NETSCC, HTA

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DETAILED PROJECT DESCRIPTION: HTA: 06/37/04: A single blind randomised controlled trial to determine the effectiveness of group cognitive behaviour therapy (CBT) in the prevention of depression in high risk adolescents

1. Project Title

A single blind randomised controlled trial to determine the effectiveness of group cognitive behaviour therapy (CBT) in the prevention of depression in high risk adolescents.

1.1. Acronym

PROMISE: **PRO**moting **M**ental health **I**n **S**chools through **E**ducation

2. Planned Investigation:

2.1. Research Objectives

A number of systematic and meta-reviews have highlighted the potential efficacy of CBT in the prevention and treatment of depression in children (1-5). Although these reviews have been positive a number of issues have been identified including the absence of comparisons with appropriate placebo groups, the need for longer term follow-up and the absence of randomised controlled trails within a UK context. This study aims to address these issues and in particular will:

1. Examine the effectiveness of school based CBT Personal Social and Health Education (PSHE) vs an attention PSHE (delivered by people external to the school) vs usual PSHE (school delivered) on the prevention of depressive symptoms in high risk adolescents aged 13-16 as assessed by the Short Mood and Feelings Questionnaire at 6 and 12 months. Our primary follow-up will be 6 months after completing the intervention.
2. Examine the effectiveness of CBT (6 & 12 months) on the secondary outcomes of negative thoughts, self-esteem and anxiety.
3. To undertake a secondary sub-group analysis to investigate the effect modification by school connectedness, bullying, self harm, alcohol and drug misuse on treatment outcome (6 months).
4. Assess the cost-effectiveness of the intervention in terms of health-related quality of life (and cost-utility) at 6 months.
5. To undertake a process evaluation to assess factors associated with adherence and acceptability of the intervention including participant perception of usefulness, examples of on-going skill usage, and satisfaction (6 & 12 months).

3.2. Existing Research

Epidemiological studies suggest that over a six month period up to 2.5% of children and 8.3% of adolescents suffer from a major depressive disorder (6). Cumulative rates indicate that up to 20% will suffer at least one clinically depressive episode by the age of 18 (4). In the UK prevalence estimates are 1.4% amongst 11-16 year olds in the community and around 20% amongst 13-16 year olds attending primary care (7-8). Adolescent 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 (6, 9-11). In addition, sub-threshold depressive symptoms in adolescence carry a similar risk to major depression for developing depression and suicidal behaviours later in life (12). Whilst approximately 50% of children are estimated to spontaneously recover for the remaining half symptoms persist and significantly impair functioning (5). It is therefore particularly concerning to note that depression in adolescents often remains unrecognised and untreated (13-14).

Depression is an important public health issue and, in view of the above, there has been growing interest in the development of interventions designed to prevent depression in adolescents. The better evaluated depression prevention programmes have tended to be based upon cognitive behavioural therapy (CBT). These include the Penn Resiliency Programme (15), Coping with Stress (16), Problem Solving for Life (17), FRIENDS (18), Resourceful Adolescent Programme (19) and other CBT programmes (20). Some have been delivered as selective interventions to adolescents with elevated symptoms of depression (21-22) whilst others have been delivered as universal interventions to whole populations (19, 23). Most preventative CBT interventions have produced immediate short term gains in terms of reductions in depression scores although these are not always maintained at follow-up. For example, Spence, Sheffield and Donovan (17) published the largest study to date which involved 1500 children aged 12-14 .The 8-session Problem Solving for Life programme resulted in significant post-

treatment reductions in symptoms of depression and an increase in problem solving skills compared to a non-intervention comparison group. However, when assessed at 12 month follow-up this difference was no longer significant (24).

The Cochrane review notes that targeted preventative interventions result in marginally greater reductions in depressive symptoms (4). This may partly be explained by initial levels of depressive symptoms in the control groups (25). In targeted interventions the sample is chosen on the basis of risk status and the control group is therefore likely to have higher levels of depressive symptoms at baseline and follow-up. This is in contrast to universal interventions where initial levels of symptoms are lower and may not therefore be high enough to demonstrate a preventative effect at follow-up. However targeted approaches encounter significant recruitment problems that severely limit their potential impact and use For example, in one targeted study 3,935 parents with depression or depressive symptoms were identified (21). Of these, 2995 were judged appropriate for the study although baseline interviews were conducted with only 551 youth parent dyads, 18% of the eligible sample. Similarly, in a recent study only 271 out of a total population of 6000 responded or were eligible to receive the preventative intervention and of the147 young people allocated to the active intervention 41 (29%) did not attend (15). Other reviewers have noted recruitment rates of less than 50% and attrition rates of approximately 30% in targeted preventative studies (26). A further limitation of targeted approaches is their failure to provide any input to low risk children that would prevent low level symptoms escalating. In a study involving 260 adolescents, 1.2% of the healthy adolescents receiving a preventative intervention moved into the high risk group at follow-up compared with 10.1% in the control group (19). Selective depression preventative programmes therefore have a limited effect and reach and engage only a small proportion of adolescents who are identified as at risk for depression.

Universal prevention programmes provide an alternative approach. Whilst not all recipients of universal approaches present with elevated depressive symptoms they nonetheless provide a pragmatic alternative, reduce possible negative effects of stigma and labelling, result in lower rates of dropout and greater participation rates (16-17, 19). Indeed, universal approaches achieve recruitment rates of 67% - 88% (17, 19, 27). Proponents of universal population based approaches argue that whilst they might have a more limited effect on individuals they will nonetheless reduce far more disorders in the population as a whole than a highly effective targeted approach (28). Indeed, Rose (29) argues that a large group of people exposed to a low risk (e.g. minor depressive symptoms) will ultimately generate more clinical cases than a small group of people exposed to a high risk. There is therefore a strong rationale for pursuing universal approaches for the prevention of depression in adolescents.

Of the evaluated universal depression prevention programmes the Resourceful Adolescent Programme (RAP) appears particularly promising. In the initial efficacy study, 260 adolescents were assigned to RAP, RAP plus family involvement or a no intervention group (19). In terms of reach 85% of the eligible cohort took part and attrition was 5.8%. Adolescents who received either version of RAP reported significantly lower levels of depressive symptomatology at post intervention and 10 month follow-up compared with the no intervention group. In terms of health status, 71% of the RAP group who were classified as “at risk” on the basis of initial depression scores had moved into the healthy range when assessed at post intervention compared with 31% in the control condition. This was maintained at 10 month follow-up where 75% of the RAP high risk group and 41% of the control high risk group scored within the normal range on measures of depression. There was also evidence of a preventative effect since none of the “healthy” adolescents in the RAP group moved into the “at risk” range at follow-up compared to 10.5% of those in the control condition.

In a New Zealand adaptation of the programme, RAP-Kiwi, 392 students were assigned to either RAP-Kiwi or an attention placebo condition (27). Once again recruitment rates were high (73%) and attrition low (9% attrition at 6 months). Depression scores were significantly lower in the RAP group post intervention. In clinical terms, sixteen students in the RAP group, as determined by scores on the Beck Depression Inventory moved from the moderate/severe to the minimal/mild category at post-test compared to six in the placebo group. The results were less conclusive at 18 month follow-up where although the difference on the Reynolds Adolescent Depression Scale remained significant scores on the Beck Depression Inventory were not.

A large multi-site randomised controlled effectiveness trial in Australia of RAP involving 2664 students from 12 schools has recently been undertaken (26). RAP participants recorded significantly lower levels of depressive symptoms than those in the control condition at both post-intervention and

12-month follow-up. Based on initial depression scores, significantly more (49.1%) of the at-risk students in the RAP condition moved into the healthy category at post-intervention compared with 35.3% in the control group. This difference was maintained at 12 month follow-up. In a subsequent qualitative evaluation with 109 young people, 61.2% of girls and 46.6% of boys were able to identify specific examples where they had used skills learned during RAP (26). The authors concluded that within the context of a real world effectiveness study RAP appears to positively affect the health status of "at risk" students

The absence of long term follow-up and the tendency for post-intervention effects of depression prevention programmes to diminish after 6 months have been noted (4, 24). It would therefore seem important for preventative interventions to include additional booster sessions in order to maintain short term benefits. In addition, there is a need to determine whether improvements are due to the specific treatment components of the intervention or the non-specific factors associated with therapy and whether these improvements are significantly greater than would normally occur over time. Active interventions therefore need to be compared with placebo conditions and usual care. In view of the promising results from RAP this project intends to undertake a pragmatic trial to evaluate the effectiveness of the universal group RAP CBT programme in the UK context. RAP will be delivered via PSHE in schools by trained mental health professionals and will be compared over a 12 month period with an attention PSHE and usual PSHE (treatment as usual).

3.3. Research Methods

***3.3.1. Design*:** A cluster randomised controlled treatment trial comparing the effectiveness and cost effectiveness of group CBT PSHE versus attention PSHE versus usual PSHE in the prevention of depression in high risk adolescents in UK school years 8 to 11 (aged 12-16).

3.3.2. Setting: 8 mixed sex comprehensive schools in Bath and North East Somerset, Bristol, Nottingham & Wiltshire.

3.3.3. Recruitment of schools: A list of 66 mixed comprehensive secondary schools in Nottingham, Wiltshire, Bath and North East Somerset and Bristol was complied from local authority information. Letters were sent to the Head Teachers and PSHE leads at each of these schools. The schools that did not respond were sent a reminder e-mail and were contacted by telephone. Schools that expressed an interest were contacted by the research team and a meeting was arranged to discuss the project. The schools were asked to return a form to confirm they were willing to participate by May 2009. They were also asked to indicate at this stage if there were any year groups that they would not be able to include in the study (i.e. those who did not have discrete PSHE lessons).

8 schools agreed to take part. One of these schools did not have a Year 11 group as they were a new school. A further three schools could not include their Year 11 groups and one of these was also unable to include their Year 10 group as these year groups did not have discrete PSHE lessons within which the program could be accommodated were they allocated to the active intervention arm. A total of 28 year groups, with 222 classes, and approximately 5,708 young people were included in the randomisation process.

Of the remaining 58 schools who were initially contacted, 5 declined without giving a reason, 2 did not teach PSHE as a discrete lesson, 5 were unable to participate at the present time due to other commitments (e.g. major changes in staffing, school buildings, responding to OFSTED), and 2 of the schools were closing down. Initial meetings were held with a 3 schools who expressed an interest initially, but two of these later declined due to staffing changes and we were unable to get a response from one school when asked them to confirm whether they would like to participate.

3.3.4. Group classification: Our target population will be boys and girls in years 8-11 (aged 12-16). The Short Mood and Feelings Questionnaire (SMFQ) completed on two separate occasions will be used to categorise the cohort. The ideal interval between SMFQ completion would be two weeks. However, some flexibility in this interval will be required to fit in with the school timetable. The primary aim of the present study is examine the effect of the interventions on children at "high risk" of developing depression. This study is <u>not</u> concerned with whether or not children present with a clinical diagnosis of depression but is concerned with identifying children with <u>elevated symptoms</u> of low mood. To account for transient changes in mood, in the current study SF-MFQ scores will be collected on two separate occasions to allow for the identification of those with more persistent low mood.

Furthermore, it is a level of low mood above community population means rather than clinical 'caseness' cut-off points that are of interest. Research with clinical and community samples demonstrates that young people who fulfil DSM diagnostic criteria for depression achieve mean scores on short forms of the MFQ ranging between 7.01 -11.95 compared with 3.24 – 4.68 for those who are not depressed (30-33). Approx 6% of a community sample achieved a total cut-off score of 11 or more (33).On this basis, we intend to use total SMFQ scores to categorise young people as follows: Low Risk of depression <5; High Risk of depression, ≥5; Probably Clinically Depressed >11 . Those with persistent symptoms (scoring ≥5 on both occasions) will become our high risk group. We expect 77% of the cohort will be categorised as low risk group; 20% high risk and 3% as probably clinically depressed. In a class of 30 this would equate to 23; 6; and 1 child respectively.

3.3.5. Method of randomisation: Individual randomisation is not practical and would create insurmountable timetabling and organisational difficulties for the school. The intervention will be delivered as part of the PSHE curriculum and as such it is important that the intervention fits within the existing school structures. Minimising contamination between the three arms of the trial is an important consideration. The cluster unit will therefore be year groups and whilst it is recognised that there is a risk of between group contamination, this is considered to be minimal. Firstly, the main friendship groups for the majority of young people will be within their year group. Between year group discussions are generally limited and as such it is unlikely that they will focus upon the specific content of these sessions. Secondly, it is doubtful whether any brief discussions that might occur would be sufficient to bring about any significant change or on-going skill usage. Within the existing school structure young people are assigned to a tutor group and it is usually within these groups that PSHE is undertaken. These may be different from registration classes and classes for core subjects, which are streamed by ability and therefore randomising by class would pose a greater risk of contamination. Classes within a year group typically follow the same scheme of work for PSHE and therefore randomisation by year group makes delivery of the intervention more convenient for participating schools.

Allocation of year groups will take place once all schools have been recruited. Balance between trial arms with respect to key characteristics of year groups will be achieved by calculating an imbalance statistic for a large random sample of possible allocation sequences (34). The variables used for balancing will be numbers of students, number of classes, the way in which PSHE is delivered (i.e. weekly, fortnightly, or other) for each year group. The number of clashes (i.e. classes having PSHE at the same time) will also be included when balancing to ensure that delivery of the interventions is feasible. 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.

3.4. Planned Interventions

- **Active Intervention – CBT PSHE**

This study will evaluate the Australian developed Resourceful Adolescent Programme (RAP) CBT programme in a UK context. RAP is a group based depression prevention programme designed for young people aged 12-16. The intervention is manualised and is provided by trainers external to the school. Students complete their own workbook and group leaders have a detailed manual specifying key learning points and objectives. Detailed content for each of the 11 sessions is summarised below. It is intended that participating schools would hold the RAP sessions within their normal PSHE sessions. The programme developer, Professor Ian Shochet, notes that the programme can be adapted to fit with the time restraints of the school. Sessions can be combined and delivered over six, 75-90 minute sessions if the school has double periods of PSHE. In this eventuality, the attention placebo condition would also be modified to ensure that number of sessions and contact time matched RAP.

RAP is based upon a cognitive behavioural theoretical (CBT) model. CBT recognises the importance of negative thoughts and low self-worth/image in the onset and maintenance of depression. These are therefore actively targeted during CBT with core treatment components including psycho education, identifying and challenging negative/dysfunctional thoughts, identifying personal strengths (thereby enhancing self-esteem/image), managing social problems, and learning to problem solve.

For the purposes of this study, the original RAP program has been modified for use in the UK (RAP-UK). Whilst the content, key messages and goals remain consistent with the original program, the

structure and method of delivery have been revised to fit in with the UK state secondary education system. The key elements of the RAP-UK program are:

1. Personal Strengths

   Young people are helped to recognize and reinforce their existing strengths and personal resources. The aim of this part of the programme is to help adolescents focus upon the importance of developing and maintaining good self-esteem.

2. Helpful Thinking

   Young people are helped to recognize and challenge unhelpful ways of thinking and to develop more balanced and helpful thinking (cognitive restructuring).

3. Keeping Calm

   Young people are helped to discover ways in which they can manage unpleasant feelings. This involves learning to recognize physical symptoms such as butterflies in the stomach or tense muscles and how to manage these (e.g. through relaxation, humor and other stress reduction techniques.

4. Problem Solving

   Young people are encouraged to define their problems, consider alternative solutions and to use a stepped approach to carry out and evaluate the solution.

4. Support Networks

   Young people are helped to acknowledge the importance of developing a support network and are encouraged to seek help, when necessary.

5. Keeping the Peace

   Young people are helped to consider how growing older and becoming more responsible can lead to disputes with peers and adults. Strategies for interpersonal problem solving designed to promote harmony and to avoid escalation of conflicts are considered.

   Similarly, during the programme young people are helped to examine the value of empathy in keeping the peace. They are encouraged to understand that getting along with people is easier if we can acknowledge and see things from the other person's perspective.

These key elements are of the RAP-UK program are organised over the following 9 sessions:

1. Find your strengths
2. Thoughts, feelings and behaviour
3. Feelings and body signals
4. I am what I think
5. You can change the way you think
6. Problems can be solved
7. There is always help at hand
8. There are two sides to every story
9. Keep the peace

Each session is designed to be delivered in approximately 50 to 60 minutes. However, the method of delivery of PSHE in the UK varies widely (e.g. regular weekly or fortnightly lessons, project days, or condensed courses over a number of weeks). Therefore, the revised program has been designed with a flexible method of delivery in mind to ensure that it is possible to fit the program in to school curricula while retaining the core content and key elements of the program.

Two additional booster sessions will be provided approximately 6 months later. These will provide opportunities to review RAP skills and to practice applying them to current difficulties.

- **Attention Placebo Intervention**

The attention placebo intervention will involve similar time and contact with external providers, but will not include the active components of the CBT intervention identified above. The school will deliver their usual PSHE curriculum, but the class teacher will be joined by two researchers from outside of the school who will assist with delivering the lessons and engaging with young people. This will therefore control for the non-specific effects of interventions that are considered important in studies of depression (35). In the same way as the RAP program, the delivery of the Attention Placebo intervention will be flexible to fit in with existing school PSHE programs.

- **Usual PSHE**

In this group young people will participate in the usual personal health and social education (PSHE) sessions provided by the school. This is therefore "treatment" as usual provided by the school staff and does not involve any external input from the research team. Records summarising the content of each session will be kept so that any potential overlap with the active intervention can be determined.

3.4.1. Intervention Leaders: The intervention leaders will be Psychology Assistants who will have completed an undergraduate degree. The active and placebo interventions will be delivered by two Psychology Assistants with the tutor group teacher being present to manage the class. Psychology Assistant posts are very popular and we would not expect any recruitment problems. In order to avoid therapist contamination different leaders will deliver each intervention. The leaders will receive a minimum of two days of initial training, which will cover the identification and management of mental health concerns, group management techniques, as well as training them to deliver the specific intervention. The active intervention is manualised and each leader will have a trainer's manual.

During the course of delivery, regular separate supervision groups will be provided for the active and attention placebo intervention group leaders. The supervision sessions will take place at least once a month and will require a minimum of 9 hours (equivalent to 1 hour for each session of RAP). Notes will be taken during these sessions to provide a record of content.

3.4.2. Treatment Fidelity: Independent observers will attend randomly selected sessions (5%) and rate the content against the key learning points and exercises detailed in the manual. The intervention leaders in the Attention Placebo and Active Intervention groups will also record the content of each lesson using a standardised checklist such that comparisons between the content of the Active Intervention and Attention Placebo can be made.

3.4.3. Attrition: An attendance register will be kept to monitor attendance and attrition during the course of delivering the intervention and placebo PSHE sessions.

3.4.4. Recruitment rates and loss to follow-up: Universal depression prevention programmes tend to achieve recruitment rates of 67-88% (17, 19, 27). Our local experience of running a universal emotional health prevention programme in 30 junior schools has resulted in recruitment rates in excess of 95% (36). Our predictions for this study are more conservative and we predict a recruitment rate of 70%. Of those who consent to assessments, we predict that 20% will become lost by the end of the 12 month follow-up.

We are expecting differential dropout for the Year 11 students for their 12 month follow-up, many of whom will have left school by this time. To maximise response rates in this group, they will be offered an option to fill the questionnaire in either online at a secure website (surveymonkey.com) or using the paper version. As they will be required to complete the survey in their own time rather than during lesson time, an incentive of a prize draw will be offered with a number of small gift vouchers offered as a prize (Love2Shop vouchers or other appropriate high street stores, values 10 x £10, 20 x £5).

3.5. Planned inclusion/exclusion criteria:

3.5.1. Inclusion: Interventions will be provided during the school day as part of the school PSHE curriculum. All eligible children, i.e. years 8-11 (12-16 years old) will be expected to participate. There will be some occasions when young people do not participate in PSHE for religious reasons or due to

absence but it is expected that these will be limited. Attendance at each session during the study will be monitored.

3.5.2. Exclusion: Young people who do not attend PSHE lessons will be the only exclusion in this study (e.g. if they are on technical training courses off site, on long term sickness absence, homeschooled). Children, identified during the study with possible clinical depression, and their carers will be contacted and advised to seek further help. They will continue to participate in the programmes running in the schools.

3.6. Ethical arrangements

3.6.1. Ethical Approval: An application was made to NHS MREC and was considered by the South West committee. They felt unable to offer a view feeling since the study was not concerned with NHS clients and was conducted in schools not NHS settings. An application was therefore submitted to the University of Bath ethics committee who reviewed and approved the study.

3.6.2. 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. and the establishment of a Trial Steering Committee (TSC) and a Data and Ethics Monitoring Committee (DMEC). Avon and Wiltshire Partnership NHS Trust have agreed to act as the sponsor of the study.

3.6. 3. Consent/Assent: Evaluation of opt-in and opt-out recruitment strategies suggest that opt in strategies result in lower recruitment rates and healthier participants (37). This led the authors to suggest that opt-out approaches for obtaining parental consent should be the default recruitment strategy for interventions that pose a low risk to participants. The participants in this study are not referred NHS patients, the intervention is low risk, and as such we propose an opt-out approach. At the start of the project a letter will be posted to the carers of all eligible young people informing them about the study. Although all young people will be expected to participate in the interventions only those who opt-in and 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. In addition, the project information sheet will be read to the young people and child consent/assent obtained before completing the questionnaires i.e. dual carer/child consent/assent will be required. Young people will be asked for alternative contact details (i.e. e-mail address/mobile number/home address) in case the research team should need to contact them in relation to the project. This is particularly relevant for Year 11 students who may have left the school before the 12-month follow up.

3.7. Risk and Benefits

The risks of participating in this study are considered to be small. At worse, the proposed interventions may not result in any additional lasting benefits although it is considered highly unlikely that they will have any detrimental effects. A study information sheet, provided at the outset of the study, will be prepared for participants informing them of risks and benefits. If the intervention is shown to have a positive effect then the potential to promote positive mental health in adolescents is a significant benefit to society and the individuals who took part. ***Young People with possible depression:*** We expect that 3% of the young people will achieve very high scores on depression measures suggesting possible clinical depression. These young people and their carers will be contacted and advised to contact either their GP or the local mental health contact if they would like further help. In exceptional circumstances, a young person may request that there be no home contact. When this occurs, a suitably qualified member of the research team will contact the young person either directly via e-mail or via an appropriate member of staff at the school involved in student welfare (e.g. school nurse, counsellor, head of pastoral care) so that they can be provided with the relevant information and sources of support. The well-being of the young person is the main priority in this situation and therefore it may be necessary to breach confidentiality in order to ask an appropriate person at the school to contact the young person. In each study locality (Bath and North East Somerset, Bristol, Wiltshire, and Nottingham) there will be a qualified mental health expert who will be the identified point of contact for young people, teachers, researchers and programme leaders who have concerns about significant mental health issues. These young people will still participate in the interventions provided in school.

3.8. Proposed sample size

The HTA commissioning brief (06/37) specifies a shift in the distribution of depression scores as an important outcome. The primary outcome for this trial will therefore be score on the SMFQ as a continuous measure.

The pilot study (n=711) provided estimates of ICC (0.025), mean year group size (n=203) and consent rate (at least 80%). A range of target differences for effect sizes of 0.36-0.42 SDs are detectable with 80% power and 5% two-sided alpha with 20-27 year groups. The eight participating schools have a total of 28 participating year groups, meaning that the study will have >80% power at the 5% alpha level to detect a planned minimum difference of 0.36 SDs.

3.8.1. Assessment Schedule: Figure 1 provides an overview of the consent/assent and assessment process and indicates how this fits in with intervention delivery. Initial screen with the Short form Mood and Feelings Questionnaire (SMFQ) will be carried out prior to the start of interventions in addition to the baseline assessment to identify individuals with consistent low mood who would be classified as high risk. .Baseline assessment T1: pre-intervention completed during first session; Assessment T2: 6 month follow-up; Assessment T3- 12 month follow-up. At each assessment point young people will complete the following psychological measures designed to assess outcomes that the intervention is expected to achieve, i.e. improvements in mood (SMFQ), reductions in negative depressive thoughts (Children's Automatic Thoughts Scale), enhanced self-esteem (Rosenberg Self-esteem Scale) and reduction in anxiety symptoms (Revised Child Anxiety and Depression Scale). Continuous scores on the SMFQ will be our primary outcome measure of depressive symptoms. Secondary psychological outcomes will be assessed by examining continuous scores on the Children's Automatic Thoughts Scale, Rosenberg self-esteem scale and Revised Child Anxiety and Depression scale.

38.2. Research Assistants: Individually administered assessments are not feasible in this study, therefore group administered self-completed questionnaires will be used. For practical reasons, schools may only be able to arrange for these assessments to be carried out in large groups or with several classes running at the same time. Therefore, a large number of researchers are needed to carry out these assessments and the assistants delivering the interventions are ideally positioned to assist with this. All research assistants will receive a full day of training to ensure data collection is fully standardised. It is virtually impossible to blind research assistants completely in a study of this kind, although observer bias will be minimised by the use of self-completed assessments. The assistants will not be made aware of group allocation until baseline assessments have been completed. Following intervention delivery, they will be rotated to different year groups so that they will not be involved in assessments with the classes they have been working with.

3.9. Proposed Outcome measures

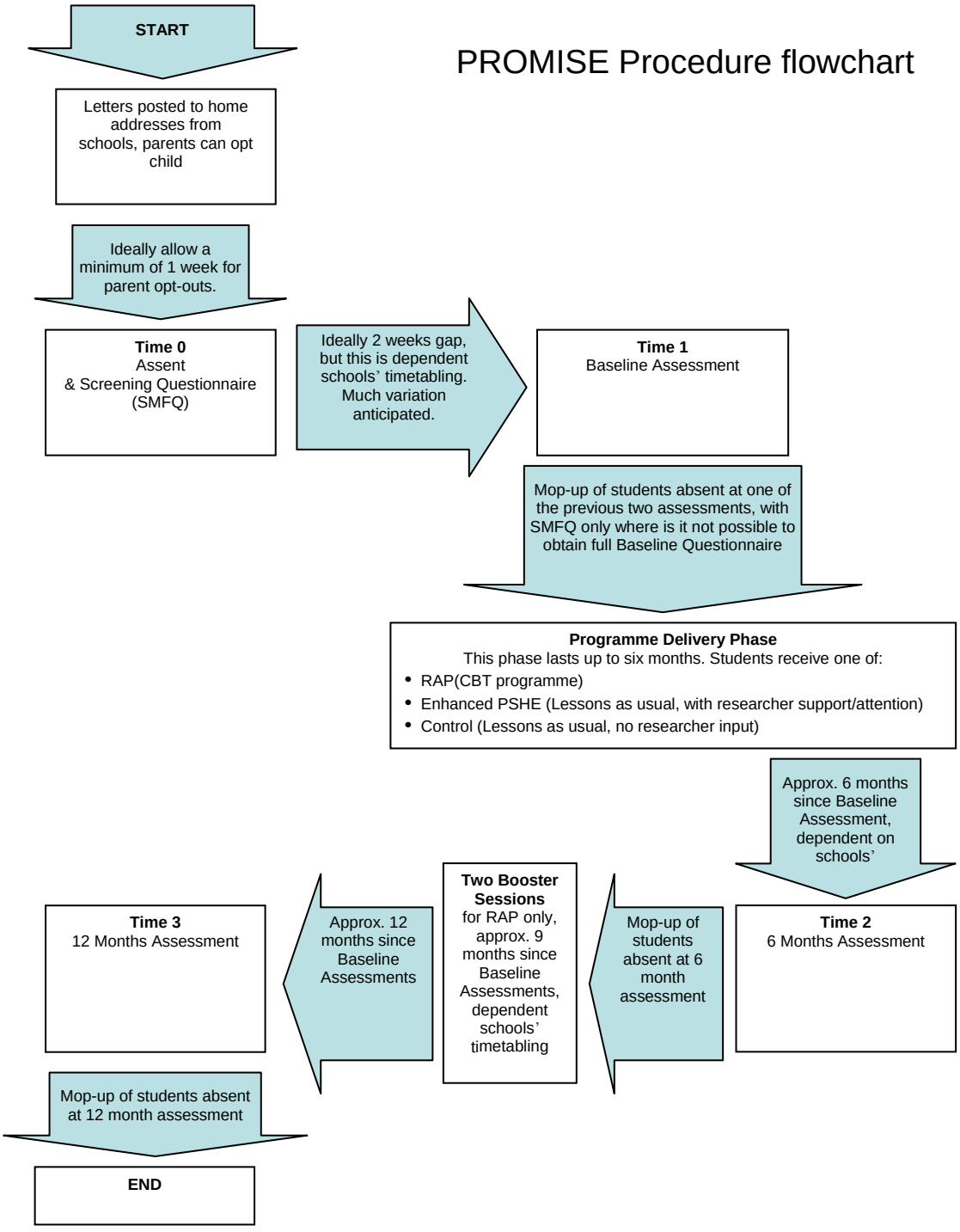
3.9.1. Psychological Functioning

- **Primary Outcome Measure - Short Form Mood and Feelings Questionnaire** (SMFQ; (30). This 13 item scale is derived from the long form (33 item) Moods and Feeling Questionnaire (38). Each item consists of a simple statement (e.g. I didn't enjoy anything at all) which is rated as being either "true" (scores 2), "sometimes true" (scores 1) or "not true" (scores 0). The short form is designed as a brief self-report screening instrument that can be used to assess severity of depression in community samples (39). The SFMQ is a unifactorial scale with a robust single factor structure (40-41). Criterion validity (i.e. ability to predict clinical diagnosis) has been established within both clinical (30) and community samples (32, 42) and with children ranging in age from 7-16. The scale correlates well with other measures of depression, has good test/re-test reliability with higher scores tending to be associated with children who fulfil diagnostic criteria for clinical depression (31-32, 39).

- **Secondary Outcome Measure - Children's Automatic Thoughts Scale** (CATS; (43). This self completed scale assesses a range of negative self statements in children and young people aged 7-16. For each item the child is asked to rate whether they have had a similar thought over the past week. Each item is rated as "not at all" (scores 0), "sometimes" (scores 1), "fairly often" (scores 2), "often" (scores 3) or "all the time" (scores 4). Confirmatory factor analysis identified 4 distinct but correlated factors relating to thoughts about physical threat, social threat, personal failure and hostility (44). Internal consistency for the total score was high (Cronbach Alpha=0.95) with acceptable test –retest reliability (0.79). The scale has been found to effectively discriminate

between a community and clinical sample with the personal failure sub-scale being the strongest predictor of depressive symptoms (45). The 10 item personal failure sub-scale will be used.

Figure 1: PROMISE Project Assessment Process



- **Secondary Outcome Measure –Rosenberg Self-Esteem Inventory** (46)
  The Rosenberg Self-Esteem Scale is a 10-item self-report measure of global self-esteem. It consists of 10 statements 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 and has been validated for use with male and female adolescents as well as substance abusers and other clinical groups, and is regularly used in treatment outcome
studies.

- **Secondary Outcome - Revised Child Anxiety and Depression Scale** (RCADS;(47)
  This self-report scale assesses symptoms of DSM-defined anxiety disorders and major depression in children aged 9-16. The scale is an adapted version of the Spence Children's Anxiety Scale (48) and after psychometric evaluation was reduced to 25 items (49). Each item is rated on a 5 point scale to indicate frequency and can be combined to form 5 sub-scales assessing symptoms of generalised anxiety disorder, separation anxiety disorder, social phobia, panic disorder and major depressive disorder. The scale has good internal consistency, test-re-test stability, and good convergent and divergent validity (50).

3.9.2. School environment and bullying

- **School Connectedness Scale** (51).
  The 8-item scale assesses the extent to which students feel accepted, valued, respected, and included in their school. Each item is rated in a 5 point scale to indicate how strongly they endorse each item. School connectedness correlated extensively with concurrent mental health symptoms when assessed 12 months apart (between 38% and 55% covariation with depression, 26% to 46% with general functioning, and 9% and 16% for anxiety symptoms). Results suggest a strong association between school connectedness and adolescent depressive symptoms.

- **Olweus Bully/Victim Questionnaire** (52)
  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.

3.9.3. Economic Evaluation

- **Quality of Life: EQ-5D** is a standardised instrument for use as a measure of health outcome. Applicable to a wide range of health conditions and treatments, it provides a simple descriptive profile and a single index value for health status. The EQ-5D comprises 5 dimensions of health (mobility, self-care, usual activities, pain/discomfort anxiety/depression) and each consists of three levels (no problems, some/moderate problems/extreme problems). The EQ-5D will be completed twice by the adolescents, once at baseline (T1) and at the six month assessment (T2).

3.9.3. Additional data

- **Socio-demographic data:** will be collected at baseline (T1). Participants will complete a modified version of the Client Service Receipt Inventory (CSRI) (53) to retrospectively assess receipt of mental health or other health services; educational support; anti-psychotropic medication i.e. depressants or others; social work/care services at baseline (T1) and six (T2) month follow-up. Basic demographic data will also be collected (gender, age, who you usually live with, ethnicity, affluence/socio-economic status).

- **Self-harm, drug and alcohol misuse**: Although high levels of depression are associated with self-harm and regular alcohol use and precede the onset of alcohol use (54-55); it is unlikely that either of these factors will act as mediators or mechanisms through which the intervention influences the main outcome of reduction in depressive symptoms. However, there might be a sub-group of young people with these problems for whom the intervention has limited effectiveness i.e. the presence or absence of self-harm or regular alcohol use may moderate the effectiveness of the intervention. In order to asses this possibility participants will complete Likert measures at baseline (T1) and six months (T2) detailing the extent to which they have engaged in harmful behaviours including self-harm, alcohol, cannabis and drug misuse over the past 6 months.

- **Attachment style:** Because attachment style is known to be a significant predictor of both depression and anxiety in adolescents (56-57) peer attachment will be captured at baseline, 6 months, and 12 months using the Attachment Questionnaire for Children (58). This is a single-item measure whereby respondents select one of three statements to best describe how they feel in their friendships. This measure was selected due to its use in previous studies (56-57). It is anticipated that adolescents who self report insecure peer attachment styles will have higher depression and anxiety scores than those who self report secure peer attachment styles. If this result is present, subsequent analyses can control for attachment style at baseline. It is also anticipated that the intervention might be seen to have an effect on changes from insecure to secure attachment styles.

3.9.4. Process Evaluation

Participants: A semi-structured assessment using qualitative and quantitative methods will be undertaken at the end of each programme to assess participant's perception of: (a). the intervention, usefulness, what they had learned and evidence of on-going skill usage; (b). the extent of possible between group contamination by exploring discussions about session content between classes. Semi-structured interviews will be conducted with 24 young people (2 from each of the 3 study groups, male/female, high risk/low risk). A topic guide for the interviews will be developed and will alter in response to the content of the interviews and in order to clarify emerging themes. Analysis will go on in parallel to the fieldwork. When young people are required to give up their own time to take part in the interviews (e.g. after school or during lunch time), they will be offered a small gift voucher as recompense for their time (£5 Love2Shop vouchers or similar appropriate high street stores).

Group Leaders: At the end of each programme a randomly selected one in five sample of group leaders will participate in a brief semi-structured interview to assess their views of the programme. Interviews will be tape recorded and will cover a range of factors including participant engagement, school/class teacher support, leader confidence and effectiveness in delivering the programme and perception of participant usefulness.

Tutor Group Teachers: Before commencing the study form tutors will be asked to indicate on the class list which students they think possibly or probably has a depressive disorder. At the end of each programme the class teacher will participate in a semi-structured interview to assess their general views about the usefulness and relevance of the programme and any observations both positive and negative about participant's behavior. Teachers will be asked to re-assess their perception of the status of those young people they initially identified as possible depressed and whether any other students now present as "at risk".

3.10. Data analysis and management

3.10.1. Analysis and presentation of data will be in accordance with CONSORT guidelines, with the primary comparative analyses being conducted on an intention-to-treat basis and 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 multi-level linear regression to compare intervention versus each of the two control groups, adjusting for stratification variables and baseline SMFQ 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.

Secondary analyses will include: 1) repeating the primary analysis adjusting also for any variables exhibiting marked imbalance at baseline to examine whether this influences the findings; 2) comparison of SMFQ as binary outcome among high risk students; 3) comparison of SMFQ as a continuous outcome using all students in the study; 4) similar analyses for other secondary outcomes (using appropriate regression models and adjusting p-values for multiple testing); 5) investigation of process measures such as number of sessions attended; 6) investigation of patterns (for example, divergent or convergent) of SMFQ scores at repeated follow ups. Finally appropriate interaction terms will be entered into the primary regression analyses in order to conduct pre-specified subgroup analyses according to depression risk at baseline (SMFQ <7 vs ≥ 7), self-harm, drug and alcohol misuse. Since the trial is powered to detect overall differences between the groups rather than interactions of this kind, the results of these essentially exploratory analyses will be presented using confidence intervals as well as p-values, and interpreted with due caution.

3.10.2. Economic Evaluation. We will perform incremental cost-effectiveness analysis (on the basis of score changes in the primary clinical outcome, SMFQ) and cost-utility analysis (i.e. cost per QALY, on the basis of utility estimates derived from EQ-5D scores) for all included comparators. These analyses will be from a societal perspective, capturing and where possible valuing cost and other potential impacts of the intervention across the health, education and social care sectors.

In addition to detailed recording of the staff time and other resources used in adapting and delivering the intervention(s), we will collect individual-level data on: use of extra educational support; use of mental or other health services; use of anti-psychotropic medication i.e. depressants or others; use of social work/care services; use of voluntary/advice services and informal care. Resource use data will be collected directly from participants at baseline (T1) and 6 month follow-up (T2). An adapted version of the parent-completed Client Service Receipt Inventory (46) will be used to assess frequency and 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 (6 month follow-up T2) 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 adolescents. 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-utility results will also be extended beyond 12 months, and key uncertainties further explored, using a simple decision model.

3.10.3 Qualitative data: Will be analysed using the latest version of NUD*IST a software programme for analysing text-based data. Tapes will be transcribed and codebooks will be generated. Insights from these data will inform data analysis of the quantitative data on attrition and perceived feasibility and acceptability of the intervention in different schools.

3.11. Research governance

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 form the trail 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 trail should not continue. This will have access to unblinded data and will consider the need for any interim analysis. The DMEC will meet at least annually. 3) Trial Management Group: A separate 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 senior researcher and researchers, and other co-applicants as appropriate. The meeting will involve monthly teleconferencing as well as 3 monthly face to face meetings.

In addition, local monthly supervision groups will be established in each of the 4 localities for the psychology assistants delivering the interventions. Separate groups will be established for the RAP and the attention interventions. Each group will meet monthly for 2 hours. Supervisors will be by experienced Senior Clinicians from the local CAMHS teams. They will participate in the initial intervention training sessions so that they are familiar and knowledgeable about the intervention. The Lead applicant will offer support and advice to the group supervisors.

3. Project timetable and milestones

Month 1-4 (Sept - Dec 08): Recruitment, induction, establishment of project infra-structure, links with project schools. Training of intervention leaders and research assistants for pilot
Month 5-10: (Jan - June 09) Feasibility and piloting of recruitment, assessments, randomisation, RAP and attention placebo intervention and process evaluation in 1 school (n=711).
Month 11-12 (July - August 09): Training of intervention leaders and research assistants for main trial
Month 13 (Sept 09-January 10): Initial screening and baseline assessments of study cohort (T1).

Month 13 -22 (Sep 09 - June 10) Intervention starts and is provided across study schools during the next 3 terms (9 months).
Month 22 -31 (March – July 10): 6 month (T2) assessments.
Month 28-37 (Sept 10 - January 11): Final 12 month (T3) assessment
Months 31-38 (February 11- June 11): Complete data entry/database cleaning
Months 38-40 (July – December 11): Data analysis, final project report, preparation of papers for publication.

4. Expertise

Professor Paul Stallard is regarded as a National expert on the use of CBT with children and young people and is leading a school based CBT anxiety prevention programme in 30 local junior schools. Professor Ricardo Araya is a practising CBT therapist and has conducted several trials with CBT components for groups of depressed adults and is currently undertaking research in schools overseas. Professor Glyn Lewis is leading a number of projects examining the treatment of depression in primary care. Dr Alan Montgomery has particular expertise in medical statistics and the design, conduct and analysis of pragmatic, community-based randomised trial, and works in the Bristol Randomised Trials Collaboration at the University of Bristol. Dr Kapil Sayal has led school-based child mental health projects aimed at improving identification and access to health services. 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 Moldavsky, Dr Phil Shoebridge and Dr Wendy Woodhouse are the school links for Nottingham, Bristol and Swindon respectively. Finally, Ms. Rose Stevens is a mental health service user with interest in child mental health who will provide service user input for the project. Professor Ian Shochet, the developer of RAP, has agreed to provide training in the intervention and advice on delivery

5.1. Dissemination

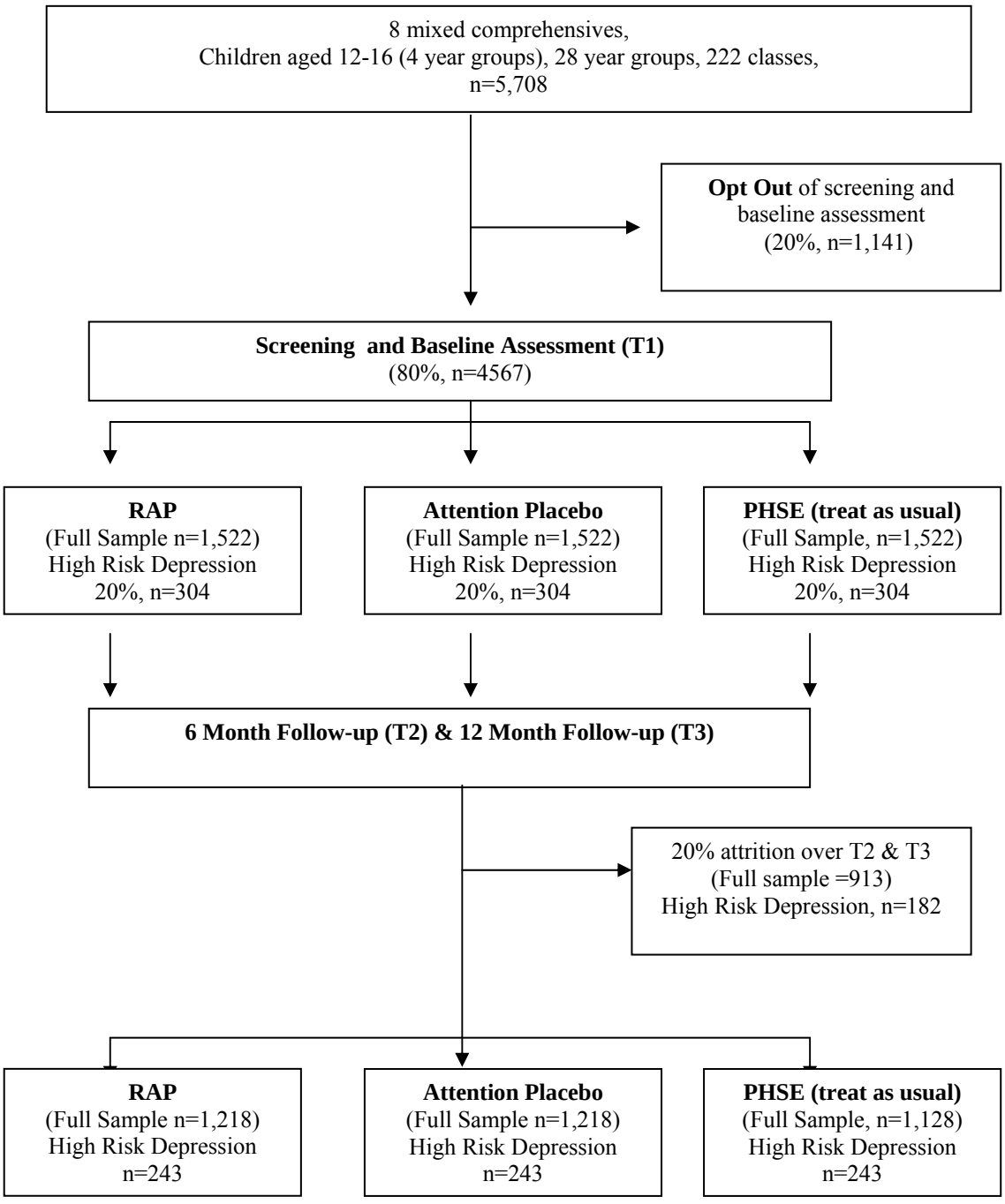
The results of this study will be of national and international significance for policy makers and academics and will therefore be widely disseminated.
Funders: Project reports will be prepared for the funding body according to their requirements. Key reports will be after the feasibility and piloting stage (month 8), after completion of the 6 month follow-up (month 24) and after the 12 month follow-up (month 36).***Participants:*** The results will be presented to all participating schools and a project summary provided. This will be distributed to parents through the school newsletter and posters summarising the study will be prepared for each participating school to display. ***Academic:*** The results will be published in high impact peer review journals. The results will be presented at local, national, European and International meetings of appropriate professionals including policy planners and developers, educationalists and child health professionals. ***Service Improvement:*** If the intervention proves effective then a cascading National training programme could be implemented. This will be informed by contextual data collected during the study about the process of implementation, types of schools and provider-specific effects that make the intervention more or less likely to be effective/cost-effective. Recommendations about school and leader characteristics that appear to mediate the effects of RAP will be embedded in the training programme.

5. Service Users

RAP is an established manualised programme and thus the content and structure is already determined. However we intend to involve young people to ensure that the content and wording is appropriate for the UK and in seeking their advice and guidance about our proposed process evaluations. We therefore plan to work with young people in two main ways:
Consultation: during the pilot and feasibility stage we will establish 4 focus groups within the pilot school (one for each year group). These will provide opportunities to discuss with young people issues of implementation, ways of maintaining the profile of the project, ideas to maximise assessment completion, their views about the content and wording of the interventions and assessments and how sensitive issues such as deliberate self-harm, drug and alcohol misuse can be presented in a clear and acceptable way.
Collaboration: two young people from the pilot schools will be recruited to become members of the project steering group. The user researcher for this project, Ms Stevens, will be instrumental in recruiting and promoting the importance of this to young people and will undertake a promotion exercise in which research is demystified and their important role and contribution highlighted. They will be supported by the user researcher to attend and participate in the Trial Steering Committee and

will therefore be active partners in the management of the project including monitoring progress and potential difficulties, interpretation of findings summarising conclusions & identifying key lessons. An allowance has been made to pay for their time and to support their travel and attendance at meetings.

6. Diagram of anticipated participant flow



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