

A cluster randomised controlled trial to determine the clinical effectiveness and cost-effectiveness of classroom-based cognitive-behavioural therapy (CBT) in reducing symptoms of depression in high-risk adolescents

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**National Institute for
Health Research**

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Abstract

A cluster randomised controlled trial to determine the clinical effectiveness and cost-effectiveness of classroom-based cognitive-behavioural therapy (CBT) in reducing symptoms of depression in high-risk adolescents

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Background: Depression in adolescents is a significant problem that impairs everyday functioning and increases the risk of severe mental health disorders in adulthood. Although this is a major problem, relatively few adolescents with, or at risk of developing, depression are identified and referred for treatment. This suggests the need to investigate alternative approaches whereby preventative interventions are made widely available in schools.

Objective: To investigate the clinical effectiveness and cost-effectiveness of classroom-based cognitive-behavioural therapy (CBT) in reducing symptoms of depression in high-risk adolescents.

Design: Cluster randomised controlled trial. Year groups ($n = 28$) randomly allocated on a 1 : 1 : 1 basis to one of three trial arms once all schools were recruited and balanced for number of classes, number of students, Personal, Social and Health Education (PSHE) lesson frequency, and scheduling of PSHE.

Setting: Year groups 8 to 11 (ages 12–16 years) in mixed-sex secondary schools in the UK. Data were collected between 2009 and 2011.

Participants: Young people who attended PSHE at participating schools were eligible ($n = 5503$). Of the 5030 who agreed to participate, 1064 (21.2%) were classified as 'high risk': 392 in the classroom-based CBT arm, 374 in the attention control PSHE arm and 298 in the usual PSHE arm. Primary outcome data on the high-risk group at 12 months were available for classroom-based CBT ($n = 296$), attention control PSHE ($n = 308$) and usual PSHE ($n = 242$).

Interventions: The Resourceful Adolescent Programme (RAP) is a focused CBT-based intervention adapted for the UK (RAP-UK) and delivered by two facilitators external to the school. Control groups were usual PSHE (usual school curriculum delivered by teachers) and attention control (usual school PSHE with additional support from two facilitators). Interventions were delivered universally to whole classes.

Primary outcomes: Clinical effectiveness: symptoms of depression [Short Mood and Feelings Questionnaire (SMFQ)] in adolescents at high risk of depression 12 months from baseline. Cost-effectiveness: incremental cost-effectiveness ratios (ICERs) based on SMFQ score and quality-adjusted life-years (from European Quality of Life-5 Dimensions scores) between baseline and 12 months. Process evaluation: reach, attrition and qualitative feedback from service recipients and providers.

Results: SMFQ scores had decreased for high-risk adolescents in all trial arms at 12 months, but there was no difference between arms [classroom-based CBT vs. usual PSHE adjusted difference in means 0.97, 95% confidence interval (CI) -0.34 to 2.28; classroom-based CBT vs. attention control PSHE -0.63, 95% CI -1.99 to 0.73]. Costs of interventions per child were estimated at £41.96 for classroom-based CBT and £34.45 for attention control PSHE. Fieller's method was used to obtain a parametric estimate of the 95% CI for the ICERs and construct the cost-effectiveness acceptability curve, confirming that classroom-based CBT was not cost-effective relative to the controls. Reach of classroom-based CBT was good and attrition was low (median 80% attending \geq 60% of sessions), but feedback indicated some difficulties with acceptability and sustainability.

Conclusions: Classroom-based CBT, attention control PSHE and usual PSHE produced similar outcomes. Classroom-based CBT may result in increased self-awareness and reporting of depressive symptoms. Classroom-based CBT was not shown to be cost-effective. While schools are a convenient way of reaching a wide range of young people, implementing classroom-based CBT within schools is challenging, particularly with regard to fitting programmes into a busy timetable, the lack of value placed on PSHE, and difficulties engaging with teachers and young people. Wider use of classroom-based depression prevention programmes should not be undertaken without further research. If universal preventative approaches are to be pursued, their clinical effectiveness and cost-effectiveness with younger children (aged 10–11 years), before the incidence of depression increases, should be investigated. Alternatively, the clinical effectiveness of indicated school-based programmes targeting those already displaying symptoms of depression should be investigated.

Trial registration: Current Controlled Trials ISRCTN19083628.

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List of abbreviations

CATS	Children's Automatic Thoughts Scale	ICER	incremental cost-effectiveness ratio
CBT	cognitive-behavioural therapy	NIHR	National Institute for Health Research
CEAC	cost-effectiveness acceptability curve	OR	odds ratio
CI	confidence interval	PCT	primary care trust
CSRI	Client Services Receipt Inventory	PSHE	Personal, Social and Health Education
DALY	disability-adjusted life-year	QALY	quality-adjusted life-year
EQ-5D	European Quality of Life-5 Dimensions	RAP	Resourceful Adolescent Programme
FAS	Family Affluence Scale	RCADS	Revised Child Anxiety and Depression Scale
GP	general practitioner	SD	standard deviation
HTA	<i>Health Technology Assessment</i>	SMFQ	Short Mood and Feelings Questionnaire
ICC	intraclass correlation coefficients		

Scientific summary

Background

Depression is common in adolescents, with cumulative rates indicating that up to 20% of young people will suffer at least one clinically depressive episode by the age of 18 years. 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, yet it often remains unrecognised and untreated. Depression in adolescence is an important public health issue and there has been growing interest in the development of preventative and early interventions.

Systematic reviews of programmes designed to reduce symptoms of depression in adolescents have noted considerable variability in results but remain supportive of prevention and early intervention approaches delivered in schools. However, significant methodological shortfalls, limited follow-up and absence of attention control or placebo comparisons have been noted as important omissions in previous studies. Of the evaluated universal depression prevention programmes, the Resourceful Adolescent Programme (RAP), using cognitive-behavioural therapy (CBT) principles, appears particularly promising. Three separate studies of RAP have demonstrated a reduction in symptoms of depression relative to a control group post intervention, and all have demonstrated good reach (> 70% of the eligible population) and low attrition (< 10%). Sustained effects of RAP at long-term follow-up (12 months) have not been adequately investigated and the suitability of the programme in the UK school context has not yet been explored.

The aims of this study are to investigate the clinical effectiveness and cost-effectiveness of classroom-based CBT in reducing symptoms of depression in high-risk adolescents compared with a school's usual Personal, Social and Health Education (PSHE) curriculum and an attention control PSHE group.

Objectives

The objectives of this project were to address the following research questions:

1. Is classroom-based CBT effective in reducing symptoms of depression in high-risk adolescents (aged 12–16 years) 12 months from the baseline assessment compared with a school's usual PSHE curriculum and an attention control PSHE group?
2. Does classroom-based CBT improve other aspects of psychological well-being (negative thoughts, self-esteem and anxiety) compared with the control groups at 6 and 12 months?
3. Are the effects of classroom-based CBT and the control programmes on depression at 6 and 12 months different in specific groups, that is according to age, year group and sex, or to reports of depression, bullying, self-harm, alcohol and drug use at the start of the project?
4. Is classroom-based CBT cost-effective in terms of changes in depressed mood and health-related quality of life over a 12-month period?
5. How successful was the process of implementing classroom-based CBT in schools, that is how many people took part, how many completed the programme and did service recipients and providers believe that it was acceptable and sustainable?

Method

Design

This study was a pragmatic cluster randomised controlled trial to evaluate the clinical effectiveness and cost-effectiveness of a universally delivered classroom-based CBT programme in the UK school context. Classroom-based CBT was delivered via PSHE lessons in schools by trained facilitators, and was compared over a 12-month period with usual PSHE and attention control PSHE control groups. Assessments were self-completed by young people and therefore were not blinded.

Intervention

The programme used in the classroom-based CBT arm was the RAP. This is a focused depression prevention programme based on CBT and interpersonal therapy principles. In the current study, RAP was adapted for UK use (RAP-UK). Sessions were delivered by two trained facilitators external to the school. The classroom-based CBT was delivered to whole classes, usually over nine weekly or fortnightly sessions, although this could be adapted to fit in flexibly with the school curriculum (e.g. during project days or tutor time) providing that all core content was delivered. Classroom-based CBT was compared with the school's usual PSHE curriculum delivered by teachers (usual PSHE) or by teachers assisted by two facilitators external to the school (attention control PSHE).

Participants

Participants were young adolescents aged 12–16 years in year groups 8 to 11 attending non-denominational mixed-sex state secondary schools in the UK. A pilot phase was carried out in one school ($n = 4$ year groups; $n = 833$ students on roll) to assess feasibility and test out the intervention and assessment procedures. The main trial was carried out in eight schools ($n = 28$ year groups; $n = 5761$ students on roll).

Randomisation was carried out by year group; for the main trial, this was balanced for number of classes, students, PSHE lesson frequency and scheduling of PSHE. All young people on the school registers who attended PSHE lessons were eligible to take part. Young people who were at 'high risk' of depression were the focus of the primary analysis. This group had elevated symptoms of depression on two separate occasions prior to the intervention [Short Mood and Feelings Questionnaire (SMFQ) score ≥ 5 at both assessments].

Outcome measures

Primary outcome: symptoms of depression at 12 months assessed using the SMFQ.

Secondary outcomes: anxiety, self-esteem, thoughts of personal failure, sense of connectedness to the school, bullying, substance misuse and self-harm. For the economic analysis, cost per child of delivering interventions, quality of life [measured using European Quality of Life-5 Dimensions (EQ-5D)] and health service usage were assessed. Incremental cost-effectiveness ratios (ICERs) were calculated based on change in SMFQ score and quality-adjusted life-years (QALYs, based on EQ-5D) between baseline and 12 months. Reach, attrition, treatment fidelity, acceptability and sustainability were examined for the process evaluation, including use of feedback questionnaires and qualitative interviews.

Results

Pilot phase

Of the eligible population ($n = 800$), 89.1% ($n = 713$) consented to take part in the assessments. Of those who completed the baseline assessment ($n = 652$), 600 (92.0%) and 523 (80.2%) completed the 6- and 12-month follow-up, respectively. Of the participating young people, 186 (26.1%) were classified as being at high risk for depression.

Classroom-based CBT was provided to students in years 8 and 10. In the classroom-based CBT arm, 357 (87.3%) young people attended seven or more sessions. Ratings provided by facilitators confirmed that the content of the classroom-based CBT and attention control PSHE programmes were sufficiently different for comparisons to be meaningful. Qualitative feedback from young people and teachers indicated that the programme had high acceptability and included a number of useful skills. However, some problems were identified with managing classroom behaviour, age-appropriateness of the CBT workbooks, engagement with some of the materials (e.g. video clips), and retention of the year 11 group for 12-month follow-up assessments as many of these young people had left the school by that point. The content of the CBT programme (RAP-UK), training for facilitators and follow-up methods were refined prior to the main trial.

Main trial

Participants were 2563 boys and 2467 girls (91.4% of the eligible population). Of the 5030 participants, 1064 (21.2%) were classified as high risk. These had been allocated to usual PSHE ($n = 298$), attention control PSHE ($n = 374$) and classroom-based CBT ($n = 392$). Valid primary outcome data at 12 months were available for usual PSHE ($n = 242$; 85%), attention control PSHE ($n = 308$; 82%) and classroom-based CBT ($n = 296$; 80%).

In the high-risk group, SMFQ scores decreased overall at 12 months ($F = 158.8$, $df 1$; $p < 0.001$), but there was no difference between trial arms [classroom-based CBT vs. usual PSHE adjusted difference in means = 0.97, 95% confidence interval (CI) -0.34 to 2.28 ; classroom-based CBT vs. attention control -0.63 , 95% CI -1.99 to 0.73]. Further adjustment for variables that were imbalanced at baseline suggested that classroom-based CBT may have had a small but potentially harmful effect compared with usual PSHE (1.21, 95% CI 0.11 to 2.30; $p = 0.031$). There was some evidence that classroom-based CBT was beneficial relative to attention control PSHE at 12 months for SMFQ as a binary outcome [odds ratio (OR) 1.64, 95% CI 1.08 to 2.51], but not compared with the usual PSHE arm (OR 0.85, 95% CI 0.58 to 1.26). There was no evidence that classroom-based CBT was effective for those who adhered to the programme (i.e. those who attended at least 60% of sessions). Substitution of missing data (multiple imputations) for the 12-month SMFQ scores in high-risk participants had no effect on the main conclusions. In the high-risk group, there was also a suggestion that classroom-based CBT had a small but potentially harmful effect relative to usual PSHE for thoughts about personal failure [Children's Automatic Thoughts Scale (CATS)] at 12 months (OR 1.95, 95% CI 0.25 to 3.66).

For all participants (high and low risk), there was no evidence of an effect of classroom-based CBT on SMFQ scores at 12 months or an effect of classroom-based CBT on SMFQ scores over time (classroom-based CBT vs. attention control PSHE interaction coefficient -0.04 , 95% CI -0.47 to 0.40 , $p = 0.869$; classroom-based CBT vs. usual PSHE 0.04, 95% CI -0.39 to 0.48 , $p = 0.848$). There was some suggestion of a beneficial effect of classroom-based CBT compared with both control groups in those who used drugs (classroom-based CBT vs. usual PSHE interaction coefficient -4.62 , 95% CI -8.14 to -1.11 ; classroom-based CBT vs. attention control PSHE interaction coefficient -3.41 , 95% CI -5.82 to -0.99), but a negative effect compared with usual PSHE among those who reported self-harm behaviour (interaction coefficient 1.57, 95% CI 0.37 to 2.78).

Costs of interventions per child were estimated at £41.96 for classroom-based CBT and £34.45 for attention control PSHE. The 95% CIs for the incremental cost-effectiveness ratios (ICERs; calculated using Fieller's method) and the cost-effectiveness acceptability curve confirmed that classroom-based CBT was not cost-effective relative to the control groups. For all of the analyses except one, the point estimate of the ICER was in the upper-left quadrant of the cost-effectiveness planes (i.e. more expensive and less effective), and so this would not be a meaningful number to report. The probability that either classroom-based CBT or attention control PSHE was both less effective and more costly than control ranged from 43% to 98% in the adjusted analyses.

In the high-risk group, the median percentage of sessions attended was 88% (interquartile range 67–100) for classroom-based CBT and 89% (quartiles 78–100) for attention control PSHE. For classroom-based CBT, 80% of participants attended at least 60% of sessions (as opposed to 92% for attention control PSHE). However, implementing the programmes was challenging. Practical difficulties encountered included the logistics of staffing given timetabling clashes within and across schools, fitting the programme into an already busy curriculum, disruption of lessons because of other activities (e.g. sports days, examinations) and cancellation of lessons (e.g. owing to school closures or staff sickness). For example, one year group terminated the classroom-based CBT programme after the fourth session because the school had closed for several days owing to adverse weather, and the time that had been allocated to classroom-based CBT needed to be used for catching up on examined subjects. Nonetheless, classroom-based CBT was successfully delivered in full to nine year groups, with approximately half of young people also completing additional booster sessions approximately 6 months after the intervention.

Altogether, 988 young people, 46 facilitators and 56 teachers completed feedback questionnaires. In addition, 42 young people, 12 members of school staff and 39 facilitators provided feedback via qualitative interviews or focus groups. The feedback indicated that PSHE in general was viewed negatively by students and that teachers felt that PSHE was under-resourced and often not valued within the school. Therefore, while PSHE provided a convenient way of fitting classroom-based CBT into the curriculum, a programme delivered in these lessons inevitably inherited negative expectations.

Teachers suggested that the classroom-based CBT programme used (RAP-UK) needed to be more differentiated in terms of age and ability. In line with this, feedback from young people in year 8 was typically more positive than in the older year groups. Embedding the programme within an already busy curriculum was challenging, and some teachers and facilitators felt that the programme could have been condensed further. However, it should be noted that depression prevention programmes with fewer than eight sessions may not be effective. The feedback suggested that the success of classroom-based depression prevention programmes could be improved by involving teachers more in development; providing more time for facilitators to acclimatise to the school environment and work with teachers; including more 'hands-on' tasks; differentiating more for age and academic ability; and targeting programmes based on need. However, schools are very busy places and in reality it is likely to be difficult for teachers to find sufficient time to work with researchers and facilitators on the development and delivery of such programmes, even when they are motivated to engage with this process.

Conclusions

To maximise the potential for effectiveness of the depression prevention programme, we selected the RAP, which had been found to be efficacious in previous studies. This was adapted for UK use (RAP-UK) and the pilot study provided an opportunity to further refine the programme. We ensured that there were sufficient sessions, delivered by trained facilitators, with the majority of content being delivered in small groups within classes, as these factors are associated with larger effects. Despite this, the findings indicated that classroom-based CBT had very little effect on outcomes in the high-risk group or for all participants. Where effects were observed, these were typically small and were mixed in terms of indicating potential benefit or harm.

Whether based on estimated differences in quality-adjusted life-years (QALYs) or differences in SMFQ scores, this research provided no case for recommending classroom-based CBT as a cost-effective way of reducing symptoms of depression in school children. For almost all of the analyses, the cost and effectiveness differences between classroom-based CBT and attention control PSHE compared with usual PSHE were small and uncertain.

There are a number of challenges with delivering classroom-based CBT in schools, including competing demands for time and resources, difficulties engaging with teachers and young people, and a culture that is not currently conducive to implementing such programmes. The following issues need to be considered:

1. how interventions are implemented and embedded within the school curriculum
2. how to achieve better engagement with teachers and young people
3. the optimal mode of delivery (e.g. targeted vs. universal, group or face-to-face, delivered by teachers or health professionals, internet-based approaches, individual or 'whole school' approaches)
4. the age at which interventions should be delivered to maximise effects; and
5. ensuring that the content of interventions is efficacious.

Classroom-based prevention programmes to reduce symptoms of depression in adolescents are an appealing concept in terms of their potential convenience and reach. However, our study indicates that depression programmes delivered in schools may not be effective and indeed may increase reporting of symptoms.

Trial registration

This trial is registered as ISRCTN19083628.

Funding

Funding for this study was provided by the Health Technology Assessment programme of the National Institute for Health Research.

Chapter 1 Introduction

Background

Depression is common in adolescents, with cumulative rates indicating that up to 20% of young people will suffer at least one clinically depressive episode by the age of 18 years.¹ 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,^{2–5} yet it often remains unrecognised and untreated.^{6,7} Depression in adolescence is an important public health issue and there has been growing interest in the development of preventative and early interventions. Systematic reviews of programmes designed to reduce symptoms of depression in adolescents have noted considerable variability in results but remain supportive of prevention and early intervention approaches delivered in schools.^{8,9} However, significant methodological shortfalls, limited follow-up and absence of attention control or placebo comparisons have been noted as important omissions in previous studies¹⁰ and the cost-effectiveness of school-based depression prevention programmes has not yet been established.

Several evaluations have been carried out of depression prevention programmes based on cognitive-behavioural therapy (CBT) principles, including the Penn Resiliency Programme,^{11,12} Coping with Stress,¹³ Problem Solving for Life,¹⁴ FRIENDS,¹⁵ Resourceful Adolescent Programme (RAP)¹⁶ and other CBT programmes.¹⁷ Although a number of studies have demonstrated short-term reduction in symptoms of depression, there is often an absence of long-term follow-up and where this is present effects typically diminish after 6 months.^{1,10,18–20} Given the limited evidence of long-term gains for depression preventative interventions, it is possible that additional booster sessions could be useful in maintaining short-term benefits. Furthermore, active interventions need to be compared with appropriate controls, including placebo conditions, to account for non-specific treatment effects and spontaneous recovery.^{1,8,9,18}

Cognitive-behavioural therapy-based depression prevention programmes have been delivered as indicated (selective or targeted) interventions to adolescents with elevated symptoms of depression^{21,22} or as universal interventions to whole populations.^{16,23} A meta-analytic review of school-based depression prevention programmes revealed that indicated programmes typically have larger effects than universal approaches.⁹ However, indicated preventative interventions do not provide any input to low-risk children that would prevent symptoms developing and they encounter significant recruitment problems that severely limit their reach and potential impact.^{11,21,24} Universal prevention programmes provide an alternative pragmatic approach, increasing reach (recruitment rates of 67–88% reported), reducing possible negative effects of stigma and labelling and resulting in lower rates of dropout.^{13,14,16,25} Thus, although universal approaches might have a marginally smaller effect on symptoms of depression for individuals, they can potentially reduce far more disorders in the population as a whole.²⁶ The question of who delivers school-based interventions also needs to be considered, as depression prevention programmes that are led by trained facilitators typically have larger effects than those led by teachers.⁹

Of the evaluated universal depression prevention programmes, the RAP appears particularly promising. Three studies have demonstrated a reduction in symptoms of depression relative to a control group post intervention, and all have demonstrated good reach (> 70% of the eligible population) and low attrition (< 10%),^{16,24,25} although sustained effects at long-term follow-up (12 months) were not assessed in two of these studies.^{24,25} The largest of these studies was a multisite randomised controlled effectiveness trial in Australia of RAP involving 2664 students from 12 schools.²⁴ Of the 'at-risk' students, 49.1% in the RAP condition moved into the healthy category post intervention compared with 35.3% in the control group. This difference was maintained at 12-month follow-up and qualitative feedback indicated a high level of skills usage in the RAP group.²⁴

The current project aimed to undertake a pragmatic trial to evaluate the clinical effectiveness of a universally delivered classroom-based CBT depression prevention programme implemented under everyday conditions in the UK school context. To maximise the potential for effectiveness, an efficacious programme was selected (RAP), booster sessions were offered, and the programme was delivered by trained professionals external to the school. To overcome the methodological limitations of previous studies, classroom-based CBT was compared with usual Personal, Social and Health Education (PSHE) curriculum and attention control PSHE groups, and a long-term follow-up (12 months) was included.

Objectives

1. Examine the effectiveness of classroom-based CBT in reducing symptoms of depression in high-risk adolescents (aged 12–16 years) 12 months from baseline compared with the usual school curriculum and an attention control group.
2. Examine the effectiveness of classroom-based CBT compared with the control groups on the secondary outcomes on symptoms of depression, negative thoughts, self-esteem and anxiety (6 and 12 months from baseline).
3. Undertake secondary subgroup analysis to investigate effect modification on symptoms of depression (6 and 12 months from baseline) according to sex, age and baseline report of school connectedness, bullying, self-harm, and alcohol and drug use.
4. Assess the cost-effectiveness of the intervention in terms of reduction in symptoms of depression, health-related quality of life and cost-utility (6 and 12 months from baseline).
5. Undertake a process evaluation to assess factors associated with adherence, acceptability and sustainability of the intervention (post intervention).

Chapter 2 Methods

Design

The study was a pragmatic cluster randomised controlled trial comparing three arms: classroom-based CBT, attention control PSHE and usual PSHE (*Table 1*). The programmes were delivered universally to whole classes of young people during lessons when they would usually be following the school PSHE curriculum. However, the focus of the evaluation was on assessing the effect upon students who had consistent elevated levels of depressive symptoms ('high risk') at screening and baseline assessments.

A pilot phase was carried in one school in the South West region during the 2008–9 academic year. A further eight schools took part in the main trial, with interventions delivered during the 2009–10 academic year.

Ethical approval and consent

The study was approved by the University of Bath School for Health Research Ethics Approval Panel (14 November 2007). Consent/assent involved three stages: interested schools were required to opt in to the study; parents/carers of all eligible students were sent information and invited to opt out if they did not wish their child to complete the project assessments; and, finally, young people were required to opt in and provide written consent if they were willing to complete the assessments.

Participants and procedure

Sample size

The study was powered to detect a difference of two points in mean Short Mood and Feelings Questionnaire (SMFQ) scores at 12-month follow-up between classroom-based CBT and each of the control arms. The pilot study provided estimates of intraclass correlation coefficients (ICCs; 0.025), mean year group size ($n = 203$), consent rate (84%) and SMFQ standard deviation (SD; 4.9) in the target population. Based on 80% consent, 80% retention and 20% of children being classified as high risk, a mean cluster size for analysis of 26 high-risk participants per year group was anticipated, requiring a minimum of 22 year groups to detect a difference of two points with 80% power and 2.7% Dunnett-correction two sided alpha.

Recruitment of schools

Information about the project was sent to 66 non-denominational comprehensive secondary schools in Bath and North East Somerset, Bristol, Wiltshire, Nottingham City and Nottinghamshire County. Schools that expressed an interest were contacted by the research team and a face-to-face meeting was arranged to discuss the project. Nine schools were recruited: one for the pilot study and eight for the main trial. In the participating schools, three year groups could not be included as they did not have discrete PSHE lessons. Therefore, 28 year groups were included in the randomisation process for the main trial. Details of participant flow are provided in *Figure 1* (pilot study) and *Figure 2* (main trial).

Inclusion/exclusion criteria

Interventions were provided during the school day as part of the school PSHE curriculum. All children were eligible unless they did not attend PSHE lessons (e.g. if they were away from school on long-term sickness absence, were withdrawn from PSHE for religious reasons or were educated elsewhere). Young people and their carers were contacted if they were identified as possibly clinically depressed during assessments

TABLE 1 Trial arms

Trial arm	Content	Delivery
Classroom-based CBT	The RAP, a focused CBT programme	Two facilitators (leading sessions)
Attention control PSHE	Usual school PSHE curriculum	One member of school staff (leading sessions) plus two facilitators
Usual PSHE	Usual school PSHE curriculum	One member of school staff

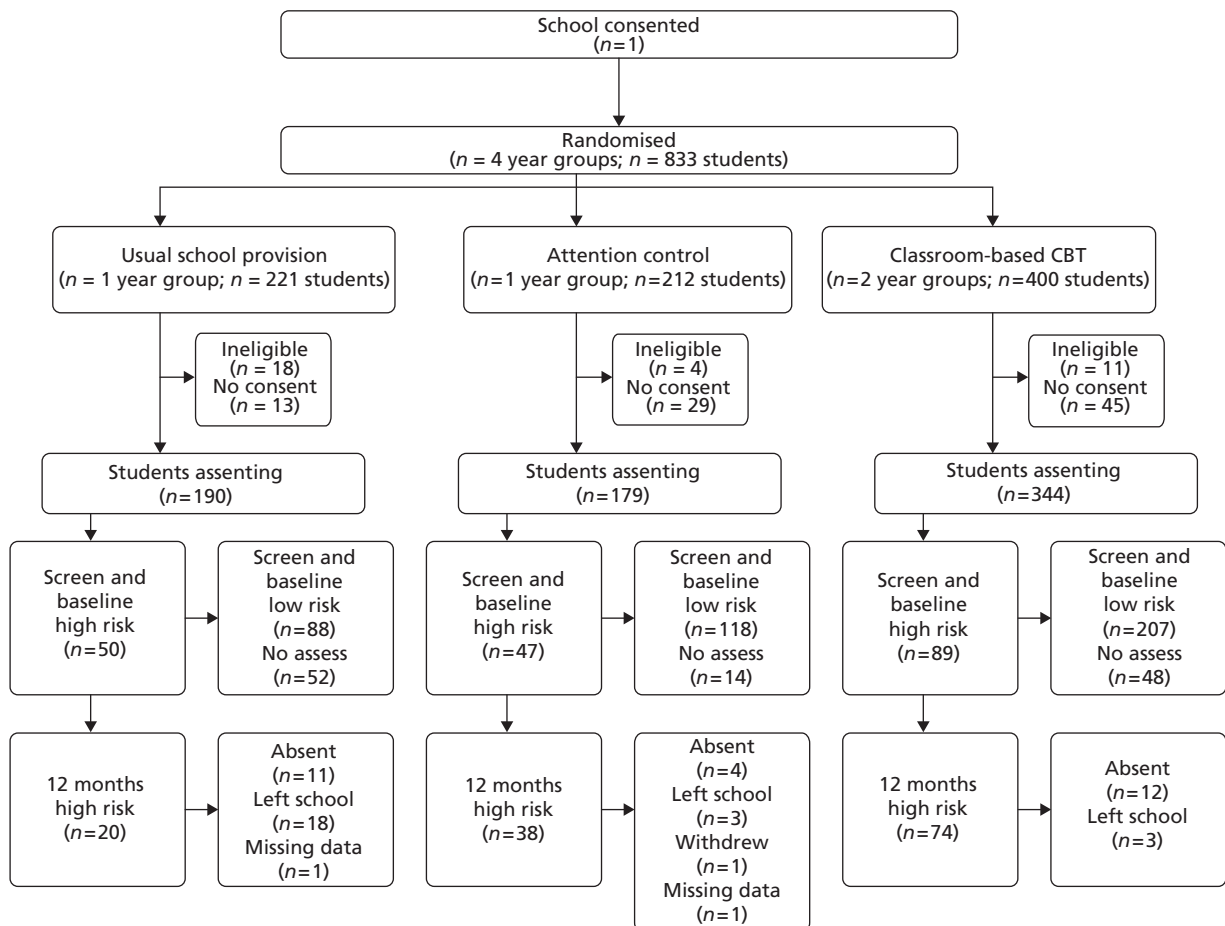


FIGURE 1 Consolidated Standards of Reporting Trials diagram: pilot trial participant flow.

(i.e. in the highest 2–3% of SMFQ scores). They were provided with information on how to seek further help should they require it, but these young people continued to participate in the programmes running in the school as usual.

Classification of the high-risk group

The target group for the effectiveness analysis were those who were at high risk of depression, that is those who had elevated and persistent symptoms of depression assessed using the SMFQ.²⁷ Those with scores of ≥ 5 at both screening and baseline assessments were classified as high risk.

Procedure for individual assessments with young people

Assessments were carried out at four time points: screening (SMFQ only), baseline, and 6 and 12 months from baseline. Some variation in assessment intervals occurred to fit around school holidays, examinations and other events. Mean times between assessments were baseline to 6 months = 176 days

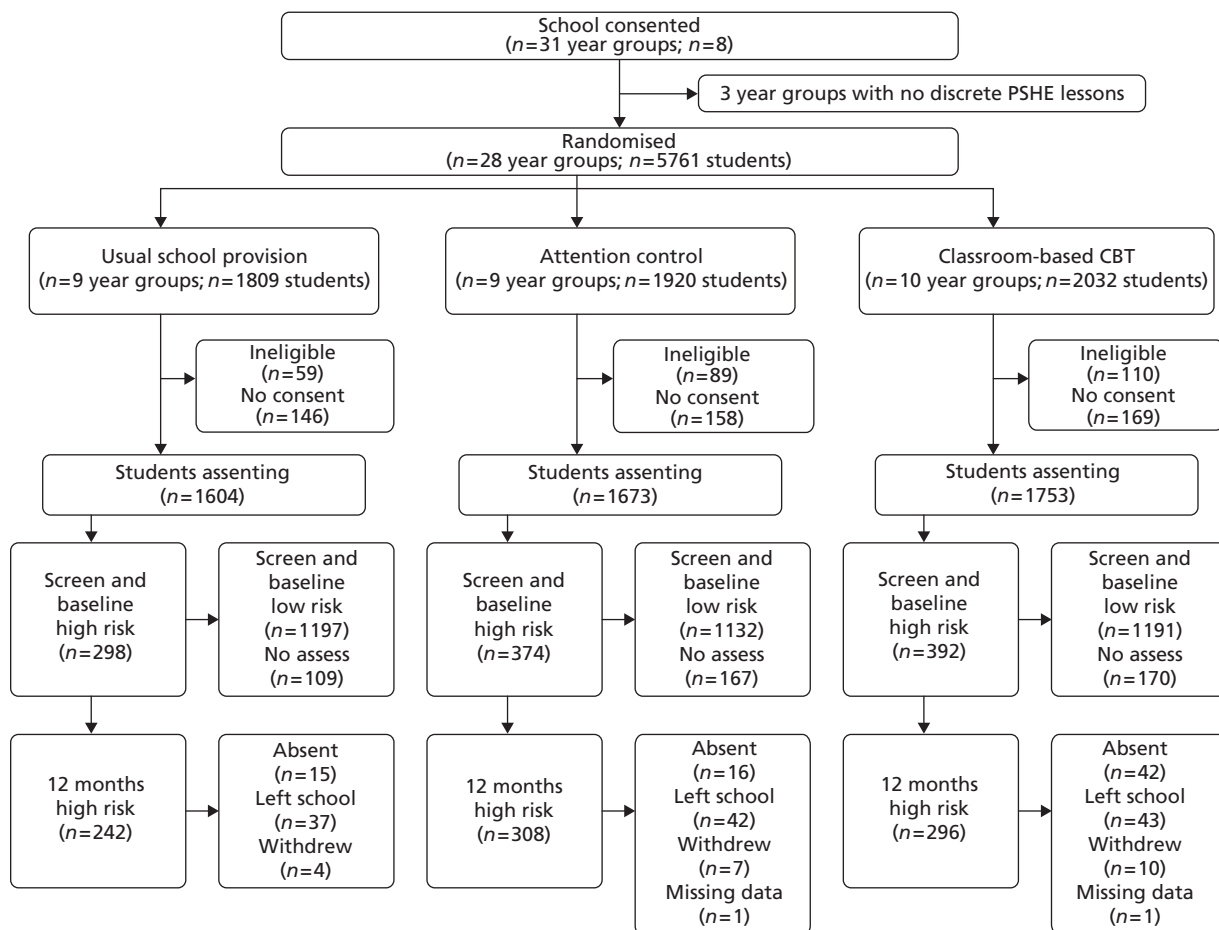


FIGURE 2 Consolidated Standards of Reporting Trials diagram: main trial participant flow.

(SD 34.2); 6 months to 12 months = 181 days (SD 35.8); and baseline to 12 months = 359 days (SD 20.4). There was no difference between trial arms for the interval between time points for primary analysis (baseline to 12 months).

Assessments with young people were self-completed in schools during lesson time in sessions that were led by the research team. Following the pilot study, we anticipated that there would be differential dropout for the year 11 students who had left school by the time of their 12-month follow-up. To maximise response rates in this group in the main trial, any year 11 students who had stayed on for year 12 were assessed in school after 12 months. Those who had left school were contacted by post and/or e-mail (contact details and permission were obtained at 6-month assessment) and offered an option of filling in the questionnaire online and an incentive of entry to a prize draw (the prize was a gift voucher: 10 of £10 and 20 of £5 were available).

Randomisation

Year groups were randomly allocated on a 1 : 1 : 1 basis once all schools had been recruited. Balance between trial arms with respect to number of classes, number of students, PSHE frequency and scheduling of PSHE lessons within the school was achieved by calculating an imbalance statistic²⁸ of all possible allocation sequences, restricted to those in which every school had at least one year group allocated to classroom-based CBT. Using a computer random numbers generator, a statistician with no other involvement in the study randomly selected one sequence from a subset of 100 with the most desirable balance properties.

Interventions

Classroom-based cognitive-behavioural therapy: the Resourceful Adolescent Programme UK

The RAP is a manualised depression prevention programme designed for use with groups of young people aged 12–15 years. It is based on a CBT model and interpersonal therapy principles. CBT recognises the importance of negative thoughts and low self-worth/image in the onset and maintenance of depression. These are actively targeted 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. Students complete their own workbook and group leaders have a detailed manual specifying key learning points and objectives.

For this study, the RAP was modified for use in the UK (RAP-UK). The content, key messages and goals were consistent with the original RAP, but the structure and method of delivery were revised to fit in with the UK education system. The key elements of RAP-UK – personal strengths, helpful thinking, keeping calm, problem solving, support networks and keeping the peace – are organised into nine sessions, each approximately 50–60 minutes long. RAP-UK was designed with a flexible method of delivery in mind to ensure that it could fit into a busy school timetable while retaining the key elements of the programme. Two additional booster sessions were offered to schools approximately 6 months after the initial programme had been completed. These provided an opportunity to review RAP-UK skills and to practise applying them to current difficulties. RAP-UK was delivered by two trained facilitators external to the school.

Attention control Personal, Social and Health Education

The attention control PSHE intervention involved similar time and contact with external providers to classroom-based CBT, but did not include the active components of the CBT intervention. The school delivered its usual PSHE curriculum, but the class teacher was joined by two facilitators from outside the school who assisted with delivering the lessons and engaging with young people. This controlled for the non-specific effects of interventions that are considered important in studies of depression.²⁹ As with classroom-based CBT, delivery of attention control PSHE was designed around nine 50- to 60-minute sessions, with flexibility to fit in with existing school PSHE programmes.

Usual Personal, Social and Health Education

'Usual PSHE' was the usual school PSHE curriculum provided by the school staff and did not involve any external input from the research team.

Programme facilitators

Facilitators had completed at least an undergraduate degree and had experience of working with young people and/or in a health-care setting. They were employed on a sessional basis. Different facilitators delivered the classroom-based CBT and attention control PSHE interventions to minimise therapist contamination. Facilitators received initial training, which covered the identification and management of mental health concerns, group management techniques and training in delivering their specific intervention. This was usually carried out with groups of new staff over 2 or 3 days, with condensed one-to-one training provided for staff joining at different points in the year as required. During the course of delivery, regular separate supervision groups were provided for classroom-based CBT and attention control PSHE facilitators. Teachers were present in all PSHE sessions and remained responsible for managing class behaviour.

Outcome measures: individual assessments with young people

Assessments completed by young people focused on the following areas: psychological functioning, social relationships, risk behaviours, health-care resource usage and sociodemographics. A copy of the

questionnaire is provided in *Appendix 1* and additional details on these measures are included in the trial protocol (see *Appendix 2*).

Primary outcome

The SMFQ²⁷ is a 13-item scale derived from the 33-item Mood and Feelings Questionnaire.³⁰ Each item consists of a simple statement (e.g. 'I didn't enjoy anything at all'), which is rated as being 'true' (scores 2), 'sometimes true' (scores 1) or 'not true' (scores 0). The SMFQ correlates well with other measures of depression and has good test–retest reliability, and higher scores are associated with fulfilling diagnostic criteria for clinical depression.^{31–33}

Secondary outcomes

Secondary outcomes were the personal failure subscale of the Children's Automatic Thoughts Scale (CATS),³⁴ Rosenberg Self-Esteem Inventory,³⁵ Revised Child Anxiety and Depression Scale (RCADS),³⁶ School Connectedness Scale,³⁷ Attachment Questionnaire for Children³⁸ and items relating to bullying (Olweus Bully/Victim Questionnaire³⁹), self-harm, cannabis use, use of other 'street drugs' (e.g. amphetamines, LSD, ecstasy, cocaine, ketamine, crack, heroin), and alcohol use over the last 6 months.

Resource and service use

As part of their standard assessments, all participants were asked to complete the European Quality of Life-5 Dimensions⁴⁰ (EQ-5D: a standardised measure of quality of life/health outcome) and a modified self-report version of the Client Service Receipt Inventory (CSRI).⁴¹ The CSRI is widely used and has been adapted across the child and adult age range and for different services.⁴¹ The wording and presentation of the questions were simplified and pilot tested for clarity and ease of completion by the younger age group during the pilot phase of this trial. The modified CSRI (see *Appendix 2*) retrospectively assessed time off school; receipt of mental health or other health services; educational support; antipsychotropic medication (i.e. antidepressants or others); and social work/care services over a 6-month period. The specific service use information recorded in the assessment for each type of service use is summarised in *Table 2*.

Sociodemographic data

Basic demographic data were collected (sex, age, who you usually live with, ethnicity). The Family Affluence Scale⁴² was used as an indicator of socioeconomic status.

TABLE 2 Details of service and resource use recorded

Types of service use	Details recorded	Notes or limits
Overnight hospital stays	Reason for stay and number of days in hospital	For up to three stays
A&E visits	Number of visits, reasons for visits	Up to three reasons
Hospital outpatient appointments	Number of visits, reasons for visits	Up to three reasons
Visits to the GP	Number of visits, number of visits for worry anxiety or unhappiness	
'Seen anyone else for psychological problems (such as worry, anxiety or unhappiness)'	Number of times seen (for each of nurse at GP's practice, school nurse, counsellor, child mental health service, child psychologist, social worker or 'someone else, please say who')	
Taking medication (for anxiety or depression)	Name of medicine, how long taken	Up to two medicines

A&E, accident and emergency; GP, general practitioner.

Process evaluation

The process evaluation followed the RE-AIM (Reach, Efficacy/effectiveness, Adoption, Implementation and Maintenance) framework.⁴³ Data were collected on attendance and attrition for classroom-based CBT and attention control PSHE by programme facilitators. An independent observer attended 5% of classroom-based CBT sessions to assess treatment fidelity. Feedback was gathered from teachers, young people and facilitators using questionnaires and qualitative interviews.

Feedback questionnaires

Twenty per cent of classes were asked to complete evaluation questionnaires post intervention. This included a series of 11-point Likert scales (0–10), asking students about engagement and usefulness of the PSHE programmes. All teachers involved with classroom-based CBT were invited to complete evaluation questionnaires, where they rated on the following five-point Likert scales (0–4): quality of organisation of the programme; relevance to young people; age appropriateness; extent to which they thought the programme would help young people with their mood and dealing with challenges in day-to-day life; whether or not the number of sessions was appropriate; and how likely they would be to continue with the programme in the future. Facilitators were asked to rate on the following five-point scales (0–4): the adequacy of training and supervision; how much they enjoyed delivering the programme; how challenging they had found it; how much they thought it would make a difference to young people's mental health; and student engagement.

Qualitative evaluation

Purposive sampling was used for the focus groups with young people to ensure that a range of views was captured across schools, year groups and sexes. There was a combination of same- and mixed-sex groups to allow for variations in discussion influenced by group composition. In total, 42 young people (19 male and 23 female) participated across seven focus groups, with all year groups being represented at least once.

The school link person (either the PSHE coordinator or a member of the senior management team) and any other teachers involved in the trial at each school were invited to provide feedback via either interviews or focus groups. Members of school staff (four male and eight female) participated across seven interviews or focus groups. For focus groups with facilitators, 39 individuals (6 male and 33 female) participated across six groups (separate groups for classroom-based CBT and attention control PSHE facilitators).

Semi-structured topic guides were used to gather the qualitative feedback, focusing on overall views of RAP, individual sessions (what worked and what did not), delivery, pupils' perceptions and maintenance of RAP (including likelihood of continuing the programme, giving consideration to cost and resources). Summary cards of RAP sessions and RAP manuals were provided to facilitate discussion. Interviews also captured general feedback on the trial, attention control PSHE, views on how PSHE is delivered in schools in general and any other comments. Focus groups were facilitated by a researcher and a co-facilitator/note-taker.

Analysis: pilot study

The aims of the pilot study were to establish whether or not the trial protocol was feasible in terms of reach and acceptability, gather data to check the sample size calculation for the main trial and trial the programmes and assessment procedure. The analysis focused on participant flow (recruitment and retention), descriptive analysis of change in symptoms over the course of the study, success in delivering sessions as intended and adherence/attrition and brief thematic analysis of feedback from students and teachers on acceptability.

Analysis: main trial

Statistical analysis

Statistical analyses were conducted using Stata 11 (StataCorp LP, College Station, TX, USA). Descriptive statistics were used to assess the balance between the trial arms at baseline. Effects on the primary outcome (SMFQ at 12-month follow-up) were assessed by intention to treat without imputation. In order to take appropriate account of the hierarchical nature of the data, multivariable mixed-effects regression was used to compare mean SMFQ at 12 months for classroom-based CBT with attention control PSHE and usual PSHE, with adjustment for baseline SMFQ and randomisation variables. In a secondary analysis, further adjustment was made for variables that were imbalanced between the trial arms at baseline. These analyses were repeated for secondary outcomes.

For SMFQ, repeated-measures mixed-effects regression models were used to investigate convergence/divergence between trial arms over time. Preplanned subgroup analyses⁴⁴ were carried out using interaction terms in the regression models between the randomised arm and the following baseline variables: symptom severity (SMFQ score 5–10, ≥ 11); self-harm (no/yes); alcohol and/or drug misuse (no/yes); year group (8–11); and family affluence.

Sensitivity analyses were conducted to assess the potential effect of missing data using multiple imputation chained equation methods,⁴⁵ with the imputation model including all variables associated with absence of primary outcome at 12 months. Variance at class and school level was investigated by including these in the multilevel models. Neither of these sensitivity analyses made any material difference to the primary results and therefore the data presented are those from two-level (individual and year group) models based on observed data only.

Finally, the effect of actual attendance at allocated lessons was examined by estimating the compiler-average causal effect (CACE) using instrumental variable regression,⁴⁶ weighted using inverse probability weights constructed using baseline SMFQ scores, randomised group and 'adherence' (defined as attendance at $\geq 60\%$ of sessions).

Qualitative analysis

Interviews and focus groups were digitally audio recorded and transcribed verbatim. The transcripts were thematically analysed, broadly following the guidelines of Braun and Clarke.⁴⁷ Transcripts were coded using NVivo 9 (QSR International, Southport, UK) software. A predefined, broad and descriptive coding framework was developed to enable the generation of initial codes. Each coding unit was coded exclusively into just one category as this allows very clearly defined coding categories to be developed.⁴⁸ Three members of the research team independently coded three randomly selected transcripts. Inter-rater reliabilities calculated using NVivo 9 revealed coding agreement ranging from 78% to 100%, indicating satisfactory consistency of interpretation. Any coding inconsistencies were resolved by discussion and consensus. The remaining 14 transcripts were then divided between the researchers and coded using the same framework. Data were then reviewed by the researchers and the themes were redefined as required. The emergent inductively coded themes were examined for consensus and conflict across the different participant groups.

Economic analysis

The service and resource use and cost-effectiveness analysis was carried out according to current best practice methods for conducting economic evaluation alongside trials,⁴⁹ and specifically alongside cluster randomised controlled trials.⁵⁰

The unit costs applied to different types of health service use and for visits to different types of professionals or services because of anxiety or depression are provided in *Table 3*. The two main sources for the unit costs were the Department of Health's *National Schedule of Reference Costs*⁵¹ [for primary care trusts (PCTs) and NHS trusts combined] and the Personal Social Services Research's *Unit Costs of*

TABLE 3 Unit costs applied for each type of service use (2010 £)

Question numbers	Resource type and unit	Unit cost (£)	Source
6–11	Inpatient stays – elective	781 per day	NSRC2009–10 ^c
6–11	Inpatient stays – non-elective short stay (1 day/night)	520 per day	NSRC2009–10 ^c
6–11	Inpatient stays – non-elective long stay (> 1 day/night)	386 per day	NSRC2009–10 ^c
13–16	A&E attendances	103	NSRC2009–10 A&E services not leading to admitted (sheet: TPCTA and EMSNA)
18–21	Hospital outpatient clinics	99	NSRC2009–10 face-to-face outpatient appointments (weighted average, consultant and non-consultant led, first attendance and follow-ups)
23 and 24	Visit to GP	32	UC2010 Section 2.8 (11.7-minute consultation) ^a
25a	GP practice nurse consultation	10	UC2010 Section 10.6 (nurse GP practice, per consultation) ^a
25b	School nurse time (per hour)	64	UC2010 (community nurse, per hour with patient, £16 per 15-minute appointment) ^a
25c	Counsellor (per hour) ^b	44	UC2010 Section 2.14 (counselling services in primary medical care, per hour with patient or per contact hour) ^a
25d	Child mental health service (per hour) ^b	48	UC2010 (mental health nurse, per hour with patient) ^a
25e	Child psychologist (per hour) ^b	81	UC2010 Section 9.5 (clinical psychologist, per hour with patient) ^a
25f	Social worker (per hour) ^b	53	UC2010 Section 11.3 [social worker (children), per hour with client] ^a

A&E, accident and emergency; GP, general practitioner; NSRC, *National Schedule of Reference Costs* (for PCTs and NHS Trusts combined);⁵¹ UC2010, *Unit Costs of Health and Social Care 2010*.⁵²

a Including direct care staff costs, but excluding qualification/training costs.

b Appointments assumed to last an average of 1 hour with these practitioners, except for school nurses (15 minutes).

c After deleting Healthcare Resource Group codes and costs for inpatient stay reasons which are either (i) extremely unlikely to be applicable to children aged 13–14 years or (ii) specific codes for those aged 19 years or older. Finally, the health and social care service use costs from baseline and both follow-up time points were summed to give the total service use costs for the period between 6 months before and 12 months after the trial's baseline for each student.

*Health and Social Care*⁵² (hourly costs of patient or client contact for various types of health or social care professional).

The service/resource use data were checked and cleaned manually where required. Reported reason(s) for inpatient stays were assessed as being either elective or non-elective and relevant unit costs were applied (see *Table 3*). For a small minority (< 1%) of participants who reported taking medication for anxiety or depression, the information provided on medication names and on how long they had been taken was too unreliable to use as a basis for estimating these costs (e.g. where young people simply recorded 'dunno' or 'can't remember', or stated that they used 'paracetamol', other over-the-counter medications or herbal remedies, which would have no cost implications for the NHS) and was therefore excluded from further analysis.

The classroom-based CBT and attention control PSHE programmes were costed using detailed project records of resource use. This included the paid time of facilitators delivering the programme, the cost of their training, travel costs, printing costs of course booklets, and an apportionment of the cost of recruiting schools. All costs were calculated as either the amount of resource used multiplied by a unit cost or the total amount incurred over the trial period divided by the number of pupils in participating classes, number of sessions delivered or number of schools, depending on the level at which the cost was incurred.

Cleaning and correction of resource use and EQ-5D data and calculation of service use costs were conducted using PASW Statistics 18 (SPSS Inc., Chicago, IL, USA). Models for analysing incremental cost-effectiveness were fitted using Stata 12.0 software. Two cost-effectiveness analyses were conducted, the first using the SMFQ score and the second using quality-adjusted life-years (QALYs) based on responses to the EQ-5D questionnaire. Derivation of the per-person QALYs from baseline to 12 months involved calculating the social preference weight (or utility) for all those who completed the EQ-5D at each of the three time points, estimating the 'area under the curve' between baseline and 6 months and between 6 months and 12 months and summing them. QALYs were therefore calculated only for students who had complete EQ-5D data at all three time points. The social preference weights for the EQ-5D were from a representative sample survey of the UK general population in 1993.⁵³

Incremental costs, incremental effects and, where relevant, incremental cost-effectiveness ratios (ICERs) were estimated, comparing each of the classroom-based CBT and attention control PSHE trial arms with usual PSHE. The incremental cost per unit decrease in the SMFQ score (as lower scores on the SMFQ indicate better outcome) and the incremental cost per unit QALY increase were estimated. Both unadjusted and adjusted analyses (adjusting for site, mode of delivery, number of students and number of classes) were carried out. The incremental cost per unit decrease in SMFQ was additionally adjusted for SMFQ score at baseline.

Random effects bivariate linear regression models⁵⁴ were fitted to model cost and effectiveness (SMFQ or QALY) simultaneously, allowing for correlation within clusters and correlation between cost and effectiveness score within participants. Estimates of the mean difference in costs and corresponding standard error, the mean difference in effect and corresponding standard error and (indirectly via the variance-covariance matrix of the regression coefficients) the correlation between the mean cost difference were obtained from these models. Where the ICER was in the north-east quadrant of the cost-effectiveness plane (i.e. intervention has both higher costs and greater effectiveness than control), Fieller's method was applied to obtain a parametric estimate of the 95% confidence interval (CI) for the ICER and construct the cost-effectiveness acceptability curve (CEAC).⁴⁹ The degrees of freedom (df) for these calculations (implemented in Stata using the 'fielleri' and 'accepti' commands) were based on the number of clusters.

For all adjusted analyses, the joint distribution of the difference in costs and effects was displayed using a scatterplot with 2000 cost-effect data pairs generated parametrically (using simulation) from a bivariate normal distribution based on the estimates from the random effects bivariate regression model used to model the cost and effect outcomes. The parametric scatterplots were similar to those generated using a non-parametric bootstrap approach and so, for consistency, we present only the former. Note that because the cost of the intervention must be apportioned across all participants in a given trial arm, both the SMFQ- and QALY-based cost-effectiveness results are based on the whole sample with valid cost and outcome data (i.e. not just those assessed as high risk as in the primary effectiveness analysis). Given the short time horizon, neither costs nor outcomes were discounted to present values.

Chapter 3 Results: pilot study

Altogether, 326 and 387 girls agreed to participate in the pilot study (89.1% of the eligible population). Ninety-two per cent of those who completed the baseline assessment were retained at 6 months and 80.2% were retained at 12 months. Details of participant flow by trial arm are provided in *Figure 1*.

Symptom change

A decrease in SMFQ scores was observed across all trial arms in the high-risk group from the baseline assessment to the 12-month follow up ($F = 7.55$, $df = 1$; $p < 0.01$). However, the pilot study was not powered to assess between group differences on the primary outcome measure (SMFQ).

Feasibility of intervention delivery

Classroom-based CBT was provided to students in school years 8 and 10. All nine RAP-UK sessions were delivered to 15 classes, with the remaining class receiving eight sessions. A total of 137 (95.2%) RAP-UK sessions were delivered as intended by two facilitators, with the other seven sessions being led by one facilitator. A total of seven sessions were unexpectedly cancelled owing to adverse weather ($n = 2$), early school closure ($n = 1$), bank holidays ($n = 1$), examinations ($n = 1$), a school project day ($n = 1$) and PSHE itself being cancelled ($n = 1$). Of the 409 eligible children in years 8 and 10, only nine (2.2%) failed to attend any RAP-UK sessions. Of these, five had either been excluded from or moved school before the sessions started. Approximately half ($n = 188$; 46.0%) attended all nine sessions, with 357 (87.3%) attending seven or more sessions.

Classroom-based CBT facilitators rated the coverage of self-esteem, emotional awareness and positive thinking over the course of the programme significantly higher ($p < 0.05$) than the attention control PSHE facilitators, who gave the highest ratings to the coverage of topics traditionally covered in PSHE (i.e. bullying, smoking, drugs, alcohol, sex education, ethical issues, diversity, religion and citizenship). There was no significant difference between the groups in the specific focus on depression, although classroom-based CBT facilitators rated the direct focus on mental health more highly.

Acceptability of the classroom-based cognitive-behavioural therapy programme (Resourceful Adolescent Programme UK)

Semi-structured interviews were undertaken with 19 students (nine from year 8 and 10 from year 10) who took part in the classroom-based CBT (RAP-UK). Overall, feedback was positive. Students liked the content, the positive focus and the way in which the individual sessions built upon each other. The accompanying workbook was liked by most of the younger students, but some of the older students thought that it was pitched at too young a level. Some students expressed a preference for more 'hands-on' activities, role plays and discussions. A number of students also felt that the video clips were outdated or unclear. The sessions that students found most helpful were those focusing on problem solving, emotional recognition, the connection between thoughts and feelings, thought checking and relaxation. Those that focused on identifying and changing unhelpful thoughts were seen as repetitive and the support network session was considered by some to be too long.

A focus group was undertaken with the eight teachers whose classes received the classroom-based CBT. Initially, teachers were concerned about addressing mental health in a group, but they felt reassured by the end of the programme. Teachers were generally positive about the programme facilitators and the way in which assessments were conducted. They felt that some of the concepts in RAP-UK were memorable for

themselves as well as for the students, such as negative thinking traps and 'snowballing'. It was felt that the benefits of the programme might not be obvious immediately, but that the skills students acquired could be useful when they encountered problems later in their lives. Teachers liked the content of the programme, but at times felt it was pitched more towards the younger students (year 8) and may not have stretched the most able students. Teachers also raised concerns about the ability of less able students to engage with the classroom-based CBT.

Disruptive student behaviour in classes was a major issue, particularly if students became disengaged. The ability of facilitators to manage student behaviour came to light, with additional support from other members of staff in the classroom being viewed as essential, particularly when working with large classes and managing small group activities. Teachers felt that the sessions were sometimes repetitive and had many ideas about how sessions could be more interactive and engaging, such as making the graphics in the workbooks more age appropriate, updating some of the materials (particularly the video clips) and using more practical tasks in addition to the discussions.

The feedback from teachers and young people was used to revise RAP-UK by condensing some of the sessions, adding more interactive tasks, modifying the workbook so that it was more age appropriate (e.g. using photos instead of cartoons, changing the colour scheme and font) and updating multimedia materials.

Chapter 4 Results: main trial

Reach and attrition

Participant flow for the main trial is shown in *Figure 2*.

A summary of the demographic profile of the eight participating schools compared with national averages is presented in *Table 4*.

The study cohort had a greater percentage of white students, were more academically able and had fewer students eligible for free school meals than the national average.

Altogether, 2563 boys and 2467 girls agreed to participate (91.4% of the eligible population). Of the 5030 participants, 1064 (21.2%) were classified as high risk. These had been allocated to usual PSHE ($n = 298$), attention control PSHE ($n = 374$) or classroom-based CBT ($n = 392$). Valid primary outcome data at 12 months were available for usual PSHE ($n = 242$; 81%), attention control PSHE ($n = 308$; 82%) and classroom-based CBT ($n = 296$; 76%).

For all participants, the median percentage of sessions attended was 89% (quartiles 67–100) in the classroom-based CBT group and 100% (quartiles 88–100) in the attention control PSHE group, with 80% of those in the classroom-based CBT group and 95% of the attention control PSHE groups attending at least 60% of sessions. One year group ($n = 199$) was withdrawn from classroom-based CBT after four sessions because of school closures in adverse weather. When this year group was removed from analysis, the median percentage of classroom-based CBT sessions attended was 89% (quartiles 78–100), with 92.2% attending at least 60% of sessions. For the high-risk participants, the median percentage of sessions attended was 88% (quartiles 67–100) in the classroom-based CBT arm and 89% (quartiles 78–100) in the attention control PSHE arm. The percentage of participants attending more than 60% of sessions was 80% and 93% in the classroom-based CBT and attention control PSHE groups, respectively. Details were not collected on PSHE attendance in the usual PSHE arm.

Balance between trial arms

Characteristics of high-risk individuals at baseline were well balanced between trial arms, apart from alcohol, street drug and cannabis use and bullying others, which were reported by fewer participants in the usual PSHE group (*Table 5*).

The proportion of high-risk participants within the arms was also slightly higher in the classroom-based CBT and attention control PSHE arms than in the usual PSHE arm (22.4%, 22.4% and 18.6%, respectively) (*Table 6*).

Implementation

Classroom-based cognitive-behavioural therapy delivery

The classroom-based CBT arm included 79 classes. Intervention delivery was adapted to fit in with the existing structure of PSHE delivery within schools, with all programmes covering the core content and key tasks. The RAP-UK programme used was delivered in weekly lessons to 41 classes, while 22 classes had fortnightly lessons and 16 classes had other formats (project days or condensed programme over 3 weeks). All nine sessions were delivered to 71 classes, while four classes had a condensed eight-session programme and four classes had a seven-session programme. The RAP-UK programme was terminated after the fourth session for a whole year group (eight classes) in one school. This was due to disruption

TABLE 4 Comparisons between study schools and UK national school data

School	Pupils in trial (n)	White (%) ⁵⁵	Special needs without statements (%) ⁵⁵	Overall absence (%) ⁵⁶	Persistent absence (%) ⁵⁶	Achieving five A*–C GCSE passes including level 2 English and maths (%) ⁵⁷	Eligible for free school meals (%) ⁵⁵
1	710	63.8	20.2	5.4	2.7	69	11.9
2	623	89.7	8.1	8.3	7.7	61	7.0
3	835	93.2	17.9	6.5	5.1	55	9.5
4	783	95.3	6.9	6.1	2.8	75	2.5
5	848	77.6	36.0	11.1	13.8	36	31.2
6	530	83.5	10.5	4.7	1.7	No year 11	3.3
7	534	92.8	10.1	7.7	6.2	47	7.6
8	167	98.7	19.7	7.9	7.4	48	9.2
Total trial	5030	85.5	16.8	7.3	6.0	56.7	11.2
UK national average	NA	81.2	19.7	6.9	4.4	50	15.4

GCSE, General Certificate of Secondary Education; NA, not applicable.

TABLE 5 Baseline demographic characteristics of the high-risk group and all participants, split by trial arm. Number (percentage) of participants unless otherwise stated

Variable	Level	High-risk group (N = 1064)			All participants (N = 5030)		
		Usual PSHE (n = 298)	Classroom-based CBT (n = 392)	Attention control PSHE (n = 374)	Usual PSHE (n = 1604)	Classroom-based CBT (n = 1753)	Attention control PSHE (n = 1673)
Sex	Male	101 (33.9)	132 (33.7)	135 (36.1)	834 (52.0)	880 (50.2)	849 (50.7)
	Female	197 (66.1)	260 (66.3)	239 (63.9)	770 (48.0)	873 (49.8)	824 (49.3)
Ethnicity	White	246 (86.6)	314 (87.7)	286 (81.7)	1275 (86.1)	1372 (86.7)	1271 (83.6)
	Non-white	38 (13.4)	44 (12.3)	64 (18.3)	205 (13.9)	210 (13.3)	250 (16.4)
Living situation	Mother and father	149 (53.4)	186 (52.0)	189 (53.7)	981 (66.9)	972 (62.2)	1019 (67.1)
	Parent and partner	46 (16.5)	64 (17.9)	69 (19.6)	193 (13.2)	224 (14.3)	189 (12.4)
	Single parent	73 (26.2)	96 (26.8)	87 (24.7)	262 (17.9)	343 (22.0)	283 (18.6)
	Other	11 (3.9)	12 (3.4)	7 (2.0)	30 (2.0)	23 (1.5)	29 (1.9)
Year group	8	112 (37.6)	66 (16.8)	79 (21.1)	569 (35.5)	470 (26.8)	374 (22.4)
	9	89 (29.9)	81 (20.7)	102 (27.3)	469 (29.2)	384 (21.9)	541 (32.3)
	10	17 (5.7)	153 (39.0)	144 (38.5)	179 (11.2)	583 (33.3)	562 (33.6)
	11	80 (26.8)	92 (23.5)	49 (13.1)	387 (24.1)	316 (18.0)	196 (11.7)
Age, mean (SD)	Years	13.9 (1.2)	14.4 (1.0)	14.1 (1.0)	13.9 (1.2)	14.1 (1.1)	14.0 (1.0)

TABLE 6 Numbers in high- and low-risk groups at baseline falling into high- or low-risk range at follow-up (SMFQ <5 vs. SMFQ ≥5) by trial arm

Trial arm	6 months		12 months	
	Low risk	High risk	Low risk	High risk
Usual PSHE (n = 1495)				
Risk status				
Low (n = 1197)	929/1110 (83.7%)	181/1110 (16.3%)	890/1040 (85.6%)	150/1040 (14.4%)
High (n = 298)	77/264 (29.2%)	187/264 (70.8%)	104/242 (43.0%)	138/242 (57.0%)
Classroom-based CBT (n = 1583)				
Risk status				
Low (n = 1191)	886/1090 (81.3%)	204/1090 (18.7%)	821/994 (82.6%)	173/994 (17.4%)
High (n = 392)	83/330 (25.2%)	247/330 (74.8%)	106/296 (35.8%)	190/296 (64.2%)
Attention control (n = 1506)				
Risk status				
Low (n = 1132)	839/1022 (82.1%)	183/1022 (17.9%)	789/954 (82.7%)	165/954 (17.3%)
High (n = 374)	78/341 (22.9%)	263/341 (77.1%)	90/308 (29.2%)	218/308 (70.8%)

caused by adverse weather, which led to several days of school closure. Owing to competing priorities (i.e. making up time for examined subjects), the school was unable to complete the programme.

The additional RAP-UK booster sessions offered were completed by 40 of the classroom-based CBT classes. Of those classes that did not complete the boosters, eight were those that had terminated the programme at session 4, 16 classes were originally in year 11 so either had left school or were not doing PSHE the following academic year, eight classes had moved from year 10 to year 11 and no longer did PSHE, and one year group opted not to complete the booster sessions. Therefore, a total of 832 young people in the classroom-based CBT group (47.8%) attended at least one RAP-UK booster session to refresh and consolidate their skills approximately 6 months after completing the core programme.

Facilitators

Classroom-based CBT was delivered by 39 facilitators, while 35 people facilitated the attention control PSHE sessions. Classroom-based CBT was led by two facilitators, as intended, in 94.3% of sessions, with 5.7% being led by a single facilitator. There were two facilitators present at 83.1% of attention control PSHE sessions with 16.9% being attended by a single facilitator. To fit in with school timetables, a large number of facilitators were required as whole year groups or even whole schools received PSHE at the same time in some cases. This meant recruiting, training and managing a much larger team of facilitators than was originally anticipated. This had an impact on cost as well as causing operational difficulties with cover for staff absences/sickness and ensuring that the facilitators had sufficient regular working hours to make the posts viable.

Treatment fidelity

Of the 36 classroom-based CBT sessions observed to assess intervention fidelity, 31 covered all the core tasks, with at least 75% of core tasks being covered in the remaining five sessions. Differences in facilitator ratings of lesson content for classroom-based CBT versus attention control PSHE were examined using one-way analysis of variance and indicated that the classroom-based CBT focused more on self-esteem, emotional awareness and positive thinking, and less on topics traditionally covered in PSHE, i.e. sex education, ethical issues, diversity, religion and citizenship (all $p < 0.05$). There was no difference between classroom-based CBT and attention control PSHE in facilitators' views of student engagement with lessons.

High-risk participants: primary outcome (Short Mood and Feelings Questionnaire)

There was a decrease in symptoms of depression between baseline and 12 months for the high-risk group overall ($F = 158.8$, $df 1$, $p < 0.001$). However, there was no evidence of an effect of classroom-based CBT on SMFQ at 12 months relative to attention control PSHE or usual PSHE (see *Table 5*). The 95% CIs for the adjusted treatment difference excluded the predefined clinically important difference of two points. Likewise, there was no evidence of an effect of classroom-based CBT when compared with usual PSHE on continuous SMFQ score at 6 months (*Table 7*).

Further adjustment for variables that were imbalanced at baseline indicated that classroom-based CBT may have had a small but potentially harmful effect compared with usual PSHE (1.21, 95% CI 0.11 to 2.30, $p = 0.031$).

There was some evidence of a beneficial effect of classroom-based CBT when compared with attention control PSHE at 12 months for SMFQ as a binary outcome (which indicates the odds of being reclassified as 'low risk' at follow-up) (*Table 8*).

Repeated-measures mixed-effects analyses showed no effect of classroom-based CBT over time for SMFQ score (classroom-based CBT vs. attention control PSHE interaction coefficient -0.17 , 95% CI -1.40 to 1.06 , $p = 0.785$; classroom-based CBT vs. usual PSHE interaction coefficient 0.72 , 95% CI -0.59 to 2.03 ,

TABLE 7 Primary analysis: SMFQ at 12 and 6 months for high-risk participants for classroom-based CBT compared with usual PSHE and attention control PSHE

Time point	Usual PSHE, mean (SD)	Classroom-based CBT vs. usual PSHE adjusted difference from baseline (95% CI)	Classroom-based CBT, mean (SD)	Classroom-based CBT vs. attention control adjusted difference from baseline (95% CI)	Attention control PSHE, mean (SD)
Baseline	10.56 (4.93)	NA	10.64 (4.91)	NA	10.60 (4.67)
12 months	6.81 (5.70) ($n = 242$)	0.97 (-0.34 to 2.28); $p = 0.067$	8.22 (6.45) ($n = 296$)	-0.63 (-1.99 to 0.73); $p = 0.249$	8.50 (5.88) ($n = 308$)
6 months	8.61 (6.01) ($n = 264$)	0.56 (-0.41 to 1.53); $p = 0.259$	9.22 (6.39) ($n = 330$)	-0.35 (-1.38 to 0.68); $p = 0.505$	9.44 (5.84) ($n = 341$)

NA, not applicable.

SMFQ adjusted for number of students, number of classes, frequency of delivery, school and baseline SMFQ.

Note: 12-month CIs are adjusted for multiple comparisons using Dunnett's methods; p -values are unadjusted.

Short Mood and Feelings Questionnaire ICCs and upper 95% confidence limits (all lower confidence limits < 0.0001): baseline < 0.001 (0.006); 6 months 0.007 (0.026); 12 months 0.012 (0.039).

TABLE 8 Short Mood and Feelings Questionnaire score as a binary outcome (< 5) at 12 months in the high-risk group

Usual PSHE: 12 months, n (%)	Classroom-based CBT vs. usual PSHE, adjusted OR (95% CI)	Classroom-based CBT: 12 months, n (%)	Classroom-based CBT vs. attention control PSHE, adjusted OR (95% CI)	Attention control PSHE: 12 months, n (%)
104/242 (43.0)	0.85 (0.58 to 1.26); $p = 0.429$	106/296 (35.8)	1.64 (1.08 to 2.51); $p = 0.021$	90/308 (29.2)

OR, odds ratio.

Binary SMFQ adjusted for number of students, number of classes, frequency of delivery, school and baseline SMFQ as continuous.

$p = 0.282$). The effect of classroom-based CBT in high-risk participants was not modified by any of the predefined subgroups we examined (Table 9). A post hoc interaction analysis showed no modification of effect by sex.

High-risk participants: secondary outcomes

In the high-risk group, there was some evidence of a potentially harmful effect of classroom-based CBT relative to usual PSHE for CATS personal failure scores at 12 months (adjusted difference 1.95, 95% CI 0.25 to 3.66). However, there was also evidence of a potentially beneficial effect of classroom-based CBT on RCADS depression at 12 months compared with usual PSHE (adjusted difference 0.64, 95% CI 0.06 to 1.21) and on self-harm thoughts at 6 months compared with attention control PSHE [odds ratio (OR) 0.58, 95% CI 0.35 to 0.97]. Details of adjusted differences, adjusted ORs and CIs for analysis of the secondary outcomes are provided in Tables 10 and 11.

In repeated-measures regression analysis, no effect of classroom-based CBT over time was observed for any of the secondary outcomes in either high-risk participants or all participants.

All participants: primary outcome (Short Mood and Feelings Questionnaire)

Including all participants in the analysis, there was no evidence of an effect of classroom-based CBT on SMFQ score at 12 months (classroom-based CBT vs. usual PSHE 0.27, 95% CI -0.08 to 0.62 ; classroom-based CBT vs. attention control PSHE -0.01 , 95% CI -0.42 to 0.39) or an effect of classroom-based CBT on SMFQ score over time (classroom-based CBT vs. attention control PSHE interaction coefficient -0.04 , 95% CI -0.47 to 0.40 , $p = 0.869$; classroom-based CBT vs. usual PSHE 0.04 , 95% CI -0.39 to 0.48 , $p = 0.848$).

TABLE 9 Subgroup analyses for SMFQ score at 12 months for high-risk participants according to baseline subgroup

Variable	Level	Classroom-based CBT vs. usual PSHE		Classroom-based CBT vs. attention control PSHE	
		Interaction (95% CI)	p -value	Interaction (95% CI)	p -value
SMFQ	5–10	Reference	0.583	Reference	0.778
	11+	0.56 (–1.44 to 2.55)		–0.27 (–2.14 to 1.60)	
Self-harm thoughts	Yes	0.52 (–1.48 to 2.53)	0.607	0.15 (–1.73 to 2.03)	0.880
Self-harm behaviour	Yes	0.52 (–1.69 to 2.73)	0.644	–1.35 (–3.38 to 0.68)	0.192
Alcohol use	Yes	–0.75 (–3.05 to 1.55)	0.522	–1.10 (–3.22 to 1.02)	0.308
Street drug use	Yes	–4.37 (–11.38 to 2.65)	0.222	–2.71 (–6.78 to 1.37)	0.193
Cannabis use	Yes	–1.95 (–5.37 to 1.46)	0.263	–2.30 (–5.08 to 0.48)	0.105
Year group	8	Reference	0.832	Reference	0.212
	9	–1.64 (–6.44 to 3.16)		–1.95 (–6.41 to 2.50)	
	10	–2.44 (–7.83 to 2.95)		–1.83 (–5.32 to 1.66)	
	11	–1.59 (–6.64 to 3.47)		–5.33 (–10.55 to –0.11)	
Sex	Female	–0.02 (–2.03 to 1.99)	0.981	0.87 (–1.02 to 2.76)	0.365
Age		–0.32 (–1.39 to 0.75)	0.559	–0.81 (–1.90 to 0.28)	0.144
Family Affluence Scale		–0.45 (–1.11 to 0.21)	0.183	–0.02 (–0.68 to 0.64)	0.945

Adjusted for number of students, number of classes, frequency of delivery, school and baseline SMFQ score where applicable.

TABLE 10 Distribution of categorical secondary outcomes for high-risk participants in each trial arm and estimate of the difference between classroom-based CBT and the two control arms

Variable	Usual PSHE			Classroom-based CBT			Attention control PSHE		
	Baseline, n (%)	6 months, n (%)	12 months, n (%)	Baseline, n (%)	6 months, n (%)	12 months, n (%)	Baseline, n (%)	6 months, n (%)	12 months, n (%)
Bullying others	80 (28.88)	77 (30.08)	41 (18.06)	96 (26.82)	73 (23.25)	55 (20.83)	118 (33.71)	88 (26.51)	57 (20.50)
Adjusted OR (95% CI) ^a									
Self-harming thoughts	147 (53.07)	111 (43.53)	90 (38.96)	197 (55.18)	142 (45.08)	123 (46.42)	189 (54.15)	167 (50.76)	126 (45.00)
Adjusted OR (95% CI) ^a									
Self-harming behaviour	77 (27.70)	69 (27.17)	51 (22.17)	106 (29.86)	95 (30.16)	77 (29.39)	109 (31.23)	105 (32.31)	71 (25.54)
Adjusted OR (95% CI) ^a									
Alcohol misuse	77 (28.00)	81 (31.89)	70 (30.57)	112 (31.28)	108 (34.73)	105 (39.33)	97 (27.95)	109 (33.33)	99 (35.61)
Adjusted OR (95% CI) ^a									
Street drug misuse	7 (2.55)	10 (3.94)	13 (5.70)	25 (7.00)	18 (5.79)	20 (7.55)	16 (4.58)	15 (4.55)	12 (4.30)
Adjusted OR (95% CI) ^a									
Cannabis misuse	30 (10.87)	31 (12.35)	44 (19.30)	53 (14.85)	57 (18.15)	65 (24.34)	63 (17.95)	66 (20.06)	55 (19.57)
Adjusted OR (95% CI) ^a									

^a Outcome adjusted for number of students, number of classes, frequency of delivery, school and baseline SIMFQ score.

TABLE 11 Distribution of continuous secondary outcomes for high-risk participants in each of the three trial arms and estimate of the difference between classroom-based CBT and the two control arms

Variable	Usual PSHE			Classroom-based CBT			Attention control PSHE			
	Baseline, mean (SD)	6 months, mean (SD)	12 months, mean (SD)	Baseline, mean (SD)	6 months, mean (SD)	12 months, mean (SD)	Baseline, mean (SD)	6 months, mean (SD)	12 months, mean (SD)	
CATS	12.20 (9.28)	10.16 (9.52)	8.18 (8.68)	12.40 (9.21)	11.51 (10.53)	10.48 (10.00)	13.35 (8.99)	11.64 (9.87)	10.63 (9.94)	
							Adjusted difference (95% CI): ^a 6 months, 1.20 (-0.39 to 2.78), 1.95 (0.25 to 3.66)			Adjusted difference (95% CI): ^a 6 months, 0.29 (-1.48 to 2.07)
Self-esteem	15.88 (4.80)	16.58 (5.22)	17.39 (5.34)	15.54 (4.70)	16.33 (5.39)	16.93 (5.65)	15.36 (4.38)	16.02 (4.38)	16.68 (5.25)	
							Adjusted difference (95% CI): ^a 6 months, 0.02 (-0.81 to 0.85), 0.12 (-0.81 to 1.05)			Adjusted difference (95% CI): ^a 6 months, 0.13 (-0.76 to 1.02), -0.13 (-1.12 to 0.87)
General anxiety	5.74 (2.87)	5.55 (2.96)	4.67 (3.05)	5.92 (2.84)	5.63 (2.96)	5.18 (3.12)	5.77 (2.86)	5.76 (3.08)	5.40 (2.91)	
							Adjusted difference (95% CI): ^a 6 months, 0.16 (-0.34 to 0.66), 0.41 (-0.15 to 0.97)			Adjusted difference (95% CI): ^a 6 months, -0.00 (-0.54 to 0.53), -0.24 (-0.82 to 0.35)
Separation anxiety	2.26 (2.19)	1.94 (2.36)	1.65 (2.17)	2.27 (2.26)	2.07 (2.50)	1.98 (2.34)	2.35 (2.31)	2.12 (2.56)	2.09 (2.45)	
							Adjusted difference (95% CI): ^a 6 months, 0.15 (-0.25 to 0.54), 0.04 (-0.37 to 0.44)			Adjusted difference (95% CI): ^a 6 months, 0.11 (-0.31 to 0.53), -0.18 (-0.60 to 0.25)
Social phobia	6.64 (3.24)	6.11 (3.17)	5.72 (3.31)	6.87 (3.33)	6.39 (3.43)	6.26 (3.57)	6.58 (3.22)	6.34 (3.52)	6.34 (3.48)	
							Adjusted difference (95% CI): ^a 6 months, 0.24 (-0.27 to 0.76), 0.34 (-0.26 to 0.93)			Adjusted difference (95% CI): ^a 6 months, 0.27 (-0.27 to 0.82), 0.02 (-0.60 to 0.64)
Panic	4.15 (3.19)	3.85 (3.48)	3.17 (3.23)	4.35 (3.17)	4.25 (3.48)	3.79 (3.49)	4.14 (3.16)	4.05 (3.34)	3.59 (3.18)	
							Adjusted difference (95% CI): ^a 6 months, 0.25 (-0.28 to 0.77), 0.25 (-0.31 to 0.81)			Adjusted difference (95% CI): ^a 6 months, 0.11 (-0.44 to 0.66), -0.25 (-0.84 to 0.34)
Depression	5.27 (2.83)	4.69 (3.19)	4.06 (3.26)	5.64 (2.88)	5.20 (3.39)	4.94 (3.32)	5.47 (3.10)	5.10 (3.25)	4.83 (3.19)	
							Adjusted difference (95% CI): ^a 6 months, 0.24 (-0.28 to 0.75), 0.64 (0.06 to 1.21)			Adjusted difference (95% CI): ^a 6 months, -0.10 (-0.65 to 0.46), -0.02 (-0.65 to 0.60)
RCADS	24.07 (10.69)	22.11 (11.59)	19.27 (11.64)	25.04 (10.80)	23.42 (12.22)	22.16 (12.38)	24.29 (11.01)	23.39 (12.23)	22.27 (11.74)	
							Adjusted difference (95% CI): ^a 6 months, 1.07 (-0.81 to 2.95), 1.48 (-0.64 to 3.59)			Adjusted difference (95% CI): ^a 6 months, 0.23 (-1.76 to 2.23), -0.60 (-2.88 to 1.67)
School connectedness	26.22 (6.19)	25.82 (6.76)	26.84 (6.94)	25.36 (6.20)	25.85 (6.85)	26.18 (6.80)	25.17 (6.04)	25.29 (6.36)	25.94 (6.64)	
							Adjusted difference (95% CI): ^a 6 months, 0.11 (-0.86 to 1.08), 0.42 (-0.70 to 1.55)			Adjusted difference (95% CI): ^a 6 months, 0.25 (-0.78 to 1.29), 0.57 (-0.65 to 1.80)

^a Outcome adjusted for number of students, number of classes, frequency of delivery, school and value of outcome measures at baseline.

In the subgroup analysis (Table 12), there was some suggestion of a beneficial effect of classroom-based CBT compared with both control groups in those who used 'street drugs' (classroom-based CBT vs. usual PSHE interaction coefficient -4.62 , 95% CI -8.14 to -1.11 ; classroom-based CBT vs. attention control PSHE interaction coefficient -3.41 , 95% CI -5.82 to -0.99), but of a possible harmful effect compared with usual PSHE among those who reported self-harm behaviour (interaction coefficient 1.57 , 95% CI 0.37 to 2.78).

All participants: secondary outcomes

Among all participants, there was some evidence of a beneficial effect of classroom-based CBT on bullying status at 12 months when compared with attention control PSHE (OR 0.69, 95% CI 0.51 to 0.94) and on cannabis use at 6 months (OR 0.56, 95% CI 0.38 to 0.82) and 12 months (OR 0.70, 95% CI 0.48 to 0.93) when compared with usual PSHE. However, there was also evidence that classroom-based CBT was less useful than usual PSHE for panic symptoms at 6 and 12 months, less useful than attention control PSHE for panic symptoms at 6 months and less useful than usual PSHE for CATS personal failure scores at 6 months and general anxiety at 12 months. Full details of adjusted differences, ORs and 95% CIs for this analysis are provided in Tables 13 and 14.

TABLE 12 Subgroup analyses of SMFQ score at 12 months for all participants, according to baseline subgroups

Variable	Level	Classroom-based CBT vs. usual PSHE		Classroom-based CBT vs. attention control PSHE	
		Interaction ^a	p-value	Interaction ^a	p-value
SMFQ	< 5	Reference	0.069	Reference	0.117
	5–10	-0.01 (-0.88 to 0.85)		-0.81 (-1.65 to 0.02)	
	11+	1.35 (0.19 to 2.51)		-0.64 (-1.76 to 0.47)	
Self-harm thoughts	Yes	0.86 (-0.00 to 1.71)	0.051	-0.31 (-1.12 to 0.50)	0.457
Self-harm behaviour	Yes	1.57 (0.37 to 2.78)	0.010	-0.47 (-1.56 to 0.60)	0.393
Alcohol use	Yes	-0.39 (-1.28 to 0.51)	0.400	-0.57 (-1.49 to 0.35)	0.225
Street drug misuse	Yes	-4.62 (-8.14 to -1.11)	0.010	-3.41 (-5.82 to -0.99)	0.006
Cannabis misuse	Yes	-0.18 (-1.61 to 1.25)	0.800	-1.33 (-2.64 to -0.02)	0.047
Year group	8	Reference	0.892	Reference	0.994
	9	0.23 (-1.36 to 1.82)		0.03 (-1.44 to 1.50)	
	10	0.48 (-1.06 to 2.03)		-0.11 (-1.28 to 1.06)	
	11	0.56 (-1.21 to 2.33)		-0.12 (-2.14 to 1.89)	
Sex	Female	-0.09 (-0.73 to 0.55)	0.780	-0.26 (-0.90 to 0.38)	0.428
Age		0.20 (-0.17 to 0.56)	0.294	-0.00 (-0.41 to 0.41)	0.998
Family Affluence Scale		-0.21 (-0.45 to 0.04)	0.100	0.07 (-0.19 to 0.32)	0.619

^a Adjusted for number of students, number of classes, frequency of delivery, school and baseline SMFQ score where applicable.

Note: interaction coefficients represent the between-arm difference in category minus the difference in category for the reference group.

TABLE 13 Distribution of continuous secondary outcomes for all participants and estimate of the difference between classroom-based CBT and the two control arms

Variable	Usual care			Classroom-based CBT			Attention control PSHE		
	Baseline, mean (SD)	6 months, mean (SD)	12 months, mean (SD)	Baseline, mean (SD)	6 months, mean (SD)	12 months, mean (SD)	Baseline, mean (SD)	6 months, mean (SD)	12 months, mean (SD)
SMFQ	3.55 (4.73)	3.60 (4.78)	3.21 (4.50)	4.11 (4.95)	4.24 (5.37)	3.95 (5.44)	3.90 (4.81)	4.28 (5.22)	4.00 (5.21)
			0.22 (-0.09 to 0.53), 0.27 (-0.08 to 0.62)				0.06 (-0.30 to 0.42), -0.01 (-0.42 to 0.39)		
CATS	4.07 (6.68)	3.98 (6.53)	3.47 (6.09)	4.62 (7.08)	4.86 (7.89)	4.45 (7.68)	4.72 (7.14)	4.82 (7.57)	4.44 (7.44)
			0.51 (0.06 to 0.96), 0.52 (-0.00 to 1.03)				0.40 (-0.13 to 0.94), 0.07 (-0.52 to 0.66)		
Self-esteem	21.44 (5.23)	21.42 (5.52)	21.74 (5.43)	20.97 (5.41)	20.97 (5.57)	21.48 (5.71)	20.88 (5.31)	20.97 (5.72)	21.31 (5.74)
			-0.07 (-0.39 to 0.24), 0.07 (-0.30 to 0.44)				-0.15 (-0.52 to 0.22), 0.08 (-0.34 to 0.50)		
General anxiety	3.11 (2.61)	3.31 (2.70)	2.93 (2.65)	3.47 (2.71)	3.66 (2.86)	3.36 (2.96)	3.19 (2.74)	3.54 (2.88)	3.34 (2.86)
			0.12 (-0.07 to 0.30), 0.23 (0.01 to 0.44)				0.05 (-0.17 to 0.26), -0.00 (-0.25 to 0.24)		
Separation anxiety	1.06 (1.56)	1.03 (1.81)	0.89 (1.67)	1.21 (1.72)	1.17 (1.89)	1.06 (1.93)	1.21 (1.81)	1.15 (1.89)	1.12 (1.96)
			0.06 (-0.07 to 0.18), 0.04 (-0.10 to 0.19)				0.07 (-0.07 to 0.22), -0.04 (-0.20 to 0.12)		
Social phobia	3.83 (2.88)	4.10 (2.89)	4.09 (2.93)	4.19 (3.09)	4.32 (3.14)	4.16 (3.27)	4.06 (2.99)	4.36 (3.17)	4.33 (3.25)
			-0.03 (-0.22 to 0.16), -0.12 (-0.35 to 0.10)				0.11 (-0.12 to 0.33), -0.13 (-0.39 to 0.13)		
Panic	1.63 (2.36)	1.72 (2.49)	1.49 (2.27)	1.90 (2.51)	2.16 (2.74)	1.95 (2.77)	1.77 (2.39)	1.96 (2.64)	1.77 (2.52)
			0.27 (0.10 to 0.43), 0.30 (0.12 to 0.49)				0.27 (0.07 to 0.46), 0.19 (-0.03 to 0.40)		
Depression	2.17 (2.50)	2.25 (2.56)	2.07 (2.53)	2.62 (2.71)	2.62 (2.81)	2.54 (2.99)	2.44 (2.73)	2.62 (2.86)	2.40 (2.87)
			0.03 (-0.14 to 0.20), 0.15 (-0.05 to 0.35)				-0.05 (-0.25 to 0.15), 0.10 (-0.14 to 0.33)		
RCADS	11.80 (9.55)	12.37 (9.88)	11.48 (9.56)	13.33 (10.30)	13.89 (10.85)	13.08 (11.61)	12.63 (10.74)	13.63 (10.81)	12.96 (10.94)
			0.38 (-0.24 to 1.01), 0.52 (-0.23 to 1.28)				0.43 (-0.31 to 1.16), 0.06 (-0.81 to 0.94)		
School connectedness	31.04 (6.11)	30.07 (6.42)	30.48 (6.33)	30.22 (6.29)	29.63 (6.63)	30.02 (6.77)	30.19 (6.39)	29.27 (6.61)	29.73 (6.79)
			-0.05 (-0.45 to 0.35), 0.13 (-0.34 to 0.60)				-0.12 (-0.58 to 0.34), 0.21 (-0.33 to 0.76)		

^a Outcome adjusted for number of students, number of classes, frequency of delivery, school and value of outcome measure at baseline.

TABLE 14 Distribution of categorical secondary outcomes for all participants and estimate of the difference between classroom-based CBT and the two control arms

Variable	Usual PSHE			Classroom-based CBT			Attention control PSHE		
	Baseline, n (%)	6 months, n (%)	12 months, n (%)	Baseline, n (%)	6 months, n (%)	12 months, n (%)	Baseline, n (%)	6 months, n (%)	12 months, n (%)
SMFQ (< 5, ≥ 5)	410 (26.61)	399 (27.29)	313 (22.93)	533 (32.09)	495 (32.23)	408 (29.10)	489 (30.91)	493 (33.27)	431 (31.39)
Bullying others	215 (14.79)	223 (15.58)	161 (12.44)	258 (16.57)	246 (16.67)	178 (13.60)	312 (20.74)	265 (18.48)	209 (16.28)
Self-harm thoughts	254 (17.43)	259 (18.15)	228 (17.52)	315 (20.27)	274 (18.58)	254 (19.36)	311 (20.66)	304 (21.16)	261 (20.17)
Self-harm behaviour	113 (7.76)	134 (9.42)	110 (8.47)	162 (10.43)	163 (11.06)	161 (12.28)	160 (10.62)	176 (12.32)	139 (10.79)
Alcohol misuse	294 (20.28)	361 (25.26)	370 (28.53)	328 (21.13)	358 (24.34)	375 (28.67)	247 (16.54)	309 (21.64)	316 (24.61)
Street drug misuse	14 (0.97)	28 (1.96)	30 (2.31)	48 (3.10)	45 (3.05)	51 (3.89)	29 (1.93)	41 (2.86)	39 (3.02)
Cannabis misuse	100 (6.89)	143 (10.05)	167 (12.88)	160 (10.33)	159 (10.77)	190 (14.48)	144 (9.59)	169 (11.79)	154 (11.96)

^a Outcome adjusted for number of students, number of classes, frequency of delivery, school and value of outcome measure at baseline.

Complier average causal effect

The instrumental variable analysis in high-risk participants did not alter the conclusions of the primary analysis for classroom-based CBT compared with attention control PSHE (adjusted difference -0.82 , 95% CI -1.79 to 0.14 ; $p = 0.093$). However, the evidence was strengthened in that mean SMFQ score at 12 months in the classroom-based CBT group was higher (i.e. more symptoms of low mood) than in the usual PSHE group, although not exceeding clinically important levels (adjusted difference 1.43 , 95% CI 1.22 to 1.64 ; $p < 0.001$).

Multiple imputations and missing data

Multiple imputations of 12-month SMFQ score for high-risk participants had no effect on the main conclusions (Table 15).

Comparison of baseline characteristics for participants categorised as high risk showed that individuals with missing primary outcome data tended on average to be slightly older; not living with both parents; using alcohol and cannabis; and bullying others. Within the usual PSHE arm in particular, those with missing primary outcome data were more likely to be engaging in regular self-harm thoughts and behaviour (Tables 16–18).

Comparison of baseline characteristics for all participants showed that those individuals with missing primary outcome data tended on average to be slightly older; to be living with a single parent or parent and their partner; to score noticeably worse on the psychometric scales; to be regularly using alcohol, street drugs and cannabis; and to be regularly bullying others. Within the usual PSHE arm in particular, those with missing primary outcome data were more likely to be engaging in regular self-harm thoughts and behaviour (Tables 19–21).

Acceptability

Evaluation questionnaire data

Questionnaires evaluating their PSHE lessons were completed by 482 boys and 506 girls from seven of the eight schools (Table 22). Of these, 386 (39.1%) received the classroom-based CBT programme (RAP-UK), 316 (32%) received attention control PSHE and 286 (28.9%) received usual PSHE.

Taking the sample overall, the majority of young people did not rate their PSHE lessons positively, with only 38.3% of the usual PSHE group and 36.5% of those who received classroom-based CBT positively rating PSHE (6 or more out of 10 for liking their lessons). Similarly, 42.1% of those in the usual PSHE group and 35.4% of those who received classroom-based CBT rated the usefulness of PSHE in everyday life as 6 or more out of 10. Approximately half felt that their lessons were relevant for their age (usual PSHE, 53.7%; classroom-based CBT, 49.6%). Usual PSHE was rated more positively than both

TABLE 15 Comparison of estimates of adjusted difference in primary outcome for high-risk participants with and without multiple imputation of missing values

Number of multiple imputations	Adjusted difference (95% CI) ^a	
	Classroom-based CBT vs. usual PSHE at 12 months	Classroom-based CBT vs. attention control PSHE at 12 months
0	0.97 (−0.07 to 2.01); $p = 0.067$	−0.63 (−1.71 to 0.44); $p = 0.249$
20	0.85 (−0.19 to 1.88); $p = 0.110$	−0.56 (−1.64 to 0.52); $p = 0.308$

a Adjusted for number of students, number of classes, frequency of delivery, school and baseline SMFQ score.

TABLE 16 Comparison of baseline characteristics for those with and without missing primary outcome, for participants classified as high risk at baseline. Figures are number (percentage) of participants unless otherwise stated

Variable		Trial arms					
		Usual PSHE (N = 298)		Classroom-based CBT (N = 392)		Attention control PSHE (N = 374)	
		Present (n = 242; 81%)	Missing (n = 56; 19%)	Present (n = 296; 76%)	Missing (n = 96; 24%)	Present (n = 308; 82%)	Missing (n = 66; 18%)
Level							
Sex	Male	84 (34.7)	17 (30.4)	105 (35.5)	27 (28.1)	104 (33.8)	31 (47.0)
	Female	158 (65.3)	39 (69.6)	191 (64.5)	69 (71.9)	204 (66.2)	35 (53.0)
Ethnicity	White	198 (86.5)	48 (87.3)	245 (88.8)	69 (84.1)	239 (82.1)	47 (79.7)
	Non-white	31 (13.5)	7 (12.7)	31 (11.2)	13 (15.9)	52 (17.9)	12 (20.3)
Living situation	Mother and father	129 (57.3)	20 (37.0)	147 (53.8)	39 (45.9)	165 (56.1)	24 (41.4)
	Parent and partner	36 (16.0)	10 (18.5)	49 (17.9)	15 (17.6)	56 (19.0)	13 (22.4)
	Single parent	53 (23.6)	20 (37.0)	69 (25.3)	27 (31.8)	66 (22.4)	21 (36.2)
	Other	7 (3.1)	4 (7.4)	8 (2.9)	4 (4.7)	7 (2.4)	0 (0.0)
Year group	8	100 (41.3)	12 (21.4)	59 (19.9)	7 (7.3)	74 (24.0)	5 (7.6)
	9	82 (33.9)	7 (12.5)	62 (20.9)	19 (19.8)	93 (30.2)	9 (13.6)
	10	13 (5.4)	4 (7.1)	124 (41.9)	29 (30.2)	129 (41.9)	15 (22.7)
	11	47 (19.4)	33 (58.9)	51 (17.2)	41 (42.7)	12 (3.9)	37 (56.1)
Age, mean (SD)	Years	13.7 (1.1)	14.7 (1.2)	14.3 (1.0)	14.9 (0.9)	13.9 (0.9)	14.9 (1.0)

TABLE 17 Comparison of continuous outcome variables at baseline for those with and without missing primary outcome, for participants classified as high risk at baseline

Variable	Trial arm, mean (SD)					
	Usual PSHE (N = 298)		Classroom-based CBT (N = 392)		Attention control PSHE (N = 374)	
	Present (n = 242; 81%)	Missing (n = 56; 19%)	Present (n = 296; 76%)	Missing (n = 96; 24%)	Present (n = 308; 82%)	Missing (n = 66; 18%)
SMFQ	10.5 (4.8)	10.9 (5.4)	10.6 (4.9)	10.8 (4.9)	10.8 (4.1)	10.6 (4.8)
CATS	12.0 (9.1)	13.2 (10.2)	11.9 (9.0)	14.0 (9.7)	12.9 (8.0)	13.4 (9.2)
Self-esteem	16.2 (4.7)	14.7 (5.1)	15.7 (4.8)	15.1 (4.4)	15.7 (4.3)	15.3 (4.4)
General anxiety	5.7 (2.9)	5.7 (2.6)	5.8 (2.8)	6.4 (3.1)	5.3 (2.4)	5.9 (2.9)
Separation anxiety	2.3 (2.2)	2.1 (2.2)	2.3 (2.3)	2.3 (2.2)	2.3 (1.9)	2.4 (2.4)
Social phobia	6.6 (3.2)	6.7 (3.3)	6.8 (3.4)	7.0 (3.2)	6.9 (3.1)	6.5 (3.2)
Panic	4.1 (3.1)	4.3 (3.4)	4.3 (3.2)	4.5 (3.0)	4.2 (2.8)	4.1 (3.2)
Depression	5.2 (2.8)	5.5 (3.0)	5.6 (2.9)	5.9 (2.9)	6.1 (3.2)	5.3 (3.1)
RCADS	24.0 (10.8)	24.4 (10.3)	24.7 (10.8)	26.1 (10.7)	24.9 (9.5)	24.2 (11.3)
School connectedness	26.2 (6.2)	26.2 (6.2)	25.2 (6.2)	25.9 (6.1)	26.2 (6.7)	25.0 (5.9)

TABLE 18 Comparison of categorical outcome variables at baseline for those with and without missing primary outcome, for participants classified as high risk at baseline. Figures are number (percentage) of participants unless otherwise stated

Variable	Level	Trial arm					
		Usual PSHE (N = 298)		Classroom-based CBT (N = 392)		Attention control PSHE (N = 374)	
		Present (n = 242; 81%)	Missing (n = 56; 19%)	Present (n = 296; 76%)	Missing (n = 96; 24%)	Present (n = 308; 82%)	Missing (n = 66; 18%)
Self-harm thoughts	Never	110 (48.7)	20 (39.2)	117 (42.7)	43 (51.8)	26 (46.4)	134 (45.7)
	Once or twice	81 (35.8)	21 (41.2)	117 (42.7)	27 (32.5)	23 (41.1)	109 (37.2)
	3 or more times	35 (15.5)	10 (19.6)	40 (14.6)	13 (15.7)	7 (12.5)	50 (17.1)
Self-harm behaviour	Never	165 (72.7)	36 (70.6)	187 (68.8)	62 (74.7)	35 (62.5)	205 (70.0)
	Once or twice	39 (17.2)	11 (21.6)	55 (20.2)	13 (15.7)	14 (25.0)	48 (16.4)
	3 or more times	23 (10.1)	4 (7.8)	30 (11.0)	8 (9.6)	7 (12.5)	40 (13.7)
Alcohol consumption	Never drank alcohol	69 (30.8)	8 (15.7)	70 (25.5)	12 (14.5)	9 (16.4)	79 (27.1)
	Once or twice	99 (44.2)	22 (43.1)	126 (45.8)	38 (45.8)	26 (47.3)	136 (46.6)
	More than 2–4 times a month	49 (21.9)	15 (29.4)	59 (21.5)	22 (26.5)	13 (23.6)	62 (21.2)
	More than once a week	7 (3.1)	6 (11.8)	20 (7.3)	11 (13.3)	7 (12.7)	15 (5.1)
Street drug misuse	Never taken	222 (98.7)	46 (92.0)	257 (93.8)	75 (90.4)	55 (98.2)	278 (94.9)
	Once or twice	3 (1.3)	2 (4.0)	15 (5.5)	5 (6.0)	1 (1.8)	14 (4.8)
	2–4 times a month	0 (0.0)	1 (2.0)	2 (0.7)	3 (3.6)	0 (0.0)	0 (0.0)
	More than once a week	0 (0.0)	1 (2.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)
Cannabis misuse	Never smoked	207 (91.6)	39 (78.0)	243 (88.0)	61 (75.3)	36 (63.2)	252 (85.7)
	Once or twice	14 (6.2)	1 (2.0)	21 (7.6)	16 (19.8)	17 (29.8)	34 (11.6)
	2–4 times a month	5 (2.2)	4 (8.0)	7 (2.5)	1 (1.2)	1 (1.8)	7 (2.4)
	More than once a week	0 (0.0)	6 (12.0)	5 (1.8)	3 (3.7)	3 (5.3)	1 (0.3)
Bullying others	Never	166 (73.5)	31 (60.8)	207 (75.5)	55 (65.5)	31 (54.4)	201 (68.6)
	Once or twice	54 (23.9)	20 (39.2)	53 (19.3)	22 (26.2)	22 (38.6)	77 (26.3)
	2–3 times a month	3 (1.3)	0 (0.0)	9 (3.3)	3 (3.6)	2 (3.5)	11 (3.8)
	Once a week	1 (0.4)	0 (0.0)	2 (0.7)	2 (2.4)	2 (3.5)	1 (0.3)
	Several times a week	2 (0.9)	0 (0.0)	3 (1.1)	2 (2.4)	0 (0.0)	3 (1.0)

TABLE 19 Comparison of baseline demographic characteristics for those with and without missing primary outcome: all participants. Figures are number (percentage) of participants unless otherwise stated

Variable	Level	Trial arm					
		Usual PSHE (N = 1604)		Classroom-based CBT (N = 1753)		Attention control PSHE (N = 1673)	
		Present (n = 1365; 85%)	Missing (n = 239; 15%)	Present (n = 1402; 80%)	Missing (n = 351; 20%)	Present (n = 1373; 82%)	Missing (n = 300; 18%)
Sex	Male	707 (51.8)	127 (53.1)	707 (50.4)	173 (49.3)	669 (48.7)	180 (60.0)
	Female	658 (48.2)	112 (46.9)	695 (49.6)	178 (50.7)	704 (51.3)	120 (40.0)
Ethnicity ^a	White	1085 (85.8)	190 (88.4)	1141 (88.2)	231 (80.2)	1074 (84.3)	197 (79.8)
	Non-white	180 (14.2)	25 (11.6)	153 (11.8)	57 (19.8)	200 (15.7)	50 (20.2)
Living situation ^a	Mother and father	874 (69.6)	107 (50.7)	828 (64.9)	144 (50.2)	898 (70.5)	121 (49.0)
	Parent and partner	146 (11.6)	47 (22.3)	175 (13.7)	49 (17.1)	148 (11.6)	41 (16.6)
	Single parent	211 (16.8)	51 (24.2)	255 (20.0)	88 (30.7)	200 (15.7)	83 (33.6)
	Other	24 (1.9)	6 (2.8)	17 (1.3)	6 (2.1)	27 (2.1)	2 (0.8)
Year group	8	529 (38.8)	40 (16.7)	432 (30.8)	38 (10.8)	346 (25.2)	28 (9.3)
	9	440 (32.2)	29 (12.1)	322 (23.0)	62 (17.7)	468 (34.1)	73 (24.3)
	10	165 (12.1)	14 (5.9)	495 (35.3)	88 (25.1)	514 (37.4)	48 (16.0)
	11	231 (16.9)	156 (65.3)	153 (10.9)	163 (46.4)	45 (3.3)	151 (50.3)
Age, mean (SD)	Years	13.7 (1.1)	14.8 (1.2)	13.9 (1.1)	14.8 (1.0)	13.8 (0.9)	14.7 (1.1)

^a Numbers do not add up to column total as some data were not provided by participants at baseline.

classroom-based CBT and attention control PSHE for liking ($F = 7.11$, $df 2,970$; $p < 0.01$), usefulness ($F = 6.46$, $df 2,966$; $p < 0.01$) and relevance for their age ($F = 8.84$, $df 2,963$; $p < 0.01$).

In the high-risk group, no differences were found in the ratings of the three trial arms ($n = 203$). Further, when the analysis was split by sex, there were no differences between trial arms in girls' ratings of PSHE, but boys preferred usual PSHE to either classroom-based CBT or attention control PSHE (liking $F = 5.49$, $df 2,469$; $p < 0.01$; usefulness $F = 7.26$, $df 2,465$; $p < 0.01$; relevance for their age $F = 7.72$, $df 2,465$; $p < 0.01$).

Project facilitator views

Feedback was obtained from 46 of the facilitators providing the PSHE sessions. Of these, 29 (63%) led the classroom-based CBT and 17 (37%) supported the teacher in delivering attention control PSHE. In general, facilitators felt sufficiently trained (65.5% agree/strongly agree) and supported (71.5% agree/strongly agree), and enjoyed their work (86.2% agree/strongly agree). Those supporting the attention control PSHE reported higher levels of student engagement (58.8% attention control PSHE vs. 48.2% classroom-based CBT). Those delivering classroom-based CBT were more likely to feel that the programme would have a positive effect on the mental health of students (55.1% agree as opposed to 35.3% for attention control PSHE). A comparison of average scores for classroom-based CBT and attention control PSHE facilitators

TABLE 20 Comparison of continuous outcome variables at baseline for those with and without missing primary outcome: all participants

Variable	Trial arm, mean (SD)					
	Usual PSHE (N = 1604)		Classroom-based CBT (N = 1753)		Attention control PSHE (N = 1673)	
	Present (n = 1365; 85%)	Missing (n = 239; 15%)	Present (n = 1402; 80%)	Missing (n = 351; 20%)	Present (n = 1373; 82%)	Missing (n = 300; 18%)
SMFQ	3.3 (4.6)	4.8 (5.5)	3.9 (4.9)	4.9 (5.2)	3.8 (4.8)	4.4 (4.8)
CATS	3.8 (6.4)	5.6 (8.1)	4.2 (6.7)	6.3 (8.3)	4.6 (7.1)	5.4 (7.2)
Self-esteem	21.7 (5.1)	19.7 (5.5)	21.3 (5.3)	19.6 (5.5)	21.0 (5.3)	20.0 (5.1)
General anxiety	3.0 (2.6)	3.6 (2.7)	3.4 (2.6)	3.9 (3.0)	3.2 (2.8)	3.3 (2.6)
Separation anxiety	1.0 (1.5)	1.3 (1.7)	1.2 (1.7)	1.2 (1.7)	1.2 (1.8)	1.4 (1.9)
Social phobia	3.7 (2.9)	4.5 (3.0)	4.1 (3.1)	4.7 (3.2)	4.0 (3.0)	4.4 (3.0)
Panic	1.5 (2.2)	2.1 (2.9)	1.8 (2.5)	2.3 (2.7)	1.7 (2.4)	2.1 (2.4)
Depression	2.0 (2.4)	3.0 (3.1)	2.5 (2.6)	3.2 (2.9)	2.3 (2.7)	3.0 (3.0)
RCADS	11.3 (9.3)	14.5 (10.4)	12.9 (10.2)	15.3 (10.7)	12.4 (10.3)	14.1 (10.3)
School connectedness	31.3 (6.0)	29.3 (6.3)	30.5 (6.2)	28.9 (6.6)	30.4 (6.3)	29.3 (6.7)

revealed that the classroom-based CBT group found their role more challenging ($t = 2.92$, $df = 44$; $p = 0.005$) and would have liked more supervision ($t = 2.99$, $df = 42$; $p = 0.005$).

Teacher views

The views of 56 of the 73 (76.7%) teachers who took part in the study were obtained. Of these, 36 were involved in the classroom-based CBT programme, with the remaining 20 providing the attention control PSHE. This section provides a summary of the data for the classroom-based CBT group only. In terms of delivery, content and materials, 24 (66.7%) thought that classroom-based CBT sessions were well or very well organised, 22 (66.1%) thought that the content was relevant and 22 (66.1%) felt that the content was age appropriate. Teachers were less sure about the number of sessions, with seven (20%) feeling that there were not enough, 14 (40%) feeling that the number was right and 14 (40%) feeling that there were too many.

Only 10 (27.8%) of the teachers felt that the classroom-based CBT would be helpful or very helpful in improving children's mood. Similarly, only 12 (33.3%) rated classroom-based CBT as useful or very useful in terms of helping children cope with future challenges. In terms of maintenance after the end of the clinical trial, of the 33 teachers who answered, most ($n = 24$, 72.7%) thought they would use some of the ideas from RAP-UK after the programme had finished, although seven teachers (21.1%) did not think they would use any of the ideas from RAP-UK after the programme had finished and only two (6.1%) felt they would use quite a lot of the ideas. Around half ($n = 19/35$, 54.3%) of teachers involved with the classroom-based CBT felt that they would be comfortable or very comfortable delivering it on their own.

Qualitative feedback

The main themes emerging from the qualitative data are summarised in *Table 23*.

TABLE 21 Comparison of categorical outcome variables at baseline for those with and without missing primary outcome: all participants. Figures are number (percentage) of participants unless otherwise stated

Variable	Level	Trial arm					
		Usual PSHE (N = 1604)		Classroom-based CBT (N = 1753)		Attention control PSHE (N = 1673)	
		Present (n = 1365; 85%)	Missing (n = 239; 15%)	Present (n = 1402; 80%)	Missing (n = 351; 20%)	Present (n = 1373; 82%)	Missing (n = 300; 18%)
Self-harm thoughts	Never	1050 (84.1)	153 (73.6)	1024 (80.6)	215 (76.0)	1007 (79.2)	187 (79.9)
	Once or twice	160 (12.8)	38 (18.3)	193 (15.2)	51 (18.0)	202 (15.9)	36 (15.4)
	3 or more times	39 (3.1)	17 (8.2)	54 (4.2)	17 (6.0)	62 (4.9)	11 (4.7)
Self-harm behaviour	Never	1162 (93.0)	181 (87.4)	1142 (89.9)	249 (88.0)	1141 (89.8)	205 (87.2)
	Once or twice	58 (4.6)	14 (6.8)	89 (7.0)	23 (8.1)	82 (6.5)	19 (8.1)
	3 or more times	29 (2.3)	12 (5.8)	39 (3.1)	11 (3.9)	48 (3.8)	11 (4.7)
Alcohol consumption	Never drank alcohol	482 (38.8)	36 (17.4)	412 (32.4)	59 (21.0)	493 (39.1)	47 (20.3)
	Once or twice	556 (44.7)	82 (39.6)	632 (49.7)	121 (43.1)	592 (46.9)	114 (49.4)
	More than 2–4 times a month	177 (14.2)	69 (33.3)	187 (14.7)	70 (24.9)	147 (11.6)	55 (23.8)
	More than once a week	28 (2.3)	20 (9.7)	40 (3.1)	31 (11.0)	30 (2.4)	15 (6.5)
Street drug misuse	Never taken	1236 (99.4)	197 (96.6)	1240 (97.8)	262 (92.9)	1247 (98.3)	224 (96.6)
	Once or twice	7 (0.6)	4 (2.0)	24 (1.9)	15 (5.3)	20 (1.6)	6 (2.6)
	2–4 times a month	0 (0.0)	1 (0.5)	3 (0.2)	4 (1.4)	0 (0.0)	1 (0.4)
	More than once a week	0 (0.0)	2 (1.0)	1 (0.1)	1 (0.4)	1 (0.1)	1 (0.4)
Cannabis misuse	Never smoked	1186 (95.2)	165 (80.5)	1176 (92.7)	213 (75.8)	1185 (93.5)	172 (73.8)
	Once or twice	46 (3.7)	20 (9.8)	64 (5.0)	43 (15.3)	66 (5.2)	43 (18.5)
	2–4 times a month	10 (0.8)	8 (3.9)	17 (1.3)	14 (5.0)	9 (0.7)	8 (3.4)
	More than once a week	4 (0.3)	12 (5.9)	11 (0.9)	11 (3.9)	8 (0.6)	10 (4.3)
Bullying others	Never	1078 (86.5)	161 (77.4)	1087 (85.3)	212 (74.9)	1031 (81.2)	161 (68.8)
	Once or twice	157 (12.6)	45 (21.6)	162 (12.7)	52 (18.4)	211 (16.6)	62 (26.5)
	2–3 times a month	7 (0.6)	0 (0.0)	13 (1.0)	6 (2.1)	15 (1.2)	6 (2.6)
	Once a week	2 (0.2)	0 (0.0)	5 (0.4)	7 (2.5)	7 (0.6)	4 (1.7)
	Several times a week	2 (0.2)	2 (1.0)	7 (0.5)	6 (2.1)	6 (0.5)	1 (0.4)

Note: not all participants answered each question.

TABLE 22 Student evaluation ratings for classroom-based CBT (RAP-UK), attention control PSHE and usual PSHE

Items (Rated 0 – not at all to 10 – a great deal)	Classroom-based CBT (n = 386), mean (SD)	Usual PSHE (n = 286), mean (SD)	Attention control PSHE (n = 316), mean (SD)
How much did you like your PSHE lessons?	4.38 (2.81)	5.06 (2.54)	4.33 (2.49)
How relevant were your lessons for people of your age?	5.23 (2.76)	5.92 (2.45)	5.24 (2.81)
How useful was what you learnt in PSHE to your everyday life?	4.22 (2.94)	5.13 (2.85)	4.36 (2.77)
How much did PSHE help you to feel happier in your mood?	3.62 (3.01)	3.81 (3.12)	3.44 (2.89)
How much did your PSHE help you to worry less?	3.34 (3.07)	3.31 (3.04)	3.22 (2.85)
How much did your PSHE help you to cope with worries when you have them?	3.71 (3.15)	3.61 (3.11)	3.37 (3.00)
How much did PSHE help you to solve problems?	3.81 (3.22)	3.92 (3.18)	3.40 (2.93)
How much did your PSHE help you to recognise your strengths?	4.44 (3.40)	4.62 (3.32)	4.13 (3.18)
How much did your PSHE help stop disagreements turning into arguments?	3.96 (3.20)	3.96 (3.19)	3.43 (2.92)
How much did your PSHE help you to get on better with people?	4.24 (3.38)	4.44 (3.38)	3.83 (3.19)
How much did your PSHE help you to ask for help when you need it?	4.17 (3.44)	4.41 (3.42)	4.03 (3.28)

There was evidence that aspects of RAP-UK were well received and perceived to be useful, particularly those that involved interactive activities:

You've got a really good little connect activity actually here, this 'two sides' of things ... And they love that.

Teacher

I thought the body signals one was handy... I think that's something that works across the age range.

Teacher

You could see the light going on for so many of them... it was almost like it was news to them ... that we don't have to think like this. I saw it happening with a lot of them, that they embraced it ... you could see it working.

Teacher

The content and structure of RAP-UK was generally felt to be good, although the programme was perceived to be a little repetitive in places and teachers felt it could have been condensed into a shorter and faster-paced programme.

Teachers reported that the quality of the delivery of the classroom-based CBT by the facilitators was variable:

Some of the people who delivered were quite comfortable and I felt quite successful in what they did. Whereas I got the impression from some of my colleagues that some of the people who came to teach it struggled really, and found it hard to deliver the materials in the way they needed to be delivered.

Teacher

TABLE 23 Summary of themes emerging from the qualitative feedback

Main theme	Subtheme	Key points
Structure and content of RAP	Types of teaching	'Hands-on' and interactive activities preferred
	Usefulness	Useful aspects of the programme were highlighted, e.g. sessions on resolving conflict, recognising body signals and problem solving
	Length of the programme	Shorter faster-paced programme would have been preferred
Delivery	Quality of delivery	Variable. Experience, confidence and reliance on scripts for facilitators and teacher engagement and support were important
	Classroom management	Teachers and facilitators found this challenging and were unsure of their roles
	Rapport with young people	Success in achieving this was variable, particularly where classes did not have the same facilitators throughout the programme
Flexibility and differentiation	Age	The classroom-based CBT programme (RAP-UK) seemed to be more appropriate for year 8 than for older year groups
	Involvement of teachers	Teachers wanted more flexibility and involvement in development of the classroom-based CBT programme
Targeting the intervention		Some young people, teachers and facilitators felt that a targeted intervention may have been more useful
Sustainability	Resources	Cost and time involved meant the classroom-based CBT would not be sustainable in its current form
	Future use of the programme	Teachers generally felt that they could deliver the programme alone with the right training, although they would be most likely to adapt it and select some parts only
Implementation in the school context	Value of PSHE	PSHE was perceived to be undervalued and under-resourced
	Busy school environment	Insufficient lead-in time, communication within schools and lack of time for contact between teachers and facilitators were problematic

Similarly, facilitators felt that active teacher engagement and support was imperative for the delivery of a successful session:

That made such a crucial difference with the teacher's attitude, just ... make or break ... whether it went ... how the class reacted to it.

Facilitator

Experience and confidence of facilitators were perceived to be important, and facilitators reported finding it much easier to deliver RAP-UK after a period of familiarisation:

It definitely got easier the more you did the sessions 'cos you just obviously knew them more by heart and didn't have to rely on the script so much and you can just take the lead.

Facilitator

While RAP-UK was felt to be appropriate and was well received by younger students (year 8), feedback was less positive in relation to the older year groups, and insufficient differentiation was raised as an issue:

All the sessions were the same ... for year 9 and 10 they were identical. It wasn't age appropriate, I don't think.

Teacher

I think the idea of Key Stages is really important ... we're going in and aiming it at year 8 who are 13 to year 11 who are 16.

Facilitator

In terms of sustainability, all of the teachers interviewed stated that it would not be possible to run RAP-UK in its current format because of timetabling restrictions and budgetary constraints, particularly as PSHE was seen to be undervalued and under-resourced:

That's the sad thing about our PSHE, unfortunately we don't have a designated team... it is squeezed on the timetable, it's not given the proper priority it should be.

Teacher

It's always one of the least funded departments, PSHE.

Teacher

The fact that the RAP sessions were in PSHE, a lesson that isn't taken particularly seriously, I think that really affected how people came into the class.

Facilitator

Teachers felt they would have liked to have been more involved in the development of the classroom-based CBT programme and believed that it could be successfully delivered by school staff if enough guidance was provided, although the quality would depend on individual teachers:

I don't think there's anything about the way it's (RAP-UK) been structured or put together, the subject matter, that makes it difficult for a teacher to pick up and go with. But again, I think it's down to that person.

Teacher

Some facilitators and young people suggested that a targeted (rather than universal) approach to delivering classroom-based CBT might be preferable, particularly as some young people did not feel the programme was relevant to them:

I'm not depressed or anything, so why do I need to learn about this?

Year 9 male

Schools are complex and busy organisations where there are many competing demands on time and resources. Teachers and facilitators acknowledged that more lead-in time and planning should have taken place, but that competing activities made it impossible to free up sufficient time to meet before or after lessons to do this. Facilitators and teachers alike highlighted that implementing the classroom-based CBT in schools was immensely challenging:

I think the length of time that you're here is quite challenging for us ... it's just trying to fit that in with our curriculum, it's really hard.

Teacher

I think it's difficult bringing mental health programmes into a school environment and it's a massive job to integrate that kind of clinical [programme] into everyday school.

Facilitator

Cost-effectiveness

Costing the intervention

Table 24 shows the key data and costs that were used to calculate the mean intervention cost per student.

The classroom-based CBT intervention cost an estimated £41.96 per child, while attention control PSHE cost an estimated £34.45 per child (Table 25). These costs exclude the costs of developing or adapting the new materials (these are 'sunk costs' and it is assumed that they would not be incurred again) or the estimated proportions of people's time, which are as a result of the research/trial context of programme delivery. The costs do, however, include a share of the initial training costs of the facilitators (time of trainers and facilitators, room hire and subsistence). Therefore, they do reflect the relatively high ratio of facilitators to total number of classes delivered, which might not be as high if the classroom-based CBT or attention control PSHE was rolled out on a larger scale and for longer. These ratios were 39 facilitators to 79 classes for classroom-based CBT, and 35 to 72 for attention control PSHE. Furthermore, with attention

TABLE 24 Costs and other key data for calculating the per-student intervention costs

Type of cost or data	Classroom-based CBT	Attention control PSHE
Total salary cost of those providing the intervention	£59,621	£51,267
Total cost of training facilitators	£18,418	£11,099
Hours of coordinator time to organise staff	150	150
Total number of classes receiving the intervention	79	72
Total number of students on the programme ^a	2030	1915
Mean number of students per class (all on roll)	25.7	26.6
Total number of sessions delivered	787	648
Mean number of sessions received per class	9.96	9.00
Total number of facilitators who delivered sessions	39	35
Number of sessions delivered per school visit (to estimate travel costs)	3	3
Cost of staff time recruiting each school to the programme	£60	£60
Cost of travel for recruiting each school to the programme	£20	£20

^a This differs from the numbers in the trial arms because the intervention costs must be shared among all who received the intervention, not just those who consented to involvement in the study and completed the assessment booklets.

TABLE 25 Per-student cost of delivering classroom-based CBT and attention control PSHE

Type of cost	Classroom-based CBT (£)	Attention control PSHE (£)
Cost of training and managing facilitators	9.84	6.61
Cost of facilitator time delivering the intervention	29.37	26.77
Booklet (printing) cost per child	1.41	NA
Travel cost of facilitators	1.23	1.07
Allocation of school recruitment cost	0.12	NA
Cost per child receiving intervention	41.96	34.45

NA, not applicable.

control PSHE there are no booklet costs and outside of a randomised controlled trial we assume that there would also be no costs associated with school recruitment to such a programme.

Cost of health and social care usage

Table 26 (hospital health care costs) and Table 27 (community-based care costs) show the health and social care service and resources data and costs that were used to calculate the mean service user cost per student in the cost-effectiveness analysis (i.e. for the subsample with complete EQ-5D responses and costs at all three study time points). Overall, these data show that the total care costs for adolescents were similar across the three trial arms at all three time points. Between 26% and 33% of adolescents in each trial arm had hospital care and between 37% and 45% had seen a general practitioner (GP) during the previous 6 months for any health reason. However, rates of service use or seeing care professionals for worry, anxiety or unhappiness were much lower: 1.6–4.6% of adolescents saw a GP for such problems; 0.5–3.0% saw a school nurse; and < 1% saw either the Child Mental Health Service or a child psychologist during a 6-month period. Of the 4.0–6.7% who saw 'someone else' for their psychological problems, most reported seeing or talking to their parents or other close relatives; teachers; friends; other doctors; youth workers; or a mentor/counsellor.

In total, over the 18 months for which service use data were collected, the per-person cost of services used by adolescents in each trial arm were £484 (SD £1294) for classroom-based CBT, £385 (SD £1169) for usual PSHE and £483 (SD £1294) for attention control PSHE. We did not test for the statistical significance of any service use cost differences between trial arms both because the study was not powered to detect

TABLE 26 Usage and cost of hospital health services (for any health reason)

Hospital services	Classroom-based CBT (N = 1006)		Usual PSHE (N = 1067)		Attention control PSHE (N = 1044)	
	n (%) ^a	Mean cost, £ (SE)	n (%) ^a	Mean cost, £ (SE)	n (%) ^a	Mean cost, £ (SE)
<i>In the 6 months up to baseline</i>						
Inpatient stays	45 (4.5)	72.09 (16.43)	33 (3.1)	50.48 (14.77)	33 (3.2)	56.43
A&E attendances	167 (16.6)	26.93 (2.60)	169 (15.8)	25.19 (2.16)	183 (17.5)	29.80 (2.97)
Outpatient visits	226 (22.5)	46.25 (3.86)	234 (21.9)	37.21 (3.36)	226 (21.6)	39.45 (3.23)
Total hospital use/costs	328 (32.6)	145.27 (18.82)	335 (31.4)	112.89 (16.63)	327 (31.3)	125.67 (16.84)
<i>In the period between baseline and 6 months' follow-up</i>						
Inpatient stays	36 (3.6)	43.62 (9.13)	27 (2.5)	52.66 (16.28)	29 (2.8)	31.07 (7.41)
A&E attendances	158 (15.7)	22.93 (2.06)	144 (13.5)	21.43 (2.18)	176 (16.9)	28.02 (2.61)
Outpatient visits	212 (21.1)	47.93 (4.84)	227 (21.3)	39.80 (3.58)	255 (24.4)	50.73 (4.03)
Total hospital use/costs	309 (30.7)	114.48 (12.51)	311 (29.1)	113.89 (17.96)	346 (33.1)	109.82 (10.40)
<i>In the period between 6 months' and 12 months' follow-up</i>						
Inpatient stays	30 (3.0)	59.71 (19.78)	20 (1.9)	21.78 (6.91)	34 (3.3)	62.87 (33.28)
A&E attendances	145 (14.4)	21.30 (2.16)	126 (11.8)	16.12 (1.75)	167 (16.0)	28.51 (4.15)
Outpatient visits	179 (17.8)	36.41 (3.50)	198 (18.6)	33.68 (3.14)	234 (22.4)	49.41 (5.20)
Total hospital use/costs	275 (27.3)	117.42 (21.82)	273 (25.6)	71.58 (8.47)	338 (32.4)	140.79 (39.85)

A&E, accident and emergency; SE, standard error.

a Number of adolescents and percentage of all adolescents in this arm who used this type of health service.

TABLE 27 Usage and cost of community-based health services for worry, anxiety or unhappiness

Community services	Classroom-based CBT (N = 1006)		Usual PSHE (N = 1067)		Attention control PSHE (N = 1044)	
	n (%) ^a	Mean cost, £ (SE)	n (%) ^a	Mean cost, £ (SE)	n (%) ^a	Mean cost, £ (SE)
<i>In the 6 months up to baseline</i>						
GP (for any reason)	448 (44.5)	28.76 (1.67)	440 (41.2)	25.49 (1.59)	449 (43.0)	26.57 (1.74)
GP (for psychological problems)	33 (3.3)	1.94 (0.39)	29 (2.7)	1.41 (0.30)	27 (2.6)	1.04 (0.21)
GP nurse	26 (2.6)	0.51 (0.13)	12 (1.1)	0.17 (0.05)	24 (2.3)	0.37 (0.11)
School nurse	30 (3.0)	0.76 (0.17)	18 (1.7)	0.97 (0.41)	31 (3.0)	1.03 (0.24)
Counsellor	14 (1.4)	2.80 (0.98)	7 (0.7)	1.07 (0.53)	13 (1.2)	2.61 (1.26)
CMHS	6 (0.6)	0.81 (0.37)	5 (0.5)	0.81 (0.39)	6 (0.6)	0.46 (0.25)
Child psychologist	7 (0.7)	3.06 (1.68)	2 (0.2)	1.14 (1.00)	6 (0.6)	2.72 (1.49)
Social worker	4 (0.4)	1.63 (0.92)	6 (0.6)	0.70 (0.31)	7 (0.7)	1.73 (0.91)
Someone else	64 (6.4)	9.58 (2.47)	43 (4.0)	4.86 (1.50)	70 (6.7)	9.25 (2.25)
Total: all service use/costs ^b	607 (60.3)	183.61 (19.64)	615 (57.6)	143.24 (17.01)	626 (60.0)	161.50 (17.71)
<i>In the period between baseline and 6 months' follow-up</i>						
GP (for any reason)	404 (40.2)	26.24 (1.86)	445 (41.7)	25.70 (1.44)	469 (44.9)	28.20 (1.48)
GP (for psychological problems)	35 (3.5)	1.92 (0.40)	27 (2.5)	1.78 (0.50)	34 (3.3)	1.99 (0.45)
GP nurse	21 (2.1)	0.46 (0.12)	11 (1.0)	0.25 (0.11)	27 (2.6)	0.53 (0.13)
School nurse	15 (1.5)	0.39 (0.11)	5 (0.5)	0.24 (0.13)	22 (2.1)	1.18 (0.42)
Counsellor	17 (1.7)	4.37 (1.46)	10 (0.9)	2.60 (1.18)	14 (1.3)	3.03 (1.18)
CMHS	5 (0.5)	1.24 (0.80)	4 (0.4)	0.45 (0.25)	5 (0.5)	0.32 (0.15)
Child psychologist	4 (0.4)	2.62 (1.52)	1 (0.1)	0.08 (0.08)	3 (0.3)	0.47 (0.29)
Social worker	4 (0.4)	1.53 (1.06)	3 (0.3)	0.35 (0.23)	8 (0.8)	0.86 (0.32)
Someone else	51 (5.1)	11.50 (3.58)	27 (2.5)	4.01 (1.26)	67 (6.4)	6.64 (1.56)
Total: all service use/costs ^b	579 (57.6)	152.22 (13.59)	608 (57.0)	143.60 (18.17)	641 (61.4)	144.65 (11.14)
<i>In the period between 6 months' and 12 months' follow-up</i>						
GP (for any reason)	368 (36.6)	22.30 (1.49)	427 (40.0)	21.89 (1.14)	402 (38.5)	24.12 (1.40)
GP (for psychological problems)	36 (3.6)	2.35 (0.53)	17 (1.6)	0.97 (0.28)	48 (4.6)	2.90 (0.55)
GP nurse	28 (2.8)	0.46 (0.11)	19 (1.8)	0.40 (0.11)	23 (2.2)	0.52 (0.15)
School nurse	14 (1.4)	0.65 (0.27)	18 (1.7)	0.43 (0.11)	26 (2.5)	1.35 (0.41)
Counsellor	21 (2.1)	4.42 (1.21)	14 (1.3)	2.43 (0.79)	5 (0.5)	6.45 (2.72)
CMHS	10 (1.0)	0.72 (0.26)	2 (0.2)	0.22 (0.16)	7 (0.7)	0.74 (0.49)
Child psychologist	2 (0.2)	0.40 (0.33)	3 (0.3)	1.21 (0.82)	7 (0.7)	1.94 (1.03)
Social worker	4 (0.4)	0.26 (0.14)	4 (0.4)	0.20 (0.10)	8 (0.8)	0.81 (0.34)
Someone else	56 (5.6)	8.94 (2.55)	39 (3.7)	4.91 (1.43)	67 (6.4)	11.80 (3.32)
Total: all service use/costs ^b	529 (52.6)	148.66 (22.26)	585 (54.8)	98.38 (8.81)	595 (57.0)	176.71 (40.46)

CMHS, Child Mental Health Service; SE, standard error.

a Number of adolescents and percentage of all adolescents in this arm who used this type of health service.

b This is the total of all hospital health care costs and GP attendances for any reason plus the cost of seeing any of the other care professionals shown here for psychological problems.

such differences and because, in a cost-effectiveness analysis, it is more important to estimate the CIs around the joint distribution of cost and effectiveness differences.

Impacts on health-related quality of life (European Quality of Life-5 Dimensions)

Figure 3a shows the EQ-5D index scores by trial arm and time point that were used to calculate incremental effectiveness in relation to health-related quality of life, and used in the cost-effectiveness analysis.

For completeness, Figure 3b shows the equivalent results for the EQ-5D visual analogue scale scores.

Both these figures and the data on which they are based (Table 28) show that any mean changes over time or mean differences between trial arms in either of these scores were minimal [varying less than 0.03 (EQ-5D index) or less than 2 points (EQ-5D visual analogue scale) over time or between trial arms]. As with the cost data, we did not test for the statistical significance of any service use cost differences between trial arms both because the study was not powered to detect such differences and because, in cost-effectiveness analysis, it is more important to estimate the CIs around the joint distribution of cost and effectiveness differences.

The detailed profiles of health-related quality of life by individual EQ-5D question and response level, by both trial arm and study time point, are shown in Tables 29 and 30. These tables show that the vast majority of self-reported health problems (affecting between 15% and 20% of adolescents) related to either pain/discomfort or anxiety/depression, while relatively few reported health problems impacting on mobility, self-care or usual activities.

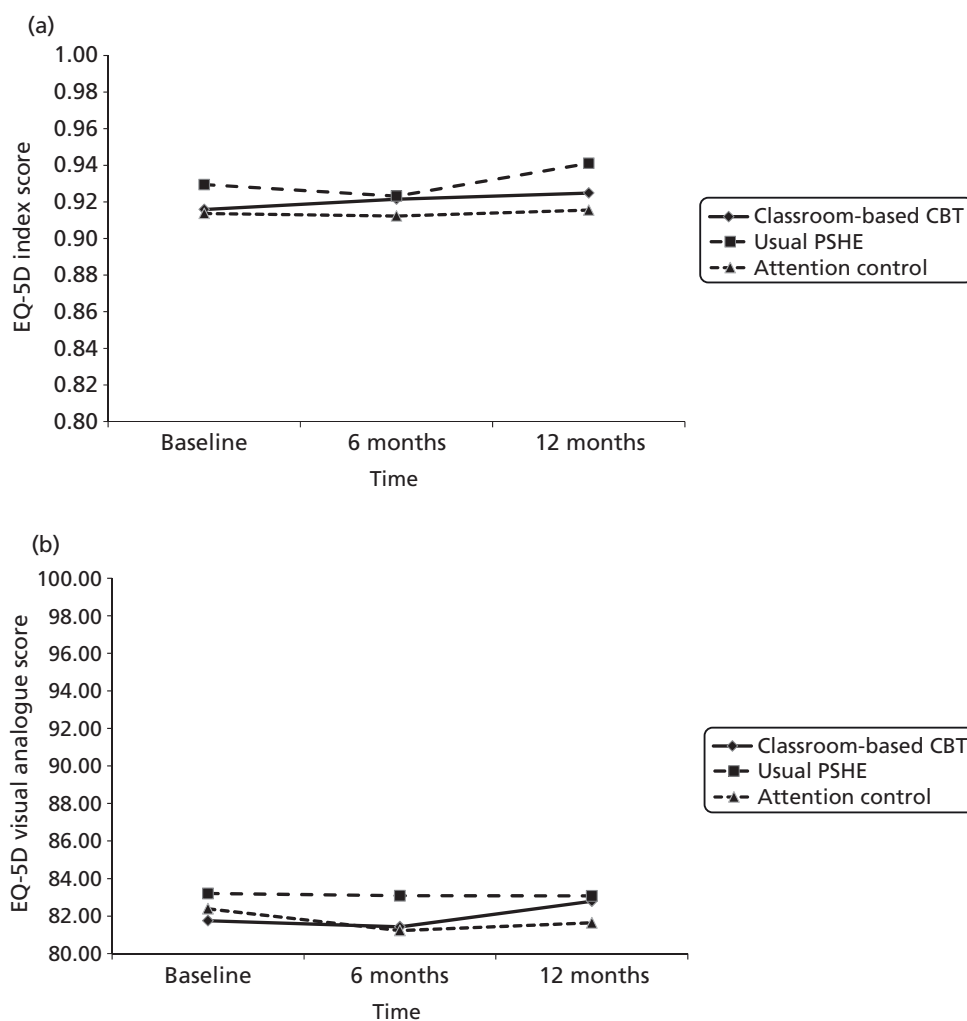


FIGURE 3 (a) European Quality of Life-5 Dimensions index scores; and (b) visual analogue scale scores by time point and trial arm.

TABLE 28 Mean and median EQ-5D scores by time point and trial arm

Trial arm	EQ-5D preference-based index (possible range -0.594 to 1.0)			EQ-5D visual analogue scale score (possible range 0 to 100)		
	Baseline	6 months	12 months	Baseline	6 months	12 months
Classroom-based CBT						
<i>n</i>	1006	1006	1006	973	985	992
Mean	0.916	0.921	0.925	81.8	81.4	82.8
SD	0.1484	0.1578	0.1585	16.18	17.26	16.70
Median	1.000	1.000	1.000	85.0	85.0	90.0
25th percentile	0.848	0.848	0.850	75.0	75.0	75.0
Usual PSHE						
<i>n</i>	1067	1067	1067	1050	1054	1053
Mean	0.929	0.923	0.941	83.2	83.1	83.1
SD	0.1348	0.1685	0.1291	15.56	14.76	15.00
Median	0.848	0.848	1.000	75.0	76.8	75.5
25th percentile	0.848	0.848	0.850	75.0	75.0	75.0
Attention control PSHE						
<i>n</i>	1044	1044	1044	1017	1025	1028
Mean	0.914	0.912	0.915	82.4	81.2	81.6
SD	0.1464	0.1632	0.1656	15.24	16.88	16.54
Median	1.000	1.000	1.000	85.0	85.0	85.0
25th percentile	0.848	0.848	0.848	75.0	75.0	75.0

Incremental cost-effectiveness

Tables 31 and 32 show the incremental cost-effectiveness for each of classroom-based CBT and attention control PSHE per person compared with usual PSHE for the 12-month period of the trial. This includes SMFQ score at 12 months and QALYs from baseline to 12 months as outcomes, and adjusted and unadjusted analyses are shown. Attention control PSHE was both less effective and more costly than usual PSHE; that is to say, both the point estimate ICER and most of the joint distribution of incremental costs and effects are in the north-west quadrant of the cost-effectiveness plane. All of the analyses except one found classroom-based CBT to be both less effective and more costly than the usual PSHE control. For the adjusted analysis of the incremental cost per QALY of classroom-based CBT compared with controls there is a very small estimated per person QALY gain (0.00054) for the additional cost of £100 per person.

Scatterplots of incremental costs and QALYs (Figures 4 and 5) and the related cost-effectiveness acceptability curve (Figure 6) were produced. The cost-effectiveness acceptability curve shows that there is an approximately 5% probability that classroom-based CBT is less costly than usual PSHE, and a 46% probability that it is less effective than usual PSHE. An incremental cost per QALY gained of £185,000 (95% CI is undefined) was estimated for classroom-based CBT in the adjusted analysis. This is both higher than the normally accepted willingness to pay for QALYs when they relate to the adoption of health technologies within the NHS⁵⁸ and highly uncertain. Further to the statistically non-significant effectiveness results for nearly all comparisons and analyses conducted, it can also be concluded that neither classroom-based CBT nor attention control PHSE would be cost-effective compared with usual PSHE. Given the small and highly uncertain differences in cost and effectiveness (SMFQ or QALYs) between classroom-based CBT and attention control PHSE, it would not be informative to estimate the incremental cost-effectiveness of these comparisons.

TABLE 29 European Quality of Life-5 Dimensions question responses by trial arm and time point (all complete EQ-5D responses)

Question	Baseline, % (n)			6 months, % (n)			12 months, % (n)		
	Classroom-based CBT (n = 1539)	Usual PSHE (n = 1432)	Attention control PSHE (n = 1492)	Classroom-based CBT (n = 1447)	Usual PSHE (n = 1411)	Attention control PSHE (n = 1424)	Classroom-based CBT (n = 1271)	Usual PSHE (n = 1275)	Attention control PSHE (n = 1270)
Mobility									
No problems walking	94.5 (1454)	96.0 (1375)	94.7 (1413)	94.3 (1364)	94.8 (1337)	93.5 (1332)	94.6 (1202)	95.8 (1222)	94.5 (1200)
Some problems	4.9 (76)	3.3 (47)	4.8 (72)	4.9 (71)	4.2 (59)	5.6 (80)	4.9 (62)	3.8 (48)	5.0 (64)
Confined to bed	0.6 (9)	0.7 (10)	0.5 (7)	0.8 (12)	1.1 (15)	0.8 (12)	0.6 (7)	0.4 (5)	0.5 (6)
Self-care									
No problems	98.8 (1521)	99.1 (1419)	99.1 (1479)	98.5 (1426)	99.0 (1397)	98.4 (1401)	99.0 (1258)	99.3 (1266)	98.7 (1253)
Some problems	0.9 (14)	0.8 (11)	0.7 (11)	0.7 (10)	0.6 (9)	1.1 (15)	0.6 (8)	0.5 (7)	0.7 (9)
Unable to wash or dress myself	0.3 (4)	0.1 (2)	0.1 (2)	0.8 (11)	0.4 (5)	0.6 (8)	0.4 (5)	0.2 (2)	0.6 (8)
Usual activities									
No problems	91.4 (1407)	93.3 (1336)	90.5 (1350)	93.4 (1351)	93.6 (1320)	91.3 (1300)	92.8 (1179)	94.7 (1208)	93.3 (1185)
Some problems	8.2 (126)	6.2 (89)	9.3 (139)	5.8 (84)	5.7 (81)	7.6 (108)	7.0 (89)	4.9 (62)	5.8 (74)
Unable to perform usual activities	0.4 (6)	0.5 (7)	0.2 (3)	0.8 (12)	0.7 (10)	1.1 (16)	0.2 (3)	0.4 (5)	0.9 (11)
Pain/discomfort									
No pain or discomfort	77.8 (1198)	81.9 (1173)	76.9 (1147)	80.6 (1166)	81.5 (1150)	77.2 (1100)	81.3 (1033)	85.2 (1086)	80.4 (1021)
Moderate	21.4 (329)	17.6 (252)	22.5 (335)	18.2 (264)	17.6 (249)	21.2 (302)	17.9 (228)	14.4 (184)	18.7 (237)
Extreme	0.8 (12)	0.5 (7)	0.7 (10)	1.2 (17)	0.9 (12)	1.5 (22)	0.8 (10)	0.4 (5)	0.9 (12)
Anxiety/depression									
Not anxious or depressed	80.6 (1241)	83.8 (1200)	79.0 (1178)	83.2 (1204)	84.1 (1186)	79.1 (1126)	85.2 (1083)	84.5 (1078)	81.0 (1029)
Moderately	17.2 (264)	15.2 (218)	19.4 (290)	14.8 (214)	14.4 (203)	19.2 (273)	12.7 (162)	14.4 (183)	17.4 (221)
Extremely	2.2 (34)	1.0 (14)	1.6 (24)	0.1 (1)	0.0 (0)	0.0 (0)	2.0 (26)	1.1 (14)	1.6 (20)

TABLE 30 European Quality of Life-5 Dimensions question responses by trial arm and time point (for those with EQ-5D responses and costs at all three time points)

Question	Baseline			6 months			12 months		
	Classroom-based CBT (n = 1539)	Usual PSHE (n = 1432)	Attention control PSHE (n = 1492)	Classroom-based CBT (n = 1447)	Usual PSHE (n = 1411)	Attention control PSHE (n = 1424)	Classroom-based CBT (n = 1271)	Usual PSHE (n = 1275)	Attention control PSHE (n = 1270)
Mobility, % (n)									
No problems walking	94.9 (955)	96.6 (1031)	95.6 (998)	94.4 (950)	94.9 (1013)	94.4 (986)	95.3 (959)	96.4 (1029)	94.4 (986)
Some problems	4.8 (48)	2.8 (30)	4.3 (45)	5.0 (50)	4.0 (43)	5.2 (54)	4.1 (41)	3.5 (37)	5.1 (53)
Confined to bed	0.3 (3)	0.6 (6)	0.1 (1)	0.6 (6)	1.0 (11)	0.4 (4)	0.5 (6)	0.1 (1)	0.5 (5)
Self-care, % (n)									
No problems	99.2 (98)	99.3 (1059)	99.5 (1039)	98.9 (995)	99.1 (1057)	98.9 (1032)	99.3 (999)	99.3 (1060)	98.8 (1031)
Some problems	0.6 (6)	0.7 (8)	0.4 (4)	0.7 (7)	0.6 (6)	0.8 (8)	0.4 (4)	0.5 (5)	0.6 (6)
Unable to wash or dress myself	0.2 (2)	0 (0)	0.1 (1)	0.4 (4)	0.4 (4)	0.4 (4)	0.3 (3)	0.2 (2)	0.7 (7)
Usual activities, % (n)									
No problems	92.3 (929)	93.9 (1002)	91.2 (952)	94.0 (946)	93.8 (1001)	92.3 (964)	93.5 (941)	95.1 (1015)	93.44 (975)
Some problems	7.4 (74)	5.9 (63)	8.6 (90)	5.4 (54)	5.3 (57)	7.1 (74)	6.4 (64)	4.6 (49)	5.7 (60)
Unable to perform usual activities	0.3 (3)	0.2 (2)	0.2 (2)	0.6 (6)	0.8 (9)	0.6 (6)	0.1 (1)	0.3 (3)	0.9 (9)
Pain/discomfort, % (n)									
No pain or discomfort	78.4 (789)	81.3 (868)	78.4 (818)	81.0 (815)	81.9 (874)	79.2 (827)	82.4 (829)	85.5 (912)	80.4 (839)
Moderate	20.9 (210)	18.5 (197)	21.0 (219)	18.4 (185)	17.2 (184)	19.9 (208)	17.0 (171)	14.2 (151)	18.8 (196)
Extreme	0.7 (7)	0.2 (2)	0.7 (7)	0.6 (6)	0.8 (9)	0.9 (9)	0.6 (6)	0.4 (4)	0.9 (9)
Anxiety/depression, % (n)									
Not anxious or depressed	83.8 (843)	84.8 (905)	80.6 (841)	84.9 (854)	85.3 (910)	81.2 (848)	86.3 (868)	85.2 (909)	81.5 (851)
Moderately	14.8 (149)	14.2 (152)	18.0 (188)	13.8 (139)	13.4 (143)	17.2 (180)	11.5 (116)	14.0 (149)	17.2 (180)
Extremely	1.4 (14)	0.9 (10)	1.4 (15)	1.3 (13)	0 (0)	0 (0)	2.2 (22)	0.8 (9)	1.2 (13)

TABLE 31 Incremental cost-effectiveness results: cost per SMFQ score difference (unadjusted and adjusted analyses)

	<i>n</i>	Costs (£)	SMFQ	Difference in costs	Difference in SMFQ	ICER unadjusted (95% CI)	Difference in costs adjusted	Difference in SMFQ adjusted	ICER adjusted (95% CI)
Classroom-based CBT vs. usual PSHE									
Usual PSHE	1140	406 (1240)	3.18 (4.46)			NA			NA
Classroom-based CBT	1096	553 (1392)	3.73 (5.34)	147	-0.58	Dominated ^a	106	-0.29	Dominated ^a
Attention control PSHE vs. usual PSHE									
Usual PSHE	1140	406 (1240)	3.18 (4.46)			NA			NA
Attention control PSHE	1108	539 (1572)	3.89 (5.12)	133	-0.74	Dominated ^a	160	-0.37	Dominated ^a

NA, not applicable.

a For the point estimate of the joint distribution of incremental costs and incremental effects, the intervention is both less effective and more costly than for usual PSHE control participants. Note: differences shown are classroom-based CBT or attention control PSHE – usual PSHE, with the exception of SMFQ scores, which are calculated as usual PSHE – attention control PSHE or classroom-based CBT.

TABLE 32 Incremental cost-effectiveness results: unadjusted, cost per QALY (unadjusted and adjusted analyses)

	<i>n</i>	Costs (£)	QALYs	Difference in costs	Difference in QALYs	ICER unadjusted (95% CI)	Difference in costs adjusted	Difference in QALYs adjusted	ICER adjusted (95% CI)
Classroom-based CBT vs. usual PSHE									
Usual PSHE	1067	385 (1169)	0.91 (0.12)			NA			NA
Classroom-based CBT	1006	526 (1294)	0.90 (0.12)	141	-0.009	Dominated ^a	100	0.00054	185,338 (95% CI undefined ^b)
Attention control PSHE vs. usual PSHE									
Usual PSHE	1067	385 (1169)	0.91 (0.12)			NA			NA
Attention control PSHE	1044	517 (1553)	0.89 (0.12)	132	-0.016	Dominated ^a	177	-0.017	Dominated ^a

NA, not applicable.

a For the point estimate of the joint distribution of incremental costs and incremental effects, the intervention is both less effective and more costly than for usual PSHE control participants. b 95% CI undefined at both bounds; only 52% of the joint distribution indicates that RAP is both more effective and more costly than usual PSHE.

Note: differences shown are classroom-based CBT or attention control – usual PSHE, with the exception of SMFQ scores, which are calculated as usual PSHE – attention control or classroom-based CBT.

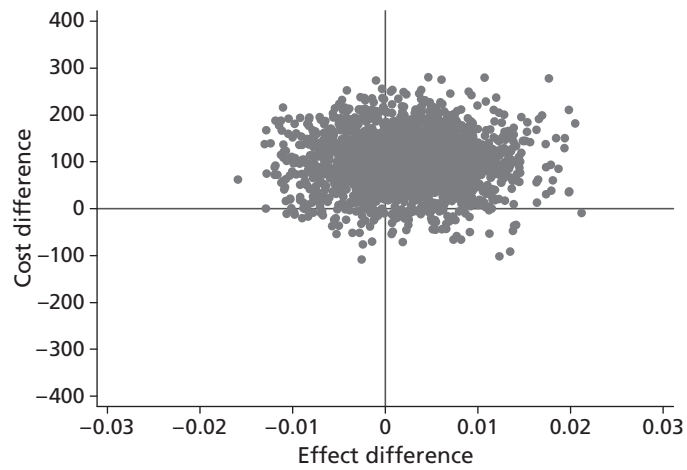


FIGURE 4 Cost-effectiveness plane. Classroom-based CBT vs. usual PSHE, ratio of incremental cost to QALYs gained (adjusted analysis).

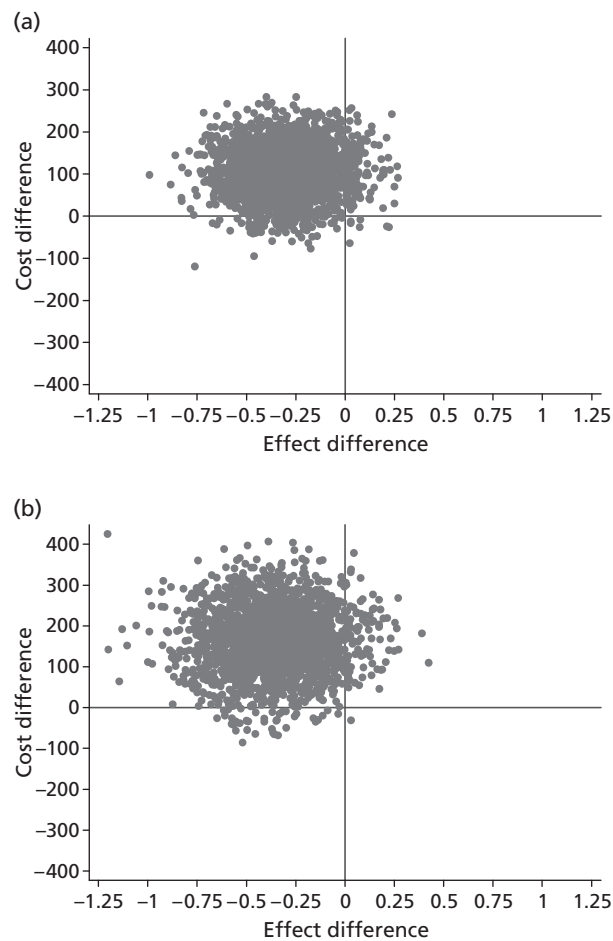


FIGURE 5 Scatterplots of incremental costs and effects for the adjusted analyses. (a) Classroom-based CBT vs. usual PSHE: SMFQ; (b) attention control PSHE vs. usual PSHE: SMFQ; (c) classroom-based CBT vs. usual PSHE: QALYs; and (d) attention control PSHE vs. usual PSHE: QALYs.

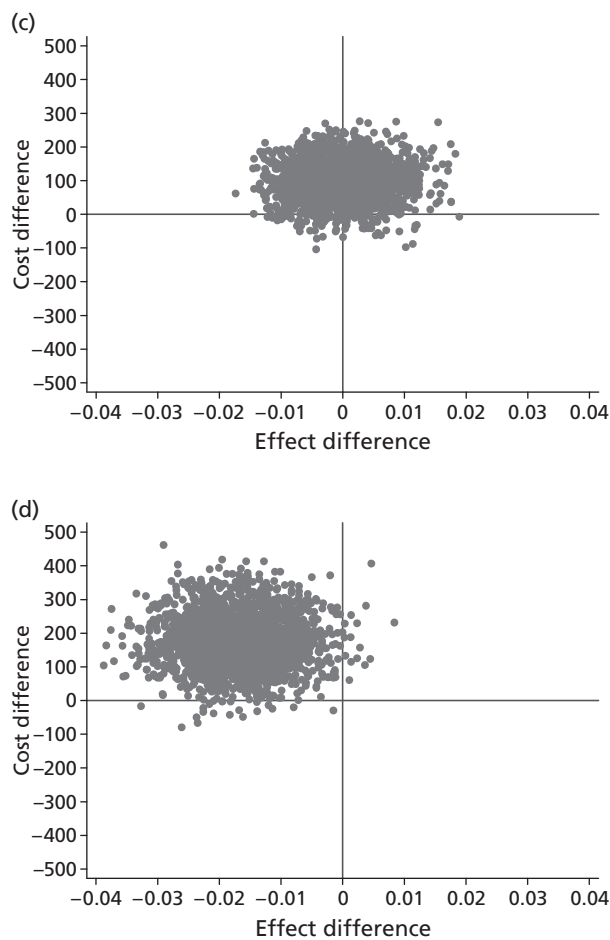


FIGURE 5 Scatterplots of incremental costs and effects for the adjusted analyses. (a) Classroom-based CBT vs. usual PSHE: SMFQ; (b) attention control PSHE vs. usual PSHE: SMFQ; (c) classroom-based CBT vs. usual PSHE: QALYs; and (d) attention control PSHE vs. usual PSHE: QALYs (*continued*).

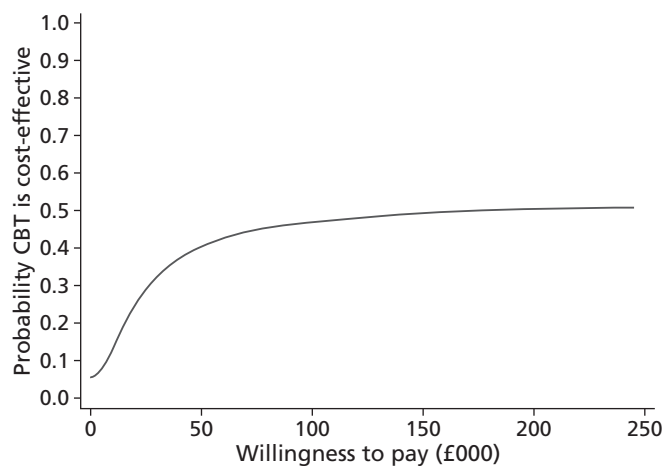


FIGURE 6 Probability that classroom-based CBT is cost-effective compared with usual PSHE based on cost per QALY (adjusted analysis).

Chapter 5 Discussion

Principal findings

This is the first large-scale pragmatic cluster randomised controlled trial to compare the effects of a focused classroom-based CBT programme (RAP-UK) on symptoms of depression in adolescents with both usual school PSHE provision group and an attention control group, and incorporating a long-term follow-up (12 months from baseline). We found no evidence that classroom-based CBT reduced symptoms of depression in the high-risk group of adolescents when implemented under diverse everyday conditions, despite high levels of treatment fidelity and adherence. Having adjusted for variables that were imbalanced at baseline, there was some evidence of increased reporting of symptoms of depression in the high-risk group at 12-month follow-up. Classroom-based CBT was not cost-effective and there was a high probability that it was both less effective and more expensive than usual PSHE. Furthermore, there were a number of challenges associated with implementing classroom-based CBT within schools, particularly with regard to fitting classroom-based CBT into a busy timetable, the lack of value placed on PSHE in schools and difficulties engaging with teachers and young people.

Nonetheless, in this unreferral community sample, around one in five adolescents reported elevated depressive symptoms on two separate occasions prior to the interventions. This high-risk group showed modest improvements in symptoms of depression over the following year that may reflect regression to the mean regardless of which trial arm they were in. However, around two-thirds of these high-risk participants continued to be at risk of depression at 12-month follow-up. Our data provide further evidence of a need for clinically effective and cost-effective community-based depression prevention and early intervention programmes for adolescents.

Pilot phase

The pilot study demonstrated that the delivery and evaluation of classroom-based CBT in the UK school context was feasible. Ninety-six per cent of students on roll were actually attending school and able to access and potentially benefit from the interventions. The complete nine-session classroom-based CBT programme was delivered to all but one class, with 95% of sessions being delivered as intended by two trained facilitators. Of those students who received classroom-based CBT, almost 90% attended seven or more sessions. However, classroom-based CBT was delivered to only two of the school year groups and it was unclear whether or not delivery and attendance rates would be similar for the other year groups. Delivering to year 11 students may be particularly problematic as the main focus for these students is on preparing for their General Certificate of Secondary Education (GCSE) examinations. Nonetheless, these results were encouraging and suggested that the majority of students in secondary school would be able to access and receive sufficient dosage from classroom-based CBT.

The consent process was both practical and acceptable, with consent to complete study assessments approaching 90%. At the 12-month follow-up, 78% of participants were retained. Retention rates of year 11 students were the lowest (45%) as many had left school. This highlighted the need to investigate ways of improving retention in this group in the main trial, including ensuring that there were alternative ways of contacting older students (e.g. mobile telephones, e-mail, putting the assessments online). The classroom-based CBT programme (RAP-UK) content and exercises were also modified for the main trial in the light of the qualitative feedback from the pilot study to try to make materials more engaging, appealing and relevant to all age groups. The training for facilitators was revised to incorporate information on working within the school environment, including discussion of issues around classroom

management and working alongside teachers. These issues were also discussed and reviewed during the ongoing supervision sessions for facilitators in the main trial.

Main trial

Reach and effectiveness

The reach of classroom-based CBT within participating schools was good, with the vast majority of young people on roll attending PSHE and therefore being able to access the intervention. Over 90% of eligible young people assented to complete assessments, and over 80% of young people completing baseline were retained at 12-month follow-up. Attendance of PSHE was good and attrition from the PSHE programmes was low. Nonetheless, initial recruitment of schools to the trial was challenging, with only 9 of the 66 schools approached agreeing to take part. This was partly due to other pressures on schools [e.g. Ofsted (Office for Standards in Education, Children's Services and Skills) inspections, staffing changes, participation in other projects]. It may have also been due to the additional demands of a research trial in terms of assessments and research procedures (e.g. randomisation, consent/assent, assessments). However, this may have been indicative of a wider lack of engagement with the project, particularly given other pressures on their time and resources and the general emphasis on academic targets within the UK education system.

The classroom-based CBT programme used (RAP-UK) specifically targeted factors reported to protect against the development of depression, that is thinking styles, emotional recognition and regulation and coping skills.⁵⁹ However, we observed that when variables that were imbalanced at baseline had been adjusted for, there was some evidence that classroom-based CBT could have had a small but potentially harmful effect on symptoms of depression compared with usual PSHE in the high-risk group. Furthermore, the high-risk group receiving classroom-based CBT reported more feelings of personal failure at 12 months than those who received usual PSHE. This may indicate a detrimental effect, reflecting limited improvement in mood over time in the high-risk group. While the possibility of a small harmful effect needs to be acknowledged, higher rates of symptoms may reflect greater self-recognition and acknowledgement of existing symptoms of depression and negative thinking styles. Furthermore, there was some evidence of potentially beneficial effects of classroom-based CBT on some of the secondary outcomes (i.e. RCADS depression at 12 months compared with usual PSHE, self-harm thoughts at 6 months, and SMFQ as a binary outcome at 12 months compared with attention control PSHE). Similarly, when all participants were included in the analysis regardless of risk status, both potential benefits and potential harms of classroom-based CBT were identified, although all effects were modest and unlikely to be clinically significant.

Unfortunately, our data do not extend beyond 12 months so the longer-term effects of the interventions are not known. Nonetheless, in the short term, our results suggested that, compared with no intervention, classroom-based CBT targeting symptoms of depression in high-risk adolescents was associated with increased levels of self-reported depressive symptoms. The possibility of worse outcomes following school-based intervention programmes has also been found for other mental health disorders such as attention-deficit hyperactivity disorder, and an improved understanding of the mechanisms underlying possible adverse outcomes merits further investigation.⁶⁰

Adoption and implementation

Classroom-based CBT was adopted and successfully implemented in the participating schools, but this process proved to be immensely challenging. Schools are very busy and complex environments where there are many competing demands. Furthermore, PSHE is generally undervalued, under-resourced and not prioritised in secondary schools. Finding time, resources and the enthusiasm required to implement a focused mental health programme in this context is difficult. RAP-UK was designed to fit in with existing school structures and enormous flexibility was required to attempt to fit the programme into schools. To accommodate this, a team of over 70 trained facilitators was required to deliver the interventions,

predominantly owing to timetabling issues. This posed a major challenge in terms of training and co-ordination of the intervention delivery.

Our experience was that successful delivery of the interventions required a great deal of organisation on the part of schools and the research team, involving regular communication, fitting in around timetables and other demands (e.g. examinations, sports days, work experience) and managing unexpected events (e.g. school closures due to adverse weather). In cases where lessons were cancelled, it could be very difficult to rearrange these. For example, the classroom-based CBT intervention was terminated after session 4 in a whole year group in one school because the school had lost several days to closures during adverse weather and they needed the time allocated to the programme to catch up on examined subjects. Therefore, despite having agreed the best way of implementing the programme with PSHE co-ordinators in schools, we experienced regular ongoing difficulties with delivery because of competing pressures.

Feedback from teachers and facilitators indicated that a shorter and more fast-paced programme might have been more engaging and easier to implement. However, reviews of depression prevention programmes in adolescents indicate that between 8 and 12 sessions are required for these to be effective.^{8,9} Part of the issue for teachers appeared to be insufficient content in the RAP-UK programme given the amount of time allocated to the classroom-based CBT intervention; therefore, including more materials and activities to ensure that the students remained engaged and time was used constructively might have been helpful, rather than reducing the programme in length. Alternatively, Wolfe *et al.*⁶¹ have argued that, to enhance maintenance, shorter programmes should be considered. Programmes could potentially be delivered more flexibly over a longer period of time. Continuous and extended programmes are advocated by Wells *et al.*⁶² and may help to sustain a given programme's benefit.⁶³ Nonetheless, the current format of delivering nine classroom-based CBT sessions within an academic year was difficult to implement and it is unlikely that this could be sustained outside the context of a research trial.

Engagement with and sustainability of school-based intervention programmes is likely to be strongly influenced by levels of teacher and pupil satisfaction.⁶⁴ A number of previous studies have reported that RAP was positively received and perceived to be useful by teachers and young people,^{16,61,65} and this was our experience in the pilot study. However, in the main trial where the interventions were implemented under more diverse conditions, the feedback was more mixed. In the main trial, a number of positive aspects of the classroom-based CBT were noted in the feedback received from young people and teachers, particularly relating to the content and structure of the RAP-UK sessions, the use of hands-on and interactive tasks, and the usefulness of some of the components of the programme (e.g. recognising body signals and problem solving). Nonetheless, the feedback relating to the acceptability and sustainability of classroom-based CBT was not generally very positive, despite us having revised the intervention and training for facilitators following the feedback from the pilot study.

One of the major challenges faced was that PSHE in general was not positively rated by students regardless of trial arm, and teachers noted that it was an undervalued subject in schools. Given that PSHE is a mandatory part of the school curriculum and deals with issues that are central to the health and well-being of young people, further work needs to be undertaken to make PSHE more engaging, useful and relevant for students. This seems especially important, as fitting programmes into a curriculum that is already so negatively viewed is unlikely to be useful. The feedback questionnaires indicated that classroom-based CBT was more negatively rated than usual PSHE by boys and by the low-risk group, but that there was little difference in the way the programmes were rated in the high-risk group and by girls. Based on the qualitative data, the classroom-based CBT programme appeared to be more acceptable to younger students (year 8) but was less well received in the older year groups, and it was suggested that there was a need for greater differentiation and flexibility, and more emphasis on hands-on tasks.

Overall, teachers were not positive about classroom-based CBT in terms of helping students with their mood. This may reflect a lack of general understanding about childhood depression or a failure to clearly communicate the purpose and aims of the classroom-based CBT programme. Although the research team

invested considerable time engaging with the senior management teams and PSHE coordinators at participating schools, interacting with individual teachers proved more difficult. Schools are very busy places, and it was not always possible to find an opportunity at the start of the project for either the research team or facilitators to meet and discuss the project with individual PSHE teachers. Teachers were consulted during the pilot phase of this study to gather feedback and inform the development of the programme before it was rolled out for the main trial. However, it became evident that the teachers involved in the main trial would have liked to be more directly involved in developing the programmes and tailoring them to their students. Teachers in a study of RAP in New Zealand also felt that they could have delivered the programme more effectively if they had been able to deviate from the manual and adapt the way some of the concepts were taught.²⁵ Involving teachers in programme development and planning may have improved engagement with teachers and young people, but this process would affect treatment fidelity unless all the key active elements were retained, so care would need to be taken with this approach. Furthermore, our experience was that teachers were very busy and had many demands on their time. Finding time to work with facilitators on planning, preparation and reviewing progress often proved impossible in reality, even when teachers were very motivated and engaged with the programme.

The majority of classroom-based CBT facilitators felt positive about their role, enjoyed their work and felt they had sufficient training in general. However, almost half of the facilitators did not feel that the classroom-based CBT would improve mental health, with similar numbers feeling that young people were not engaged with the programme. Facilitators' knowledge and confidence have been identified as important factors in relation to the effectiveness of a programme.⁶⁶ Providing more training, including an acclimatisation period in schools, allowing more time for facilitators and teachers to work together and develop a relationship and providing more time to familiarise with the programme could have improved acceptability for classroom-based CBT facilitators. However, this may have been less of an issue outside the confines of a research trial if facilitators were able to work regularly with a group of schools over a longer period of time.

Maintenance

Feedback from teachers and PSHE co-ordinators indicated that delivering classroom-based CBT in secondary schools in its current form would not be sustainable. During interviews, teachers unanimously felt that the classroom-based CBT would be too expensive and lengthy to deliver. Training school staff in mental health programmes provides an alternative and potentially more cost-effective model, although school staff tend to be less effective than trained facilitators or health professionals.^{9,19} Around half of the teachers involved in classroom-based CBT did not feel confident that they could deliver the programme on their own, suggesting the need for a significant teacher training and support programme if all teachers were expected to deliver it. Teacher feedback also suggested that if they were to deliver the RAP-UK programme used in the current study, it would be reduced and amended, indicating that treatment fidelity would be compromised. Furthermore, enthusiasm and motivation from teachers would be required to engage with young people in delivering classroom-based CBT, and this was not always present. Therefore, neither delivery by external facilitators (more expensive) nor delivery by teachers (likely to be less effective) appeared to represent sustainable models for delivering classroom-based CBT in schools in its current form.

Economic evaluation

Whether based on estimated differences in QALYs or on differences in SMFQ scores, this research provides no evidence that either classroom-based CBT or attention control PSHE is a cost-effective way of reducing symptoms of depression in adolescents in schools. For all of the analyses bar one, the point estimate of the ICER was in the upper-left quadrant and so it would not be a meaningful number to report. The probability that classroom-based CBT or attention control PSHE were both less effective and more costly than usual PSHE ranged from 43% to 98% in the adjusted analyses. Although the adjusted estimate of the mean incremental cost per QALY of classroom-based CBT compared with usual PSHE is about £185,000 per QALY, the 95% CI surrounding this ratio is not definable. The very small estimated QALY gain and the considerable uncertainty surrounding this estimate are consistent with the overall

effectiveness results of the trial in relation to the SMFQ outcome. Even for this analysis, however, there is still a 43% estimated probability that classroom-based CBT is both more costly and less effective than usual PSHE, and only a 25% probability that the cost-effectiveness ratio is less than £20,000 per QALY, which is the current threshold below which the National Institute for Health and Care Excellence is likely to recommend treatments on the basis of value for money.

There are currently very few economic evaluations of similar group-CBT programmes for low mood or depression, and none that is for depression prevention trials targeting school children. However, a study comparing individual versus family CBT for children with anxiety disorders in the Netherlands similarly found no significant differences in costs or effectiveness (QALYs).⁶⁷ However, individual CBT was found to be both more effective and less costly than family CBT in most sensitivity analyses.⁶⁷ In contrast, an earlier modelling-based cost-effectiveness study in Australia, comparing individual CBT with 'current practice' to treat major depression in children and adolescents (aged 6–17 years), estimated that CBT saved disability-adjusted life-years (DALYs) at a cost of A\$9000 per DALY saved.⁶⁸ Therefore, it is not possible to judge whether or not our findings are consistent with those of similar studies because of the lack of trial-based economic evaluations of group CBT to prevent depression, low mood and anxiety in children.

Implications

Our findings suggest that a more cautious approach is required to the widespread implementation of depression prevention programmes in schools. To maximise the potential for effectiveness of the depression prevention intervention, we selected an efficacious CBT-based programme, the RAP,^{24,25} and adapted this for the UK (RAP-UK). We ensured that there was a sufficient number of sessions, delivery was by trained facilitators rather than teachers and the majority of content was delivered in small groups within classes, as these factors are usually associated with larger effects.^{8,9} The pilot study described above assessed feasibility and provided an opportunity to refine and adapt the RAP-UK programme before commencing the main trial. Despite this, the findings indicated that classroom-based CBT had very little effect on outcomes either in the high-risk group or for all participants. Where effects were observed, these were typically small and were mixed in terms of indicating possible benefits or harms.

While secondary schools provide a convenient focus for mental health interventions, the suitability of this setting for depression-focused interventions cannot be assumed. The success and sustainability of mental health interventions within this setting will be determined by a number of factors other than programme efficacy, including compatibility with organisational objectives, perceived relevance, programme flexibility and fit within existing structures.⁶⁹ Secondary schools are organisationally complex and, while the importance of developing social and emotional awareness is increasingly being recognised, the primary objective of schools is to develop academic skills. While we addressed this issue by using a dedicated team of trained facilitators to deliver the intervention, the absence of a positive effect and the feedback from teachers suggested that this is not a sustainable or viable option.

Systematic reviews of programmes designed to reduce symptoms of depression in adolescents have noted considerable variability in results but remain supportive of prevention and early intervention approaches delivered in schools.^{8,9} Significant methodological shortfalls, limited follow-up and absence of attention control or placebo comparisons have been noted as important omissions in previous studies and the current study has addressed some of these issues. Although previous studies have succeeded in showing that classroom-based CBT can be efficacious in the short term,^{16,24,25} effects appear to be diluted when rolled out under more diverse conditions. The lack of clinical effectiveness of classroom-based depression prevention programmes has also been observed in other recent large-scale trials. The long-term follow-up of a large-scale trial ($n = 5633$) of the Beyondblue intervention failed to show clinical effectiveness of the programme in preventing depression, despite having taken an integrative approach and working on a whole-school as well as an individual level.^{19,20} Likewise, in a recent evaluation of the UK Resilience Programme with year 7 students across 22 schools under 'everyday' conditions, no sustained effect of the

programme was found at 1 year.⁷⁰ It has been suggested that classroom-based CBT may be better at promoting positive mental health rather than having an effect on clinical problems.⁶⁵ However, no effect was found on self-esteem in the current study, and so our data do not support this view.

Universally delivered classroom-based CBT programmes may not be sufficiently focused and intensive to support high-risk adolescents. They may even pose a small risk of harm, which needs to be considered if further investigation of this approach is to be carried out to ensure that the benefits of such interventions outweigh any risks. Indicated interventions for depression typically have larger effects than universally delivered programmes,⁹ although issues around identifying young people and improving compliance would need to be addressed. Lower intensity and more cost-effective models of delivery could also be employed. For example, using an indicated approach, brief group CBT, bibliotherapy and group supportive-expressive interventions have all been found to have long-term benefits (1- and 2-year follow-up) in high-risk adolescents, with bibliotherapy being a particularly economical approach.⁷¹ Internet-based depression prevention interventions have been shown to have short-term benefits, although evidence of long-term effects using this approach is inconsistent.⁷² Given the popularity of the internet and social-networking websites among young people, internet-assisted delivery would be worth investigating further.

The age at which depression prevention programmes are introduced also needs to be considered. Symptoms of depression were already common in the year 8 students in the current study and it may be necessary to start prevention programmes at a younger age. It has been suggested that preventative interventions should occur before the general increase in depressive symptoms at about age 13–14 years, and continue during the time when rates and symptoms would be expected to rise, at about age 15–18 years.⁷³ However, others have suggested that the optimal time for depression prevention programmes may actually be in late childhood (9–10 years of age).^{74–76}

Finally, preventing depression in adolescents is challenging. It is a complex problem, in which genetic and developmental factors, the role of puberty and sex hormones, and psychosocial stress and adversity all play an important role.⁵⁹ CBT-based prevention and early intervention programmes may have an important role to play in community settings if these can be refined and effects consistently demonstrated. However, a broader approach is likely to be required to preventing depression in young people that takes into account factors such as their school and home environment and facilitates timely access to effective health-care services when necessary.

Strengths and limitations

This study involved a large cohort, with an excellent response rate, low attrition from interventions and good treatment fidelity within participating schools. Furthermore, this was a multicentre study including a range of schools in terms of size, demographics and location (urban, suburban, semi-rural). These data therefore provide a strong profile of mental health in this age group in the UK. We also sought to maximise the clinical effectiveness of the intervention by selecting a programme that had been shown to be efficacious in smaller trials, providing external facilitators to deliver the programmes, ensuring that they had sufficient training and ongoing supervision and assessing treatment fidelity. The inclusion of both 6- and 12-month follow-up assessments with good retention rates (> 80%) provided high-quality data for the longitudinal analysis and the trial had sufficient power for the planned analysis.

Limitations included some sampling biases that need to be considered when generalising from the findings. There were initial difficulties in recruiting schools for the trial, and the participating schools had a greater percentage of white students, were more academically able and had fewer students eligible for free school meals than UK national averages. There was also selective drop-out in those who were slightly older, not living with both parents, using alcohol and cannabis and bullying others at baseline, although multiple imputation of missing data did not have any impact on the main conclusions of the trial. The assessments relied on self-report and no clinical or diagnostic interviews were used, although this was

because we were interested in symptoms of and risk for depression rather than identifying established clinical cases of depressive disorder. Young people were not blinded to trial allocation after randomisation as this was not feasible, but assessments were self-completed by young people in classes so the potential for researchers to influence responses was minimal.

The collection of cost data and cost-effectiveness analysis were carried out according to current best practice methods for conducting economic evaluation alongside randomised trials.^{49,58} Analysis was based on effectiveness measures of established validity and reliability and the self-report data were relatively complete. It incorporated a relatively detailed 'bottom-up' costing of classroom-based CBT and attention control PSHE, based on accurate records of staffing, resources and other activities required. Efforts have been made to adjust for or omit those intervention costs (sometimes called 'protocol-driven' costs) which would, in all likelihood, not be incurred outside of a research trial context, or those which would not be incurred with the widespread roll-out of such interventions (e.g. adaptation of course materials). The statistical methods of the cost-effectiveness analysis have accounted for the clustered nature of the data and correlation between costs and effects. Sensitivity analyses, using the bootstrap, were also used to validate the estimates from the parametric methods, given the skewness that is typical of cost and resource use data.

There are some limitations to the cost-effectiveness analysis that should be acknowledged. Individuals with relevant cost and effectiveness data at all three assessment time points (which are necessary for calculating both the costs and the QALYs) inevitably represent a smaller proportion of all those randomised than those with an assessment for the primary end point only. However, given the level of completeness of the data collection relative to that for the primary outcome (SMFQ), and the overall similarity of the subsample characteristics of those used in the cost-effectiveness analysis, the cost and EQ-5D data were still adequately complete and representative to justify a complete case analysis. As with the SMFQ data at 12 months, those who were in the younger year groups at baseline (8, 9 and 10) and those living with both parents tended to have more complete data for the cost and EQ-5D questions. In addition, while the EuroQol Group endorses the use of the EQ-5D in people down to the age of 12 years, its reliability and interpretation in this age group (e.g. in relation to what constitutes usual activities) is not well researched. The fact that the recently developed EQ-5D-Youth instrument yields different frequencies of reported problems from the EQ-5D supports the view that the dimensions of quality of life and problem levels may have different meanings in younger age groups.⁷⁷ Moreover, for the preference-based EQ-5D index scores, adult valuations have been used, implicitly assessing how these health states would be valued when experienced by adults.

Service use questions mostly sought data on health service use for any health reason (whether or not related to mental health issues), which is standard best practice for data collection alongside trials. However, to limit the size of the questionnaire, questions about support or care provided outside hospitals asked this only in relation to seeing professionals about psychological problems (i.e. for 'problems such as worry, anxiety or unhappiness'). Despite the pilot work, some questions relating to service use could have been more clearly worded or laid out. Children had difficulty clearly recalling and spelling the names of drugs that they were taking for anxiety or depression and these data had to be omitted from the cost and cost-effectiveness analyses owing to poor quality. Lastly, without linked data collection from health or other support services, it is not possible to assure the validity and reliability of the self-report of service use data from children of these ages. Other research, in adults, suggests that patient self-report agrees closely with service/provider records for hospital use, with recall periods of up to 6 months, but that for medication and other care products patient recall can be quite incomplete.⁷⁸ However, as we were mainly interested in differences in service use between the trial arms, these issues would affect all trial arms fairly equally and only modestly affect the size of any estimated cost differences.

Research recommendations

The null effect reported in this study leaves unanswered the key question of how depression in children and adolescents can be prevented. Despite the appeal and reach of universal prevention programmes, those delivered in secondary schools have little effect on reducing symptoms of depression in adolescents.

- If universal approaches are to be pursued then the clinical effectiveness and cost-effectiveness of universal prevention programmes with younger children (aged 10–11 years) before the incidence of depression increases should be investigated.
- The clinical effectiveness and cost-effectiveness of alternative preventative approaches should be investigated; for example, indicated programmes targeting those who already have increased symptoms or are at high risk (e.g. mother has depression).
- Indicated approaches should report upon reach and acceptability as well as clinical effectiveness and cost-effectiveness.
- Current preventative models involve the delivery of a single intervention at one point of time. The development and clinical effectiveness of alternative approaches, for example brief interventions woven throughout school life designed to enhance psychological resilience over time, should be assessed.

Chapter 6 Conclusions

Universally delivered classroom-based prevention programmes to reduce symptoms of depression in adolescents are an appealing concept in terms of their potential convenience and reach. However, our study indicates that classroom-based CBT programmes aiming to prevent depression delivered in schools may not be clinically effective and indeed may increase reporting of symptoms.

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Author contributions

PS was the principal investigator for the project and led on developing the rationale and design for the study and interpretation of findings. RP was the trial manager. KS led the trial team in the East Midlands. AAM and MS carried out the statistical analysis. RA and OCU carried out the economic analysis. JT, EC and LG carried out the qualitative analysis. These co-authors also drafted specific sections of the results for this report relating to their areas of expertise, which were collated and edited by RP. KS, RA and GL provided guidance throughout the project on design, analysis and interpretation. All authors had access to all study data and participated in interpretation of the findings, contributed core ideas and were involved in critically revising the report for important intellectual content. All authors read and approved the final report.

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Appendix 1 Assessments

Promise Project

Time 1 Booklet

ID Code

- - -

Date of birth _____

/ /

Tutor Group _____

Gender

Male ₀ Female ₁

Assessment Booklet Version 2 September 2009

You and your family

- Ethnicity**

How would you describe the ethnic status (or cultural group) of you and your parents? Please tick **one** box for each person.

	You	Mother	Father
White	<input type="checkbox"/> ₁	<input type="checkbox"/> ₁	<input type="checkbox"/> ₁
Black Caribbean	<input type="checkbox"/> ₂	<input type="checkbox"/> ₂	<input type="checkbox"/> ₂
Black African	<input type="checkbox"/> ₃	<input type="checkbox"/> ₃	<input type="checkbox"/> ₃
Black other	<input type="checkbox"/> ₄	<input type="checkbox"/> ₄	<input type="checkbox"/> ₄
Indian	<input type="checkbox"/> ₅	<input type="checkbox"/> ₅	<input type="checkbox"/> ₅
Pakistani	<input type="checkbox"/> ₆	<input type="checkbox"/> ₆	<input type="checkbox"/> ₆
Bangladeshi	<input type="checkbox"/> ₇	<input type="checkbox"/> ₇	<input type="checkbox"/> ₇
Chinese	<input type="checkbox"/> ₈	<input type="checkbox"/> ₈	<input type="checkbox"/> ₈
Other	<input type="checkbox"/> ₉	<input type="checkbox"/> ₉	<input type="checkbox"/> ₉
Dual heritage/mixed race:	<input type="checkbox"/> ₁₀	<input type="checkbox"/> ₁₀	<input type="checkbox"/> ₁₀

- Who do you live with?**

Please tick one box to show who you **usually** live with (apart from any brothers/sisters).

- My mum and dad ₁
- My mum & her partner/new husband ₂
- My dad & his partner/new wife ₃
- My mum ₄
- My dad ₅
- Relatives/friends ₆
- Other, please describe ₇
- _____

A. How have you been feeling?

These questions are about how you have been **feeling** recently. Please tick the box which best describes how you feel.

	Never	Sometimes	Often	Always
1. I worry about bad things happening to me	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
2. I worry that something bad will happen to me	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
3. I worry about what will happen	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
4. I worry that something awful will happen to someone in my family	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
5. I think about death	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
6. I worry about being away from my parents	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
7. I feel scared if I have to sleep on my own	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
8. I would feel afraid of being on my own at home	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
9. I would feel scared if I had to stay away from home overnight	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
10. I am afraid of being in crowded places	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
11. I worry about making mistakes	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
12. I worry that I will do badly at my school work	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
13. I worry when I think I have done poorly at something	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃

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	Never	Sometimes	Often	Always
14. I feel scared when I have to take a test	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
15. I feel afraid if I have to talk in front of my class	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
16. My heart suddenly starts to beat too quickly for no reason	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
17. I suddenly start to tremble or shake when there is no reason for this	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
18. When I have a problem, I feel shaky	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
19. When I have a problem, my heart beats really fast	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
20. I suddenly feel as if I can't breathe when there is no reason for this	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
21. Nothing is much fun anymore	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
22. I feel sad or empty	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
23. I am tired a lot	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
24. I feel like I don't want to move	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
25. I have problems with my appetite	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃

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B. How is your mood?

These questions are about how you have been **feeling** or **acting** recently.

For each question, please put a tick to show how much you have felt or acted this way **in the past two weeks.**

	Not True	Sometimes	True
1. I felt miserable or unhappy	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂
2. I didn't enjoy anything at all	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂
3. I felt so tired I just sat around and did nothing	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂
4. I was very restless	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂
5. I felt I was no good anymore	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂
6. I cried a lot	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂
7. I found it hard to think properly or concentrate	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂
8. I hated myself	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂
9. I felt I was a bad person	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂
10. I felt lonely	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂
11. I thought nobody really loved me	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂
12. I thought I could never be as good as other young people	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂
13. I felt I did everything wrong	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂

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C. What do you think about yourself?

These questions are about the way you **think** about **yourself**.

Please tick the box to show how much you agree or disagree with each statement.

	Strongly Agree	Agree	Disagree	Strongly Disagree
1. On the whole, I am satisfied with myself	<input type="checkbox"/> ₃	<input type="checkbox"/> ₂	<input type="checkbox"/> ₁	<input type="checkbox"/> ₀
2. At times I think I am no good at all	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
3. I feel that I have a number of good qualities	<input type="checkbox"/> ₃	<input type="checkbox"/> ₂	<input type="checkbox"/> ₁	<input type="checkbox"/> ₀
4. I am able to do things as well as most other people	<input type="checkbox"/> ₃	<input type="checkbox"/> ₂	<input type="checkbox"/> ₁	<input type="checkbox"/> ₀
5. I feel that I do not have much to be proud of	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
6. I certainly feel useless at times	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
7. I feel that I am a person of worth, at least as equal as others	<input type="checkbox"/> ₃	<input type="checkbox"/> ₂	<input type="checkbox"/> ₁	<input type="checkbox"/> ₀
8. I wish I could have more respect for myself	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
9. All in all, I am inclined to feel that I am a failure	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃
10. I take a positive attitude towards myself	<input type="checkbox"/> ₃	<input type="checkbox"/> ₂	<input type="checkbox"/> ₁	<input type="checkbox"/> ₀

D. How do you think about things?

Listed below are some of the thoughts that children and adolescents have said “**pop into their heads**”.

Tick a box to show how often, if at all, each thought has popped into your head over the **past week**.

	not at all	sometimes	fairly often	often	all the time
1. I can't do anything right	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
2. I am worthless	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
3. Nothing ever works out for me anymore	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
4. It's my fault that things have gone wrong	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
5. I've made such a mess of my life	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
6. I'll never be as good as other people are	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
7. I am a failure	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
8. Life is not worth living	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
9. I will never overcome my problems	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄
10. I hate myself	<input type="checkbox"/> ₀	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄

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E. How do you feel about school?

These questions are about how you feel about school. Tick a box to show how true each statement is for you.

	Not at all true			Completely true	
1. I feel like a real part of this school.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
2. Sometimes I don't feel as if I belong here.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
3. People at this school are friendly to me.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
4. I am treated with as much respect as other students.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
5. I can really be myself at this school.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
6. The teachers here respect me.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
7. I wish I were in a different school.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅
8. I feel proud of belonging to this school.	<input type="checkbox"/> ₁	<input type="checkbox"/> ₂	<input type="checkbox"/> ₃	<input type="checkbox"/> ₄	<input type="checkbox"/> ₅

F. Your relationships with other people

1. Listed below are three descriptions of how people feel in their relationships with others. Which description below best describes how you generally feel?
Read each description below and then write A, B, or C here:

A. 'I find it easy to become close friends with others. I trust them and I am comfortable depending on them. I do not worry about being abandoned or about another person getting too close to me.'

B. 'I am uncomfortable being close friends with others. I find it difficult to trust them completely, difficult to depend on them. I get nervous when another person wants to become close friends with me. Friends often come more close to me than I want them to.'

C. 'I often find that others do not want to get as close as I would like them to be. I am often worried that my best friend doesn't really like me and wants to end our friendship. I prefer to do everything together with my best friend. However, this desire sometimes scares other people away.'

G. How is your Health?

Place a tick in one box in each group to show which statement best describes your **own health today**.

1. Mobility

I have no problems in walking about 1

I have some problems in walking about 2

I am confined to bed 3

2. Self-Care

I have no problems with self-care 1

I have some problems washing or dressing myself 2

I am unable to wash or dress myself 3

3. Usual Activities (*e.g. work, study, family or leisure activities*)

I have no problems with performing my usual activities 1

I have some problems performing my usual activities 2

I am unable to perform my usual activities 3

4. Pain/Discomfort

I have no pain or discomfort 1

I have moderate pain or discomfort 2

I have extreme pain or discomfort 3

5. Anxiety/Depression

I am not anxious or depressed 1

I am moderately anxious or depressed 2

I am extremely anxious or depressed 3

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To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to draw a straight line on the thermometer to show how good or poor your health is today.

Best
imaginable
health state

100

90

80

70

60

50

40

30

20

10

0

Worst
imaginable
health state

H. Days off school

1. Have you had any days off school in the **last 6 months?**

Yes ₁ No ₀

If YES,

2. How many days have you been off school?

3. How many of these days were due to worry, anxiety or unhappiness?

4. How many days did your mum/dad/carer have to take off work to look after you?

Stayed overnight in Hospital

5. Have you stayed **overnight in hospital in the last 6 months?** Yes ₁ No ₀

If YES, what was the reason(s) for your stay in hospital?

6. Admission 1.....

7. Number of days you spent in hospital

8. Admission 2.....

9. Number of days you spent in hospital

10. Admission 3.....

11. Number of days you spent in hospital

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Attended Hospital

12. Have you needed to attend **Accident & Emergency** ('A & E') in the **past 6 months?**

Yes ₁ No ₀

13. If **YES**, how many times have you attended A&E

What was the reason for your visit(s)?

14. Visit 1.....

15. Visit 2.....

16. Visit 3.....

Have you visited **Hospital for an appointment** in the **past 6 months?**

17. Yes ₁ No ₀

18. If **YES**, how many times have you visited Hospital for an appointment

What was the reason for your visit(s)?:

19. Visit 1.....

20. Visit 2.....

21. Visit 3.....

Visited your Family Doctor

22. Have you visited your **Family Doctor** in the **past 6 months?**

Yes ₁ No ₀

23. If **YES**, how many times have you visited your Family Doctor

24. How many of these visits were about worry, anxiety or unhappiness?

Seen anyone about psychological problems?

25. Have you seen anyone about problems such as worry, anxiety or unhappiness in the last 6 months?

Yes ₁ No ₀

If yes, please show who you have seen out of the options below. Write the number of times you have seen each person.

	Number of times seen
a) Nurse at my GP practice	
b) School Nurse	
c) Counsellor	
d) Child Mental Health Service	
e) Child Psychologists	
f) Social Worker	
g) Someone else	

26. If stated 'someone else', please say who.....

Depression and Anxiety

27. Has a doctor ever told you that you have **depression**?

Yes ₁ No ₀

28. Has a doctor ever told you that you have **anxiety**?

Yes ₁ No ₀

29. Have you been taking any medication for **anxiety or depression** over the **last 6 months**?

Yes ₁ No ₀

If Yes, What are the medicines called (don't worry about the spelling)?

30. Medicine 1.....

31. Medicine 2.....

How long did you take them (or have been taking them)?

32. Medicine 1.....

33. Medicine 2.....

I. Your life

These questions are about you and your life. Your replies are **confidential** and this information will **not be shared with the school or your parents/carers**.

Your responses are anonymous and you can not be identified from this questionnaire.

Self-harming

1. Have thought about hurting yourself, even if you would not really do it, in the **last 6 months**?

- | | | |
|-----------------|--------------------------|---|
| Not at all | <input type="checkbox"/> | 0 |
| Once or twice | <input type="checkbox"/> | 1 |
| 3 or more times | <input type="checkbox"/> | 2 |

2. Have you ever hurt yourself on purpose in any way (e.g. by taking an overdose of pills or by cutting yourself) in the **last 6 months**?

- | | | |
|-----------------|--------------------------|---|
| Not at all | <input type="checkbox"/> | 0 |
| Once | <input type="checkbox"/> | 1 |
| 2 or more times | <input type="checkbox"/> | 2 |

Drinking Alcohol

3. Tick the box that describes your drinking of alcohol over the **last 6 months**

- | | | |
|--|--------------------------|---|
| I have never drunk alcohol | <input type="checkbox"/> | 0 |
| I have drunk alcohol once or twice | <input type="checkbox"/> | 1 |
| I have drunk alcohol more than 2-4 times per month | <input type="checkbox"/> | 2 |
| I have drunk alcohol more than once per week | <input type="checkbox"/> | 3 |

Use of Cannabis

4. Tick the box that describes your use of cannabis over the **last 6 months**

- I have never smoked cannabis ₀
- I have smoked cannabis once or twice ₁
- I have smoked cannabis 2-4 times a month ₂
- I have smoked cannabis more than once per week ₃

Use of other Drugs

5. Tick the box that describes your use of other drugs (e.g. amphetamines, LSD, Ecstasy, Cocaine, Ketamine, Crack, Heroin, etc) over the **last 6 months**

- I have never taken any of these drugs ₀
- I have taken drugs like this once or twice ₁
- I have taken drugs like this 2-4 times per month ₂
- I have taken drugs likes this more than once per week ₃

Bullying

6. Over **the past term** how often have you been bullied (e.g. verbally such as being teased or made fun of, or physically such as being hit or threatened)?

- I haven't been bullied ₀
- Once or twice ₁
- 2 or 3 times a month ₂
- About once per week ₃
- Several times a week ₄

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7. How often have you taken part in **bullying other students** (e.g. verbally or physically) over **the past term?**

I haven't bullied other students 0

Once or twice 1

2 or 3 times a month 2

About once per week 3

Several times a week 4

Thank you for answering these questions

You will be given an information sheet about who you can contact if you would like to talk to anyone about any of the issues covered in this questionnaire

Process Evaluation: Feedback Questionnaires**Young Person: PSHE Evaluation Questionnaire**

ID: _____

We would like to ask you what you thought of your **PSHE and Citizenship** over the **last 12 months**. Sometimes these are called 'learning for life' lessons or 'project days'. Whatever kind of PSHE and Citizenship you have had, we are interested in your opinions about it, whether they are positive or negative, so that we can improve things. Your answers will be completely confidential.

If you completed a program called **RAP** over the last year, we'd especially like to know what you thought of these lessons. If you did RAP, please tell us about these lessons only (i.e. don't include the rest of your PSHE lessons or project days last year). However, if you didn't do RAP, we'd like to know about your PSHE and Citizenship lessons overall over the past year.

Please answer the following questions as honestly as possible by **circling ONE number** under each question. Please ask the researchers if you need any help.

1. What did you think of your PSHE and Citizenship lessons over the last 12 months?*(Please circle ONE number under each question below)***a. Overall, how much did you like your PSHE/Citizenship lessons?**

0	1	2	3	4	5	6	7	8	9	10
Not at all										A great deal

b. How relevant were the PSHE/Citizenship lessons for people your age?

0	1	2	3	4	5	6	7	8	9	10
Not at all										A great deal

c. How useful was what you learnt in PSHE/Citizenship in your day-to-day life?

0	1	2	3	4	5	6	7	8	9	10
Not at all										A great deal

2. How much did your PSHE/Citizenship lessons over the last six months help you?

0	1	2	3	4	5	6	7	8	9	10
Not at all										A great deal

On a scale of 0 to 10, with 0 being 'not at all' and 10 being 'a great deal', how much do you think PSHE/Citizenship has helped you to:

*(Please circle ONE number for each question)***a. Feel happier in your mood**

0	1	2	3	4	5	6	7	8	9	10
Not at all										A great deal

b. Worry less

0 1 2 3 4 5 6 7 8 9 10
 Not at all A great deal

c. Cope with worries when you have them

0 1 2 3 4 5 6 7 8 9 10
 Not at all A great deal

d. Solve problems

0 1 2 3 4 5 6 7 8 9 10
 Not at all A great deal

e. Recognise your strengths

0 1 2 3 4 5 6 7 8 9 10
 Not at all A great deal

f. Stop disagreements from turning into arguments

0 1 2 3 4 5 6 7 8 9 10
 Not at all A great deal

g. Get on better with other people

0 1 2 3 4 5 6 7 8 9 10
 Not at all A great deal

h. Ask people for help when you need it

0 1 2 3 4 5 6 7 8 9 10
 Not at all A great deal

Research/Psychology Assistant Feedback Form: RAP

Thank you for all your hard work on the PROMISE Project. We'd like your feedback about RAP so that we can improve it for future use. We'd really appreciate it if you could complete the following questionnaire. Your answers will be completely confidential.

1. **Since September 2009, how many different classes have you worked with (across all the schools)?**

Year 8 _____ Year 9 _____ Year 10 _____ Year 11 _____

2. **Which school(s) have you worked in?** _____

How much do you agree/disagree with the following statements? (please circle ONE number)

Training & Supervision:

3. **I felt I had sufficient initial training to prepare me for my role as RAP leader**

Strongly disagree 0 1 2 3 4 Strongly agree

4. **The supervision sessions provided enough on-going support to manage the demands of the post effectively.**

Strongly disagree 0 1 2 3 4 Strongly agree

Delivering RAP:

5. **Overall, I enjoyed leading the RAP sessions**

Strongly disagree 0 1 2 3 4 Strongly agree

6. **I found the role very challenging**

Strongly disagree 0 1 2 3 4 Strongly agree

7. **I think RAP will make a genuine difference to the mental health of the young people who took part**

Strongly disagree 0 1 2 3 4 Strongly agree

8. **Overall, the level of student engagement I encountered in my sessions was good**

Strongly disagree 0 1 2 3 4 Strongly agree

Please tell us about the positives and negatives of the post in general:

9. **What were the most positive things about undertaking your role?**

a.)

b.)

c.)

10. What were the most negative things about undertaking your role?

- a.)
- b.)
- c.)

Please tell us about the positives and negatives of RAP:

11. What sessions/activities/concepts in the RAP worked best?

- a.)
- b.)
- c.)

12. What sessions/activities/concepts in the RAP did not work very well?

- a.)
- b.)
- c.)

13. If you were revising the RAP, what would you do differently next time around?

- a.)
- b.)
- c.)

14. Do you have any specific feedback surrounding the following areas?

- a.) Age relevance of RAP material
- b.) Pitching RAP for different abilities
- c.) Working with teachers
- d.) Variation in tasks within sessions
- e.) Communication: within staff team and with teachers/schools

15. Are there any other comments you would like to make?

Thank you very much for your feedback.

PROMISE Project: Teacher Feedback Questionnaire

School ID: _____

Date: _____

We are currently reviewing the Resourceful Adolescent Program (RAP) and Enhanced PSHE programs so that they can be improved before any subsequent roll out at the end of the trial. We would be very grateful for your feedback.

We are keen to hear about both the positive and negative aspects of the program, so please be as honest as possible. Your responses will be kept completely confidential.

The Resourceful Adolescent Program (RAP)

1. How many of your classes took part in the RAP program? *If none, please go to Q15 on p. 4.*

Year 8 _____ Year 9 _____ Year 10 _____ Year 11 _____

2. Please tell us what you thought the most positive things were about the RAP program:

1.
2.
3.

3. Please tell us what you thought the most negative things were about the RAP program:

1.
2.
3.

4. Overall, how well organised did you think the RAP sessions were? *(Please circle one number)*

0	1	2	3	4
Very poorly organised				Very well organised

5. Overall, how relevant was the content of the RAP program for the young people in your classes? *(Please circle one number)*

0	1	2	3	4
Not at all relevant				Completely relevant

6. Overall, how age-appropriate was the content of the RAP program for the young people in your classes? *(Please circle one number)*

0	1	2	3	4
Inappropriate for this age group				Completely age appropriate

7. To what extent do you think RAP will help the young people in your classes with their mood? (*Please circle one number*)

0 1 2 3 4
Not at all Very
helpful helpful

8. How useful do you think RAP will be in helping young people deal with the challenges they face in day to day life? (*Please circle one number*)

0 1 2 3 4
Not at all Very
useful useful

9. Did you feel that the number of sessions was appropriate?

Too few..... 0

About right..... 1

Too many..... 2

10. Ideally, how many sessions do you think there should be in the RAP program?

.....

11. Do you have any suggestions on how the RAP program could be improved?

- a) Lesson structure & delivery for RAP (e.g. ratio of small group: whole class work, classroom management, volume of content for each lesson)
- b) RAP workbooks (content & presentation)
- c) Other RAP materials (e.g. examples, videos)
- d) RAP research staff (e.g. skills & training needs, communication)
- e) Anything else?

12. Would you feel comfortable delivering the RAP on your own in future (either as it stands, or in a slightly adapted form)? (*Please circle one number*)

0 1 2 3 4
Completely Completely
uncomfortable comfortable

13. Will you use any ideas from the RAP after the PROMISE project has finished?

No, none of it.....₁

Some of it.....₂

Yes, quite a lot of it.....₃

14. If so, what will you use?

Focus Group and Interview Schedules

Post-RAP Young Person Focus Group

Group ID and size:

Student IDs:

Facilitator initials:

Date of interview:

Introduction

- We would like you to give us some feedback on what you thought of the RAP program
- It's the first time this program has been run in UK, so we need to know what was good and bad about it so that we can do it better next time
- You have been picked at random from everyone who took part in the RAP lessons
- Your comments will be completely confidential
- We would really like you to be completely honest with us - both good and bad feedback is really important
- We'd like to hear everyone's views
- Establish group rules – confidentiality, listen to other people's views, everyone gets a chance to contribute, try to talk one at a time
- Consent to audio-record

Icebreaker activity:

- Write names on sticky labels and put them on
- Each person says their name and says the first word that springs in to their mind about RAP

Topics:

1. Overall impressions of RAP

[Have session summary sheet and RAP workbook to show]

- a) What did you think of the **RAP lessons overall**?
- b) Did any of the sessions really **stand out** for you?
[Show lesson summary sheet]
- c) What was your **favourite part** of RAP?
Why? What did you like about it?
- d) Was there anything you **didn't like** about RAP?
- e) What did you think of the **people** who ran the RAP lessons?
- f) What was it like having these **extra people** in your PSHE classes?
- g) What did you think of the **RAP workbook**?
- h) What would you **change** about the workbook?
- i) Did you **understand** the RAP sessions?
- j) Were the tasks and examples **clear**?
- k) Which bits were the **most tricky**?

- l) What did you think about the **group work**?
Too much? Too little? Size of groups?
- m) Did you get enough **chances to contribute** your ideas?
- n) If you were going to be a **RAP leader, what would you change** about RAP?
Would you run the sessions differently?
Would you change the tasks or examples?
What could we do to improve the sessions?

2. Using the skills you learnt

- a) Overall, do you think RAP has **helped you** or any of your friends in any way?
How? Did you find anything in particular helpful?
- b) Did any of the **skills or ideas** that were talked about in RAP stand out to you as being **helpful** for young people?
[Refer to session summary sheet]
- c) Have you (or anyone you know) **used** any of the **skills or ideas** you learnt in RAP?
Which ones? Can you give an example of how you/they used this skill?
- d) Do you think that you might use these skills in the **future**?
- e) If you've taken **ONE thing** away from RAP, what is it?

3. Talking with others

- a) Has anyone talked about any of the ideas **discussed** in RAP with **anyone else at your school**?
If so, who? Were they in your year group?
Did you talk about RAP with anyone in a different year group? If so, which year?
- b) If you talked about RAP with other people, **what sort of things** did you talk about?
E.g. what you'd done in the lessons, some of the ideas you learnt, whether you liked the lessons or not.
- c) Did anyone talk about any of the ideas in RAP with **anyone else** (outside school)?
E.g. Family, friends outside of school. If so who?
What sort of things did you talk about?
- d) Have you heard anything about RAP in school outside of your PSHE lessons/project days?
For example, have your teachers spoken about it in assembly, or have some of your teachers mentioned things you learnt in RAP in other lessons? If so, what was said and when?

4. Any other comments

Is there anything else you would like to say about RAP that we haven't talked about?

Thank you very much for telling us what you thought about RAP.

PROMISE Project: RAP RA/PA Debriefing Interview Topic Guide

Introduction

- Thanks for assistance
- Opportunity to make changes & improve the RAP program
- Honest opinions – really want to hear about good and bad points so that we can improve
- Comments all confidential
- Audio-recording the interview – this will be transcribed and anonymised, but will be more accurate than notes

The PROMISE Project

1. What was your **overall impression** of the PROMISE Project?
2. What did you think of the **assessments**?
 - Were they well organised?
 - What about the length of the assessment sessions?
 - Were there any students who may have had problems with the assessments?
3. Did you feel you had enough **communication with the school**?
4. Did you feel you had enough **communication with the research team**?
5. Is there anything you would have **changed** about the project?

The RAP Program

Overall impressions

6. What were your **overall impressions** of RAP?
7. What did you **like** about RAP?
8. What parts of RAP were **not as good**?
9. What **changes** would you make?

Individual RAP sessions

[Hand out RAP session summary cards]

10. Did any of these sessions really **stand out** for you?
11. What did you think of the way lessons were **structured**?
12. What did you think of the **workbooks**?
13. What did you think of the **other materials**?

Delivery of RAP

14. How did you find the **teachers** you were working with in delivering the program?
15. Were they **helpful**?
16. Was **classroom management** an issue?
17. How did you find the **small group activities**?

Pupils' perceptions of RAP

18. How do you think the **pupils** found the RAP program?
19. What could be done to make them more **engaged**?
20. Do you think RAP **helped** the pupils? How?
21. **Which pupils** do you think would **benefit** most from RAP?
22. Who would benefit the least?

Training and supervision

23. Did you feel you had **sufficient training** for this post?
24. Did you find the **supervision** sessions useful?
25. Did you develop any **new skills** through this project?
26. Do you think you will use any of these skills in your work in the **future**?
27. What would you **change** about the supervision and training for this post?

Adopting the programs

28. If you had the opportunity, would you **continue to deliver** the RAP program after this project had finished?
29. How did you feel about **working in schools**?
30. What did you think of working on a **sessional** basis?
31. What did you think of the rate of **pay**?

Additional comments

Is there anything else you would like to say about the RAP Program?

Do you have any further comments about the PROMISE Project in general?

PROMISE Project: Co-ordinating Teachers' Debriefing Interview Topic Guide

Introduction

- Thanks for assistance
- Opportunity to make changes & improve the RAP program
- Honest opinions – really want to hear about good and bad points so that we can improve
- Comments all confidential
- Audio-recording the interview – this will be transcribed and anonymised, but will be more accurate than notes

RAP

Overall impressions

1. What were your **impressions** of RAP overall?
2. What did you **like** about RAP?
3. What parts of RAP were **not as good**?
4. What **changes** would you make?
5. What did you think about the **pitch** of RAP?
e.g. age appropriateness, student ability
6. How did it **compare to usual PSHE** lessons?

Individual RAP sessions

[Hand out RAP session summary cards]

7. Did any of the sessions really **stand out** for you?
8. What did you think of the way lessons were **structured**?
9. What did you think of the **workbooks**?
10. What did you think of the **other materials**?

Delivery of RAP

11. What did you think about the **research assistants** delivering the program ?
Were they helpful?
How did they get on with the teachers and young people?
12. Was **classroom management** an issue?
13. How did you find the small **group activities**?
14. Were the **notes** you were given **sufficient**?

Pupils' perceptions of RAP

15. How do you think the **pupils found** the RAP program?
16. What could be done to make them more **engaged**?
17. Do you think RAP **helped** the pupils?
If so, how?
If not, why?

18. Which pupils do you think would **benefit most** from RAP?
19. Who would **benefit the least**?

Maintenance of RAP

20. Do you intend to **continue** with the RAP program after the project had finished?

If yes:

- a. **Which parts** of it are you most likely to use?
- b. Will class **teachers be delivering it alone** or with support from other staff?
- c. Do you think class teachers would be **confident** in delivering this program alone?
- d. Would teachers need additional **training** to deliver RAP alone?
- e. Do you think the program will work as well **without the input of the Research Assistants**?

If no:

- i. **Why** not?
- ii. Would you continue if additional **resources** were available (e.g. external funding for RA support and workbooks/materials).

Costs

21. The RAP Program currently costs approximately **£37 per pupil** to deliver (*i.e. 9 initial sessions plus 2 booster sessions run by two research assistants and the class teacher*).
 - iii. Do you think this represents **good value for money**?
 - iv. How likely do you think the school would be to **continue** with the program at this cost if it was not funded from elsewhere?
22. The RAP Workbooks cost approximately **£5** each.
 - v. Do you think this represents **good value for money**?
 - vi. How likely do you think the school would be to **continue** to use the workbooks at this cost if they were not funded from elsewhere?

Enhanced PSHE (*i.e. Attention Control PSHE*)

23. What did you think of the **Enhanced PSHE program overall** (*where 2 researchers joined the teachers who were delivering their usual curriculum*)?
24. What did you **like** about Enhanced PSHE?
25. What aspects of it were **not as good**?
26. What **changes** would you make?
27. How did it **compare to usual** PSHE lessons?

The PROMISE Project overall

28. What was your **overall impression** of the PROMISE Project?
29. Did you feel you had enough **communication** with the research team?
30. Is there anything you would have liked us to **do differently**?

Delivery of PSHE in school: General

31. What do you think about the way that PSHE is **usually delivered in your school**?
32. What do you **like** about it?
33. Are there any aspects of the PSHE program that are **not so good**?
34. How do you think it **compares to other schools**?
35. Would you make any **changes** in the way PSHE is delivered in schools?
36. Has being involved in the **PROMISE project influenced** how PSHE is likely to be delivered in your school in future?

Additional comments

37. Is there anything else you would like to say about the **RAP** Program?
38. Do you have any further comments about the **PROMISE** Project in general?

Thank you for your feedback.

Appendix 2 PROMISE trial protocol

Promoting Mental Health in Schools Through Education (PROMISE) Project Protocol, HTA: 06/37/04

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: PROmoting **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.^{1,79–82} 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 trials 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.² Cumulative rates indicate that up to 20% will suffer at least one clinically depressive episode by the age of 18.¹ 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.^{83,84} 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.^{2–5} In addition, sub-threshold depressive symptoms in adolescence carry a similar risk to major depression for developing depression and suicidal behaviours later in life.⁸⁵ Whilst approximately 50% of children are estimated to spontaneously recover for the remaining half symptoms persist and significantly impair functioning.⁸² It is therefore particularly concerning to note that depression in adolescents often remains unrecognised and untreated.^{6,7}

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,¹⁴ Coping with Stress,¹⁶ Problem Solving for Life,¹⁷ FRIENDS,¹⁸ Resourceful Adolescent Programme¹⁰ and other CBT programmes.¹⁹ Some have been delivered as selective interventions to adolescents with elevated symptoms of depression^{23,24} whilst others have been delivered as universal interventions to whole populations.^{10,25} 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 Donovan¹⁷ 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.²⁰

The Cochrane review notes that targeted preventative interventions result in marginally greater reductions in depressive symptoms.¹ This may partly be explained by initial levels of depressive symptoms in the control groups.⁷¹ 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 3935 parents with depression or depressive symptoms were identified.²³ 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 the 147 young people allocated to the active intervention 41 (29%) did not attend.¹⁴ Other reviewers have noted recruitment rates of less than 50% and attrition rates of approximately 30% in targeted preventative studies.¹² 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.¹⁰ 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.^{10,16,17} Indeed, universal approaches achieve recruitment rates of 67%–88%.^{10,11,17} 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.²⁶ Indeed, Rose⁸⁶ 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.¹⁰ 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.¹¹ 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.¹² 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.¹² 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.^{1,20} 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 compiled 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 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 we 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 to examine the effect of the interventions on children at “high risk” of developing depression. This study is not concerned with whether or not children present with a clinical diagnosis of depression but is concerned with identifying children with elevated symptoms of low mood. To account for transient changes in mood, in the current study SMFQ 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 fulfill 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.^{27,32,33,87} Approx 6% of a community sample achieved a total cut-off score of 11 or more.⁸⁵ 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.²⁸ 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, humour 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.

5. Support Networks

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

6. 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 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.²⁹ 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%.^{14,16,25} Our local experience of running a universal emotional health prevention programme in 30 junior schools has resulted in recruitment rates in excess of 95%.⁸¹ 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 × £10, 20 × £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.⁸⁹ 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 worst, 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:

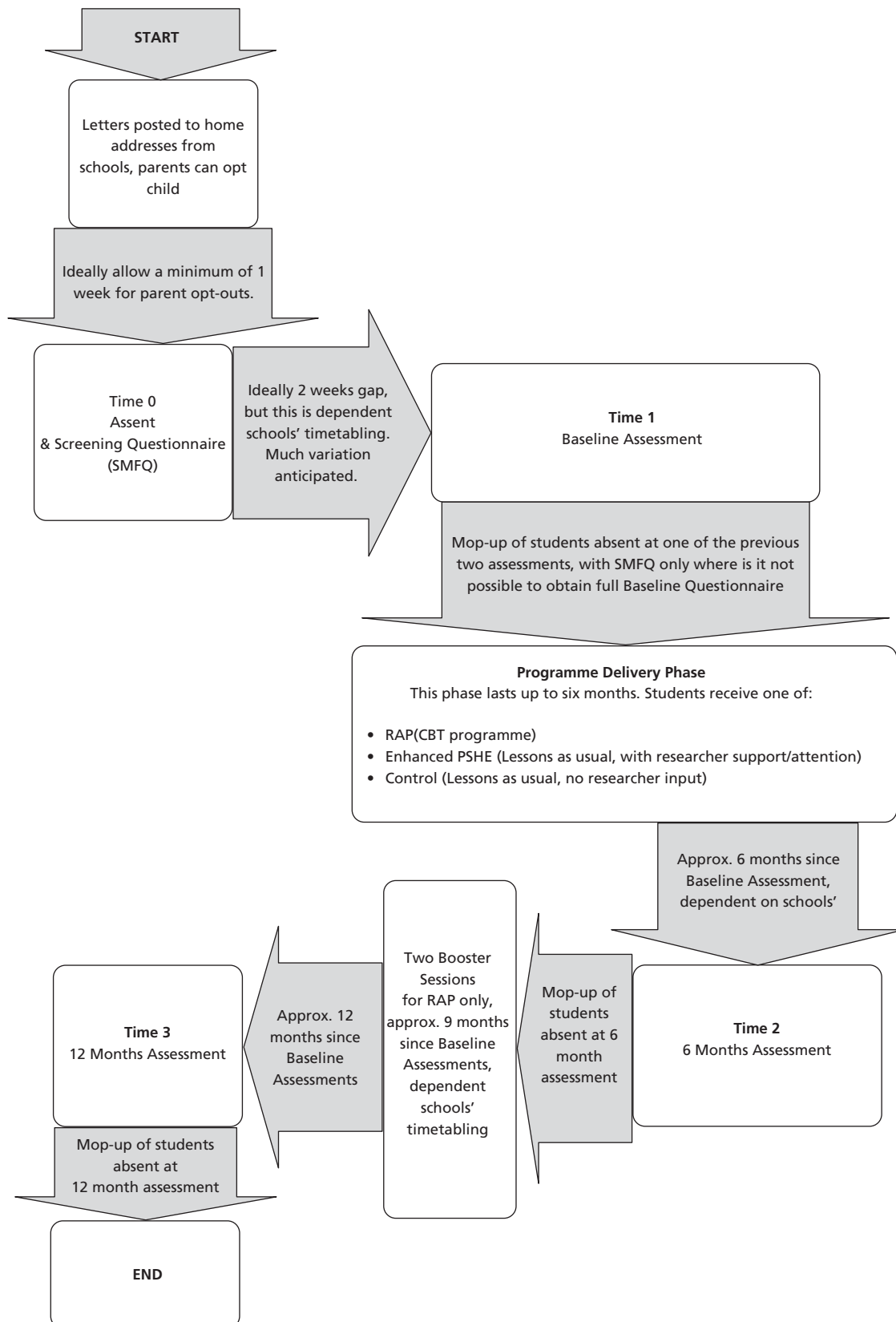


FIGURE 1 PROMISE Procedure Flowchart.

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.

3.8.2. 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;²⁷ This 13 item scale is derived from the long form (33 item) Moods and Feeling Questionnaire³⁰. 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 samples³¹. The SMFQ is a unifactorial scale with a robust single factor structure.^{90,91} Criterion validity (i.e. ability to predict clinical diagnosis) has been established within both clinical²⁷ and community samples^{33,92} 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 fulfill diagnostic criteria for clinical depression.^{31–33}
- Secondary Outcome Measure – Children's Automatic Thoughts Scale** (CATS;³⁴ 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.⁹³ 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.⁹⁴ The 10 item personal failure sub-scale will be used.
- Secondary Outcome Measure – Rosenberg Self-Esteem Inventory**³⁵ 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);**³⁶ 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 Scale⁹⁵ and after psychometric evaluation was reduced to 25 items.⁹⁶ 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.⁹⁷

3.9.2. School environment and bullying

- **School Connectedness Scale.**³⁷
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.**³⁹
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).

Additional data

- **Socio-demographic data:** will be collected at baseline (T1). Participants will complete a modified version of the Client Service Receipt Inventory (CSRI)⁴¹ 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;^{98,99} 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 assess 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^{100,101} peer attachment will be captured at baseline, 6 months, and 12 months using the Attachment Questionnaire for Children.³⁸ 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.^{100,101} 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 participants' 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 participants' behaviour. 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 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. 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 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.

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