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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Scientific summary

Classroom-based CBT in reducing symptoms of depression

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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.

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