revised child anxiety and depression scale in a clinical sample. Behaviour Research and Therapy. 2005;43(3):309-22.

Chorpita BF, Yim L, Moffitt C, Umemoto LA, Francis SE. Assessment of symptoms of DSM-IV anxiety and depression in children: a revised child and anxiety scale. Behaviour Research and Therapy 2000; 38:835-855.

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 . Behaviour Research and Therapy 1997; 35:569-581,

Costello, E.J., Mustillo, S., Erkanli, A., Keeler, G & Angold, A. Prevalence and development of psychiatric disorders in childhood and adolescence. Archives of General Psychiatry. 2003; 60, 837-844.

Department for Education and Skills Every child matters: change for children. London. 2004.

Department for Education and Skills. Primary national strategy. Excellence and enjoyment: social and emotional aspects of learning. London. 2005.

Department of Health (DoH). The National Service Framework for children, young people and maternity services. London: HMSO. 2004,

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. Journal of Abnormal Psychology 2011; 39:173-185.

Edwards P, Roberts I, Clarke M, DiGuiseppi C, Pratap SA, Wentz R. Increasing response rates to postal questionnaires: systematic review. British Medical Journal 2002; 324:1183.

Essau, C.A., Conradt, J. & Petermann, F. Frequency, comorbidity, and psychological impairment of anxiety disorders in German adolescents. Journal of Anxiety Disorders. 2000; 14, 3, 263-279.

Ferguson DM, Horwood LJ, Ridder EM & Beautrais AL. Sub threshold depression in adolescence and mental health outcomes in adulthood. Archives of General Psychiatry. 2005; 62, 66-72

Ford, T., Goodman, R. & Meltzer, M. Service use over 18 months among a nationally representative sample of British children with psychiatric disorder. Clinical Child Psychology and Psychiatry. 2003; 8, 1, 37-51

Goodman, R. The Strengths and Difficulties Questionnaire: A Research Note. Journal of Child Psychology and Psychiatry. 1997; 38.5. 581-586

Goodman, R. & Scott, S. Comparing the Strengths and Difficulties Questionnaire and the Child Behavior Checklist: Is Small Beautiful? Journal of Abnormal Child Psychology. 1999; 27, 1, 17-24

Harrington R, Fudge H, Rutter M, Pickles A. & Jill J. Adult outcomes of child and adolescent depression. I. Psychiatric Status. Archives of General Psychiatry. 1990; 47, 5, 465-473.

Humphrey, N., Kalambouka, Bolton, J., Lendrum, A., Wigelsworth, M., Lennie, C. & Farrell. Primary Social and Emotional Aspects of Learning (SEAL) - Evaluation of Small Group Work. DCSF. 2008

Junghan, C. Feder G, Hemmingway H, Timmis A & Jones M. Recruiting patients to medical research: double blind randomised trial of “opt-in” versus “opt-out” strategies. British Medical Journal. 2005; 331, 940-944.

Kim-Cohen, J., Caspi, A., Moffitt, T.E., Harrington, H., Milne, B.J. & Poulton, R. Prior Juvenile Diagnoses in Adults with Mental Disorder Developmental Follow-Back of a Prospective-Longitudinal Cohort. Archives of General Psychiatry. 2003; 60:709-717

Lock, S. & Barrett, P.M. A longitudinal study of developmental differences in a universal preventive intervention for child anxiety. Behaviour Change. 2003; 20, 183-199.

Lowry-Webster, H., Barrett, P., & Dadds, M.R. A universal prevention trial of anxiety and depressive symptomatology in childhood: Preliminary data from an Australian study. Behaviour Change. 2001; 18, 36-50.

Lowry-Webster, H., Barrett, P., & Lock, S. A universal prevention trial of anxiety symptomatology during childhood: Results at one-year follow-up. Behaviour Change. 2003; 20, 25-43.

Meltzer, H., Gatward, R., Goodman, R. & Ford, T. Mental health of children and adolescents in Great Britain. International review of Psychiatry. 2003; 15, 185-187.

Muris P, Meesters C, Schouten E. A brief questionnaire of DSM-IV-defined anxiety and depression symptoms among children. Clinical Psychology & Psychotherapy. 2002; 9(6):430-42.

Muris P, Meesters C, Gobel M. Reliability, validity, and normative data of the Penn State Worry Questionnaire in 8-12 year old children. Journal of Behaviour Therapy and Experimental Psychiatry 2001. 32:63-72.

National Institute of Clinical Excellence. Depression in children and young people: identification and management in primary, community and secondary care. National Clinical Practice Guideline 28. Leicester: British Psychological Society and Royal College of Psychiatrists. 2005.

Neil, A.L. & Christensen, H. Efficacy and effectiveness of school-based prevention and early intervention programs for anxiety. Clinical Psychology Review. 2009; 29, 208-215.

Raab GM. & Butcher I. Balance in cluster randomized trial. Statistics in Medicine. 2001; 20:351-365

Rees G, Goswami H, Bradshaw J. (2010) Developing an index of children's subjective well-being in England. The Children's Society, London.

Rice F, Frederickson N, Seymour J. Assessing pupil concerns about transition to secondary school. British Journal of Educational Psychology 2010: 81:244-263.

Sandin B, Chorot P, Valiente RM & Chorpita BF. Development of a 30 item version of the revised child anxiety and depression scale. Revista de Psicopatologia y Psicologia Clinica 2010; 15: 165-178.

Shucksmith, J. Summerbell, C. Jones, S & Whittaker, V. Mental wellbeing of children in primary education (targeted/indicated activities). London: National Institute for Health and Clinical Excellence. 2007.

Spence, S.H. The Spence Children's Anxiety Scale (SCAS). In I. Sclare (ED). Child Psychology Portfolio. Windsor, UK, NFER-Nelson. 1997.

Stallard, P., Simpson, N., Anderson, S., Carter, T., Osborn, C. & Bush, C. An evaluation of the FRIENDS programme - a cognitive behaviour therapy intervention

to promote emotional resilience. Archives of Disease in Childhood. 2005; 90, 10, 1016-1019

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. European Journal of Child and Adolescent Psychiatry. 2008; 17, 5, 283- 289.

Stallard, P., Simpson, N., Anderson, S., Hibbert, S. & Osborn. C. The FRIENDS emotional health programme: initial findings from a school based project. Child and Adolescent Mental Health. 2007; 12, 1, 32-37.

Woodward, L.J. & Fergusson D.M. Life Course Outcomes of Young People With Anxiety Disorders in Adolescence. Journal of the American Academy of Child & Adolescent Psychiatry. 2001; 40(9):1086-1093

World Health Organisation Prevention of Mental Disorders: effective interventions and policy options. Geneva. WHO. 2004,