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Humanistic counselling plus pastoral care as usual versus pastoral care as usual for the treatment of psychological distress in adolescents in UK state schools (ETHOS): a randomised controlled trial

Mick Cooper, Megan R Stafford, David Saxon, Jennifer Beecham, Eva-Maria Bonin, Michael Barkham, Peter Bower, Karen Cromarty, Charlie Duncan, Peter Pearce, Tiffany Rameswari, Gemma Ryan

Summary

Background About one in seven adolescents have a mental health disorder in England, UK. School counselling is one of the most common means of trying to address such a problem. We aimed to determine the effectiveness and cost-effectiveness of school-based humanistic counselling (SBHC) for the treatment of psychological distress in young people in England, UK.

Methods We did a two-arm, individually randomised trial in 18 secondary state-funded schools across the Greater London area of the UK. Participants were randomly assigned (1:1) using a centrally secure randomisation procedure with random permuted blocks to either SBHC plus schools' pastoral care as usual (PCAU), or PCAU alone. Participants were pupils aged 13–16 years who had moderate-to-severe levels of emotional symptoms (measured by a score of ≥5 on the Strengths and Difficulties Questionnaire Emotional Symptoms scale) and were assessed as competent to consent to participate in the trial. Participants, providers, and assessors (who initially assessed and enrolled participants) were not masked but testers (who measured outcomes) were masked to treatment allocation. The primary outcome was psychological distress at 12 weeks (Young Person's Clinical Outcomes in Routine Evaluation measure [YP-CORE]; range 0–40), analysed on an intention-to-treat basis (with missing data imputed). Costs were assessed at 24 weeks (Client Service Receipt Inventory and service logs). The trial was registered with ISRCTN, number ISRCTN10460622.

Findings 329 participants were recruited between Sept 29, 2016, and Feb 8, 2018, with 167 (51%) randomly assigned to SBHC plus PCAU and 162 (49%) to PCAU. 315 (96%) of 329 participants provided data at 12 weeks and scores were imputed for 14 participants (4%). At baseline, the mean YP-CORE scores were 20·86 (SD 6·38) for the SBHC plus PCAU group and 20·98 (6·41) for the PCAU group. Mean YP-CORE scores at 12 weeks were 16·41 (SD 7·59) for the SBHC plus PCAU group and 18·34 (7·84) for the PCAU group (difference 1·87, 95% CI 0·37–3·36; p=0·015), with a small effect size (0·25, 0·03–0·47). Overall costs at 24 weeks were £995·20 (SD 769·86) per pupil for the SBHC plus PCAU group and £612·89 (1224·56) for the PCAU group (unadjusted difference £382·31, 95% CI £148·18–616·44; p=0·0015). The probability of SBHC being more cost-effective reached 80% at a willingness to pay of £390 for a 1-point improvement on the YP-CORE. Five serious adverse events occurred for four participants in the SBHC plus PCAU group, all involving suicidal intent. Two serious adverse events occurred for two participants in the PCAU group, one involving suicidal intent.

Interpretation The addition of SBHC to PCAU leads to small reductions in psychological distress, but at an additional economic cost. SBHC is a viable treatment option but there is a need for equally rigorous evaluation of alternative interventions.

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Department of Psychology, University of Roehampton, London, UK (Prof M Cooper DPhil, M R Stafford BA, T Rameswari MSc); **Department of Psychology, University of Sheffield, Sheffield, UK** (D Saxon PhD, Prof M Barkham PhD); **Personal Social Services Research Unit, University of Kent, Canterbury, UK** (Prof J Beecham PhD); **Care Policy and Evaluation Centre, London School of Economics and Political Science, London, UK** (Prof J Beecham, E-M Bonin PhD); **National Institute for Health Research School for Primary Care Research, Centre for Primary Care and Health Services Research, University of Manchester, Manchester, UK** (Prof P Bower PhD); **Durham, UK** (K Cromarty); **British Association for Counselling and Psychotherapy, St John's Business Park, Lutterworth, UK** (C Duncan BSc, G Ryan MSc); **and Metanoia Institute, London, UK** (Prof P Pearce D Psych)

Correspondence to: Prof Mick Cooper, Department of Psychology, University of Roehampton, London SW15 4JD, UK
mick.cooper@roehampton.ac.uk

Introduction

Adolescence is a period of rapid biological, psychological, and social change, making young people particularly susceptible to mental ill health.[1] In England, approximately one in seven individuals aged 11–16 years have a mental disorder, with highest rates for young people living in low-income households.[2] Prevalence of mental disorders in individuals aged 5–15 years has risen over the past two decades.[2] Childhood disorders often continue into adulthood and can have longstanding social and economic consequences.[3] In the UK, the cost of mental health problems for children and young people across health, education, and social services has been estimated as approximately £1·5 billion per year.[4]

The UK Government plans to transform children and young people's mental health provision in England

Research in context

Evidence before this study

We did a systematic review to identify randomised controlled trials of humanistic counselling in schools with adolescents (aged 11–18 years). We searched Web of Science, PsychInfo, and PubMed from inception to Dec 17, 2018, using terms for "humanistic" and "therapy", in combination with ten terms covering population and trial design of interest. We also hand searched systematic reviews. Only articles in English were included. We identified 22 papers with relevant abstracts. Full text screening yielded 11 papers, referencing eight randomised controlled trials. Humanistic counselling showed similar results to cognitive behavioural interventions in improving emotional problems and functioning, but was less effective in reducing symptom severity. Four studies were UK-based, individually randomised pilot trials of the effects of adding 6–12 weeks of school-based humanistic counselling (SBHC) to pastoral care as usual (PCAU) for young people with emotional symptoms. Sample sizes varied from 32 to 64 adolescents. A meta-analysis of results on the principal outcome measure, the Young Person's Clinical Outcomes in Routine Evaluation, indicated that SBHC plus PCAU led to significant improvements over PCAU alone at 6 weeks (standardised mean difference 0·62, 95% CI 0·19 to 0·84; four studies) and the endpoint, 12 weeks (0·87, 0·49 to 1·25; three studies), but not at 24 weeks (12 weeks after completing therapy; 0·45, –0·14 to 1·03; one study). In terms of cost-effectiveness, just one of these studies did a pilot analysis and found some evidence that expenditure and cost savings were about equivalent. The study concluded that further investigations on a larger scale were warranted. An additional search for literature on cost-related findings for counselling services identified 36 relevant articles, but no further evidence on combined cost and outcome analyses.

Added value of this study

To our knowledge, ETHOS is the first adequately powered trial of SBHC for young people with emotional symptoms, one of the most common mental health interventions in the UK and worldwide. Additionally, compared with previous pilot studies, ETHOS has a comprehensive cost-effective analysis, examines outcomes on an intention-to-treat basis, reports adverse events, and bases the intervention on a comprehensive manual with dedicated adherence rating scale.

Implications of all the available evidence

The addition of SBHC to PCAU brings about small reductions in psychological distress, and these effects persist up to 3 months after counselling is completed. However, the intervention does not lead to reductions in other costs and is unlikely to be considered cost-effective. There is an urgent need for the evaluation of the effectiveness and cost-effectiveness of other mental health interventions in UK school settings.

at universal preventative, selective, and indicated levels, with a strategy developing mental health support in schools and colleges.[5] Mainstream mental health services can be hard for children and young people to access, might be stigmatising, and do not cater for levels of disturbance that do not meet diagnostic thresholds.[4] By contrast, schools might provide young people with unparalleled access to services, alleviating barriers such as time, location, and cost.[6] Consequently, school-based services can increase young people's use of mental health support[7] and reduce inequities in mental health care.[8]

One of the most common forms of school-based mental health intervention is counselling.[9] Studies indicate that counselling is viewed positively by many pupils, school staff, and local authority leads: providing accessible, independent, and non-stigmatising support.[9] School-based counselling is well established in over 60 countries worldwide, and is mandatory in at least 40 countries, including Wales.[10] In England, approximately 60% of secondary schools provide some form of on-site counselling.[9,11] Around 70 000–90 000 young people attend school-based counselling every year in the UK.[9]

Worldwide, school-based counselling takes different forms, including vocational guidance, psychoeducation, and cognitive behavioural therapy (CBT).[10] In more than 20 countries, including the UK, school-based counselling most commonly takes the form of a humanistic therapeutic intervention.[10] Such intervention is a form of psychological therapy that provides young people with an empathic, non-judgmental, and supportive relationship to find their own answers to their problems.[12] Unlike psychological interventions such as CBT, humanistic counselling is not specific to diagnosis. This non-specificity might make it particularly appropriate as a first-line indicated intervention within a school context, in which a diverse array of mental health challenges can exist (eg, bereavement, bullying, problems with parents). In 2013, standardised competences were developed in the UK for this form of intervention.[12] A national training curriculum was also developed and a large practitioner base exists.

Despite the existence of this intervention in schools, only a small body of supporting evidence exists. Data from four small trials have provided some initial indications of its effectiveness,[13–16] but only one trial assessed outcomes beyond the end of the intervention. Research into the cost-effectiveness of school-based humanistic counselling (SBHC) has also been scarce, with just one pilot study testing whether or not a cost-effectiveness evaluation is feasible, and providing a preliminary analysis of costs.[17]

Given the extensive use of humanistic counselling in schools plus a small evidence base, the aim of this study

was to complete the first adequately powered effectiveness and cost-effectiveness trial of SBHC for psychological distress in young people.

Methods

Study design

The effectiveness and cost-effectiveness trial of school-based humanistic counselling (ETHOS) study is a two-arm, parallel-group individually randomised controlled trial. The study was done in 18 secondary schools in the Greater London area of the UK (typical age range 11–18 years). Schools that already had counselling provision were ineligible for participation. Ethical approval for the trial was obtained under procedures agreed by the University Ethics Committee of the University of Roehampton (reference PSYC 16/227), on Aug 31, 2016. The protocol for the trial has been published.[18] Panels of young people and parents or carers recruited through the National Children's Bureau (NCB) and their Young Person's Advisory Group provided advice at all stages of the study.

A panel of young people (drawn from the Young Person's Advisory Group at the NCB) and a panel of parents and carers (drawn from the Parent and Carers Advisory Group at the NCB) met face-to-face with the researchers at the start of the project, with follow-up email consultation, to advise on the development of methods. Involvement of these panels was at the level of interactive advice and light consultation,[19] with guidance on the choice of outcome measures, the development of participant-facing materials, and strategies for reducing the burden of the research on participants. Self-nominating representatives from both panels then joined the Trial Steering Committee. This committee met, face-to-face, throughout the duration of the study; advising on all elements of study design, progress, and dissemination. The young people's and parent or carers' involvement in the Trial Steering Committee was supported by an NCB facilitator, who met with them before the start of committee meetings, and accompanied them during the meetings, to ensure that they understood the committee's aims and the issues emerging, and could express their views. Members of the Young Person's Advisory Group were aged 13–18 years, interested in issues of mental health and wellbeing, and not involved as participants in the trial. They were reimbursed for their time.

Participants

Eligible participants were aged 13–16 years and had moderate-to-severe levels of emotional symptoms (as indicated by a score of ≥5 on the Emotional Symptoms subscale of the self-report Strengths and Difficulties Questionnaire [SDQ], range: 0–10).[20] They had an estimated English reading age of at least 13 years, wanted to participate in counselling (as assessed by the assessor at the assessment meeting), had a school attendance record of 85% or higher (to increase likelihood of attending testing meetings), were not currently receiving another therapeutic intervention, and were considered capable of comprehending the outcome measurement forms. Adolescents were excluded if they were incapable of providing informed consent for counselling or their parent or carer had not provided informed consent, they were planning to leave the school within the academic year, or were deemed at risk of serious harm to self or others. Informed parent or carer consent was obtained either in writing, or via the telephone with a member of the pastoral care staff or an ETHOS researcher acting as a proxy to obtain consent in this way. Consent obtained by proxy was either audio-recorded or witnessed by a third party.

Participants were recruited through the schools' pastoral care teams who were briefed on the trial and, as a pre-screening stage, asked to identify potentially eligible young people. If those who were eligible expressed interest in participating in the trial, their parents or carers were contacted by a member of the pastoral care team to provide written consent. Young people were then referred for assessment by a member of the research team with experience of adolescent mental health work, who formally assessed their eligibility and invited them to provide written assent. Young people who were not eligible for participation were referred back to their pastoral care team to consider alternative sources of support.

Randomisation and masking

Young people were randomly assigned (1:1) to receive either SBHC, along with access to provision of pastoral care as usual (PCAU), or access to provision of PCAU alone. They were enrolled and assigned to trial groups by an assessor (ie, member of the research team), who did not carry out any further tests with that young person (although some of the assessors did act as testers for other young people). Our PCAU control condition was chosen to maximise the value of our study to policy makers, funders, and commissioners, providing direct evidence on the benefits or disbenefits of having a counselling service, compared with not having one. Allocation was concealed, done centrally via remote access to a secure randomisation procedure. This system used the method of permuted blocks within school strata, with adjacent block sizes, varying randomly within prespecified limits (from two to eight). Follow-up tests were done at weeks 6, 12, and 24, by testers who were masked to the allocations. The statistician who did the analysis was not involved in the administration of the trial, and treatment assignment was coded as non-identifiable categories for the primary analysis.

Procedures

SBHC is a manualised form of humanistic therapy based on evidence-based competences for humanistic counselling with young people aged 11–18 years.[12] SBHC assumes that distressed young people have the capacity

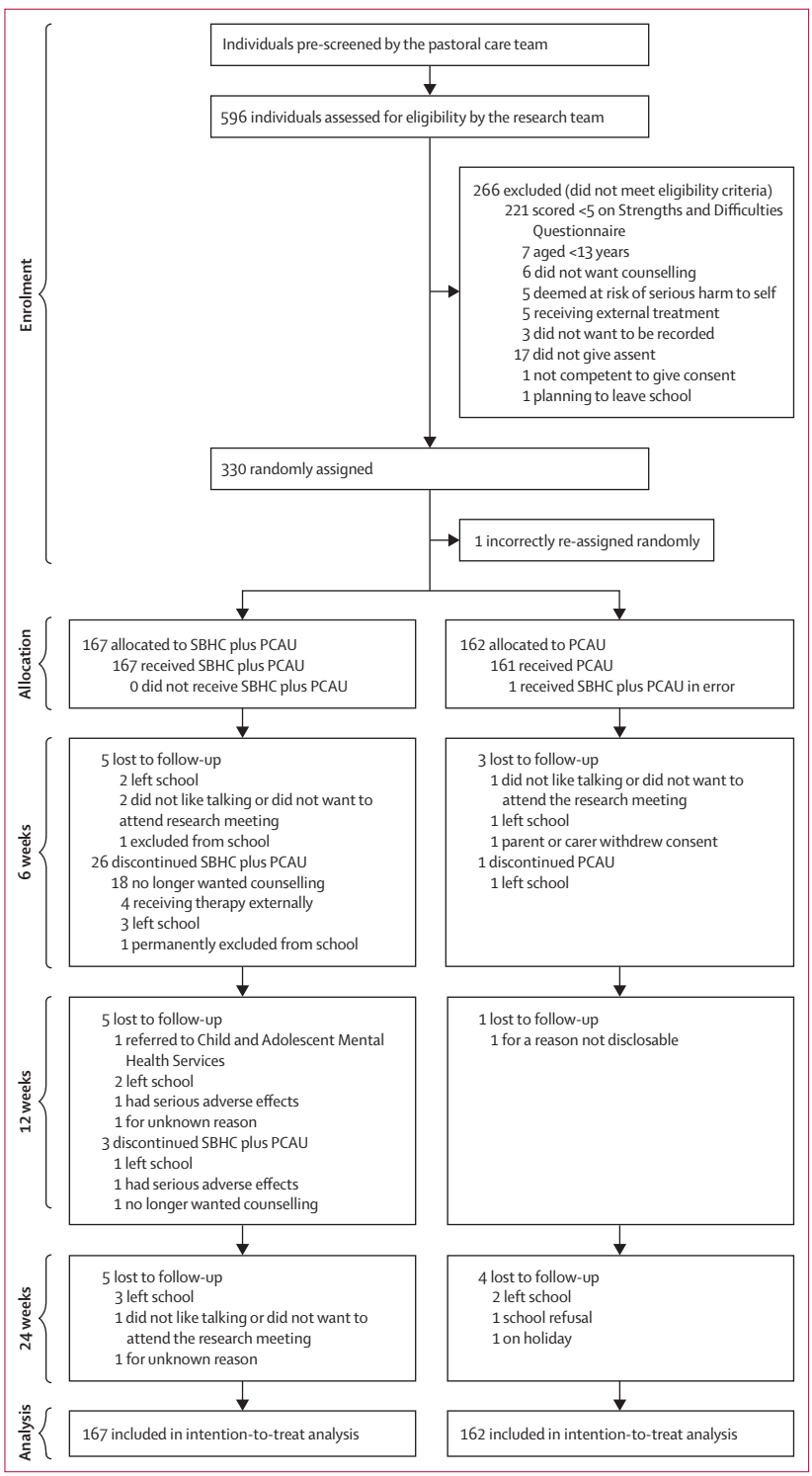

Figure 1: **Trial profile**
As per the intention-to-treat analysis, the participant in the PCAU group who received SBHC plus PCAU in error was included in PCAU for all outcomes. SBHC=school-based humanistic counselling. PCAU=pastoral care as usual.

to address their difficulties if they can explore them with an empathic, supportive, and trustworthy counsellor. SBHC counsellors use a range of techniques, including active listening, empathic reflections, and inviting young people to express underlying emotions and needs. In this trial, SBHC also included weekly use of an outcome feedback tool, the Outcomes Rating Scale,[21] so that counsellors and young people could discuss their progress during therapy. Sessions were delivered on an individual, face-to-face basis, and lasted for 45–60 mins. They were scheduled weekly for up to 10 school weeks, with young people able to terminate counselling before this timepoint.

SBHC was delivered by a pool of 19 counsellors, with 14 schools having one counsellor each throughout the trial, and four schools having two counsellors (non-concurrently). 16 of the counsellors were female, with a mean age of 45·0 years (SD 9·0, range 25–63 years). 14 of the counsellors were of a white British ethnicity and five were of a Black Caribbean or African ethnicity. All counsellors were qualified to diploma level (part-time training for at least 2 years) and had been qualified for an average of 7·2 years (SD 6·6, range 1–25 years).

The counsellors were instructed to adhere to a SBHC manual, developed for the trial.[22] They received, at minimum, 4 days of group training with 1 additional day's training in the research protocols. Adherence to SBHC was assessed by two independent auditors by use of a young person's adapted version of the Person Centred and Experiential Psychotherapy Rating Scale.[23] The mean adherence rating for counsellors was 4·6 on this 6-point scale (SD 0·3), with all counsellors exceeding the predefined adherence cutoff point, based on literature on this scale, of 3·5 (range 3·9–5·1).

All counsellors received one-to-one clinical supervision throughout the trial, approximately 1 h every 2 weeks. Supervisors were instructed to adhere to a SBHC supervision manual, specifically developed for the trial, and participated in a 2 day training programme. Supervision was recorded and assessed for adherence with a three-item scale specifically for the trial. The mean adherence rating for supervisors was 2·1 (SD 0·3; maximum score was 3), with all supervisors exceeding the predefined adherence cutoff point of 1·5 (range 1·6–2·5).

Participants in the SBHC group also had full access to their school's usual pastoral care support, which was the schools' pre-existing service for supporting the emotional health and wellbeing of young people. Pastoral care could vary substantially across schools and pupils, and we did not attempt to standardise it. However, typically, this care involved time with school staff, such as learning and behavioural support, class teachers, pastoral care managers, and heads of year. In some instances, the service could also involve referral to community-based specialists, such as social workers or police liaison officers (appendix p 4). Amount of support could vary considerably, from single, one-off meetings of 5 mins or less, to 1 day or

more of ongoing help (eg, with a learning support mentor).

The PCAU group comprised access to the school's usual pastoral care support, alone. Participants in the PCAU group were offered the opportunity to access SBHC 6–9 months after their assessment.

Outcomes

The primary outcome was self-reported psychological distress, measured by the Young Person's Clinical Outcomes in Routine Evaluation (YP-CORE) at 12 weeks. This is a ten-item measure with total scores ranging from 0 to 40, whereby higher scores indicate greater distress. The YP-CORE is the most widely used indicator of mental health in school counselling for young people. The tool has good evidence of internal consistency (Cronbach's α=0·80) and sensitivity to change.[24]

Secondary outcomes were self-reported psychological distress, measured by the YP-CORE, at 6 weeks and 24 weeks. Additionally, at weeks 6, 12, and 24 from baseline, we assessed psychological difficulties using the self-report SDQ,[20] symptoms of depression and anxiety using the Revised Children's Anxiety and Depression Scale—Short Version,[25] self-esteem using the Rosenberg Self-Esteem Scale,[26] engagement with school using the Behavioural Engagement subscale of the Student Engagement Scale,[27] wellbeing using the Warwick-Edinburgh Mental Wellbeing Scale,[28] and attainment of personal goals using the Goal-Based Outcome Record Sheet.[29] At 12 weeks, we administered the Experience of Service Questionnaire[30] to assess satisfaction with treatment provision. To evaluate the possible impact of SBHC on educational outcomes, we asked each school, at baseline and at 24 weeks, to provide details of the participants' attendance and exclusion rates, numbers of detentions and disciplinary proceedings, and current grades in English and Maths for the preceding 3 months.

An adverse event was defined as any negative psychological, emotional, or behavioural occurrence, or sustained deterioration in a research participant. For monitoring of adverse events, all professionals in contact with trial participants were provided with a detailed document on adverse event information,[22] which defined criteria for assessing whether the adverse event was serious or not, its causality, and its severity, as well as procedures for detecting and reporting adverse events. These professionals were also required to use an adverse event reporting log, which recorded whether or not the adverse event was serious (ie, defined as life-threatening or fatal), the adverse event severity (a 5-point scale from mild to extremely severe), and whether or not it could be attributed to participating in the trial.

Statistical analysis

The sample size was calculated to take account of clustering within schools and participants lost to follow-up on the basis of previous pilots.[13–16] For 90% power to detect a standardised mean difference of 0·5, with an intraclass correlation coefficient of 0·05 and an attrition rate of 20%, 153 participants were required per group, yielding a total sample size of 306.

The analyses followed a statistical analysis plan and an economic analysis plan,[22] approved by the Trial Steering Committee, on the recommendation of the Data Monitoring and Ethics Committee, before data preparation. For the statistical analysis, a mixed effects model was fitted to the data with Stata software (version 15) that included randomised group (as a fixed effect), baseline YP-CORE (as a fixed effect), and school (as a random effect). The model results were examined with the parameter estimates, 95% CIs, and the p value of all covariates fitted in the model, together with the overall log likelihood. Standardised effect sizes, computed by use of the model, were calculated as the difference between groups divided by the baseline pooled SD.

The number of missing YP-CORE scores at different timepoints were summarised, overall and by treatment arm. For the primary outcome, an intention-to-treat analysis was adopted with the last observation carried forward to impute YP-CORE scores missing at 12 week follow-up. Where measures were not collected at 12 weeks, participants' scores were imputed from the 6 week tests. If these data were also missing, the

	SBHC plus PCAU group (n=167)	PCAU group (n=162)
Sex		
Female	127 (76%)	129 (80%)
Male	37 (22%)	32 (20%)
Other	3 (2%)	1 (<1%)
Age, years	13·7 (0·8)	13·8 (0·8)
School year		
Year 8	28 (17%)	27 (17%)
Year 9	79 (47%)	71 (44%)
Year 10	53 (32%)	52 (32%)
Year 11	7 (4%)	12 (7%)
Ethnicity		
White	90 (54%)	88 (54%)
Asian or Asian British	16 (10%)	15 (9%)
African, Caribbean, or Black British	27 (16%)	30 (19%)
Mixed	29 (17%)	23 (14%)
Other	4 (2%)	5 (3%)
Data missing	1 (<1%)	1 (<1%)
Disability		
No disability	142 (85%)	136 (84%)
Has a disability	23 (14%)	22 (14%)
Data missing	2 (1%)	4 (2%)

Data are n (%) or mean (SD). SBHC=school-based humanistic counselling. PCAU=pastoral care as usual.

Table 1: **Baseline characteristics**

baseline score was used. We also did various sensitivity analyses for our primary outcome, including a per-protocol analysis for participants who had attended a minimum of three counselling sessions (50% of the number of sessions considered to constitute an acceptable dose, six sessions) and for whom the counsellor had assessed as meeting adherence criteria to SBHC (as assessed by our PCEPS-YP auditing procedure), and a worst case or best case imputation analysis (appendix p 6).

	Intervention group		Outcome measure		
	SBHC plus PCAU	PCAU	Effect size	Difference between groups	p value
Young Person's Clinical Outcomes in Routine Evaluation score					
Baseline	20·86 (6·38); n=167	20·98 (6·41); n=162	..	..	..
6 weeks	17·09 (6·92); n=159	19·58 (6·78); n=157	0·36 (0·14 to 0·59)	2·28 (1·01 to 3·55)	0·0004
24 weeks	16·52 (8·08); n=151	18·52 (7·09); n=154	0·26 (0·04 to 0·49)	1·87 (0·28 to 3·46)	0·021
SDQ total score					
Baseline	19·87 (4·20); n=167	20·25 (5·04); n=162	..	..	..
6 weeks	18·28 (5·00); n=158	19·15 (5·15); n=156	0·17 (–0·05 to 0·39)	0·67 (–0·22 to 1·55)	0·14
12 weeks	17·00 (5·49); n=155	18·49 (5·49); n=158	0·27 (0·05 to 0·49)	1·17 (0·22 to 2·12)	0·016
24 weeks	17·21 (5·64); n=150	17·95 (5·36); n=154	0·14 (–0·09 to 0·36)	0·43 (–0·70 to 1·56)	0·46
SDQ externalisation score					
Baseline	9·78 (3·20); n=167	9·93 (3·53); n=162	..	..	..
6 weeks	9·51 (3·10); n=158	9·59 (3·24); n=156	0·03 (–0·20 to 0·25)	0·02 (–0·44 to 0·47)	0·95
12 weeks	9·15 (3·37); n=155	9·47 (3·26); n=158	0·10 (–0·13 to 0·32)	0·18 (–0·32 to 0·68)	0·48
24 weeks	9·21 (3·21); n=150	9·10 (3·24); n=154	–0·03 (–0·26 to 0·19)	–0·17 (–0·72 to 0·39)	0·56
SDQ internalisation score					
Baseline	10·09 (2·59); n=167	10·32 (2·72); n=162	..	..	..
6 weeks	8·76 (3·20); n=158	9·56 (3·11); n=156	0·25 (0·03 to 0·47)	0·66 (0·06 to 1·26)	0·032
12 weeks	7·85 (3·32); n=155	9·02 (3·40); n=158	0·35 (0·13 to 0·57)	1·01 (0·38 to 1·64)	0·0016
24 weeks	7·99 (3·59); n=150	8·84 (3·41); n=154	0·24 (0·02 to 0·47)	0·63 (–0·07 to 1·34)	0·079
SDQ impact score					
Baseline	7·78 (2·68); n=166	7·60 (2·88); n=159	..	..	..
6 weeks	6·79 (3·16); n=153	6·89 (3·15); n=151	0·03 (–0·19 to 0·26)	0·13 (–0·49 to 0·76)	0·68
12 weeks	6·60 (3·01); n=149	6·63 (3·47); n=150	0·01 (–0·22 to 0·24)	0·06 (–0·58 to 0·70)	0·85
24 weeks	6·39 (3·41); n=145	6·57 (3·13); n=148	0·05 (–0·18 to 0·28)	0·13 (–0·63 to 0·89)	0·74
Revised Children's Anxiety and Depression Scale score					
Baseline	30·22 (11·48); n=167	31·04 (11·06); n=162	..	..	..
6 weeks	27·25 (12·40); n=158	29·56 (11·71); n=157	0·19 (–0·03 to 0·41)	1·67 (–0·30 to 3·44)	0·099
12 weeks	25·97 (12·70); n=155	28·44 (12·07); n=158	0·20 (–0·02 to 0·42)	1·51 (0·63 to 3·65)	0·17
24 weeks	26·42 (13·66); n=151	28·26 (11·49); n=154	0·15 (–0·79 to 0·37)	0·92 (–1·53 to 3·38)	0·46
Rosenberg Self-Esteem Scale score					
Baseline	13·39 (4·72); n=167	12·96 (5·27); n=162	..	..	..
6 weeks	14·85 (5·44); n=158	13·02 (5·07); n=156	0·35 (0·13 to 0·57)	1·41 (0·57 to 2·26)	0·0011
12 weeks	16·04 (5·95); n=155	13·81 (5·35); n=157	0·39 (0·17 to 0·62)	1·81 (0·83 to 2·79)	0·00028
24 weeks	16·09 (6·38); n=151	14·12 (5·52); n=154	0·33 (0·10 to 0·56)	1·49 (0·44 to 2·55)	0·0055
Behavioural Engagement subscale of the Student Engagement Scale score					
Baseline	35·00 (7·62); n=167	34·74 (7·16); n=162	..	..	..
6 weeks	35·01 (7·95); n=157	34·34 (7·44; n=157	0·09 (–0·13 to 0·31)	0·46 (–0·61 to 1·54)	0·40
12 weeks	36·11 (8·56); n=153	34·89 (7·34); n=158	0·15 (–0·07 to 0·38)	0·95 (–0·28 to 2·17)	0·13
24 weeks	36·35 (8·64); n=150	35·14 (7·78); n=153	0·14 (–0·09 to 0·36)	0·75 (–0·61 to 2·11)	0·28
Warwick-Edinburgh Mental Wellbeing Scale score					
Baseline	38·55 (8·38); n=167	38·44 (8·47); n=162	..	..	..
6 weeks	40·73 (9·41); n=158	39·28 (9·01); n=158	0·16 (–0·06 to 0·38)	1·18 (–0·50 to 2·86)	0·17
12 weeks	43·66 (10·69); n=154	40·52 (10·26); n=157	0·30 (0·08 to 0·52)	2·79 (0·78 to 4·79)	0·0064
24 weeks	42·98 (10·69); n=151	41·10 (10·43); n=154	0·18 (–0·05 to 0·40)	1·87 (–0·48 to 4·23)	0·12

(Table 2 continues on next page)

	Intervention group		Outcome measure		
	SBHC plus PCAU	PCAU	Effect size	Difference between groups	p value
(Continued from previous page)					
Goal-Based Outcome Record Sheet score					
Baseline	2·87 (1·36); n=166	3·01 (1·40); n=162	..	..	..
6 weeks	4·90 (1·95); n=158	3·83 (1·99); n=154	0·55 (0·32 to 0·77)	1·16 (0·82 to 1·54)	<0·0001
12 weeks	6·10 (1·99); n=153	4·36 (1·98); n=158	0·87 (0·63 to 1·10)	1·82 (1·33 to 2·32)	<0·0001
24 weeks	6·19 (2·27); n=148	4·84 (2·31); n=154	0·58 (0·36 to 0·82)	1·42 (0·91 to 1·93)	<0·0001
Experience of Service Questionnaire score					
12 weeks	14·44 (3·48); n=138	13·20 (3·95); n=102	0·34 (0·08 to 1·60)	1·24 (0·25 to 2·23)	0·014
School or education outcomes					
Attainment in English (standardised scores)					
Baseline	−0·07 (0·83); n=124	0·17 (0·94); n=122	..	..	..
24 weeks	−0·08 (0·89); n=122	0·12 (0·93); n=123	−0·22 (−0·47 to 0·03)	−0·13 (−0·19 to 0·16)	0·88
Attainment in Maths (standardised scores)					
Baseline	−0·13 (1·10); n=122	−0·08 (0·99); n=124	..	..	..
24 weeks	−0·13 (1·10); n=120	−0·07 (1·05); n=122	−0·06 (−0·31 to 0·19)	−0·04 (−0·22 to 0·14)	0·65
Number of exclusions					
Baseline	0·21 (0·85); n=165	0·12 (0·44); n=159	..	..	..
24 weeks	0·13 (0·65); n=149	0·16 (0·48); n=152	0·06 (−0·16 to 0·29)	0·06 (−0·06 to 0·18)	0·32
Number of detentions					
Baseline	4·24 (8·81); n=135	3·73 (7·78); n=127	..	..	..
24 weeks	3·65 (6·35); n=123	2·72 (4·97); n=127	−0·16 (−0·41 to 0·09)	−0·98 (−2·20 to 0·24)	0·12
Number of disciplinary proceedings					
Baseline	5·23 (14·31); n=162	5·87 (14·12); n=157	..	..	..
24 weeks	5·27 (15·68); n=147	6·62 (18·46); n=149	0·08 (−0·15 to 0·31)	0·77 (−1·91 to 3·45)	0·57

Data are mean (SD) or n (95% CI), unless otherwise stated. PCAU=pastoral care as usual. SBHC=school-based humanistic counselling. SDQ=Strengths and Difficulties Questionnaire.

Table 2: **Secondary outcomes**

Mixed models were also used for the analysis of the secondary outcomes. These secondary analyses used completer samples for each measure at each timepoint.

The economic analysis comprised of a cost-effectiveness analysis of SBHC plus PCAU versus PCAU alone from a public sector perspective. Participants' use of health and social care services, and education support were measured with a specially adapted Client Service Receipt Inventory[31] covering a retrospective school term and completed by participants at baseline and at 24 weeks. Additionally, a pastoral care log, developed by the research team, was completed by school staff for each participant. Use of the SBHC intervention was logged by counsellors with a counselling session log and contained data for each young person in the intervention group, including session date, session number, session length, and any follow-up actions or comments. To determine the costs associated with this support, a unit cost for each service was identified[32,33] or calculated by an equivalent approach,[34] and multiplied by the number of service contacts reported (appendix p 3).

Cost-effectiveness was explored with a net-benefit approach,[35] with the change in YP-CORE scores between baseline and 24 weeks as the outcome measure. Results are presented as cost-effectiveness acceptability curves,[36] plotting the probability that the intervention will be considered cost-effective against a range of levels of willingness to pay for a 1-point improvement in outcome.

All economic analyses were done with Stata version 15. All costs are shown in 2016 or 2017 prices. No discount rate was applied as all costs and outcomes were within a 12 month period. This trial is registered with the ISRCTN, number ISRCTN10460622.

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. A representative of the funder was present at the Trial Steering Committee meetings. All authors had access to the raw data. The corresponding author had full access to all of the data in the study and had final responsibility for the decision to submit for publication.

Results

Participants were recruited between Sept 29, 2016, and Feb 8, 2018, from 18 secondary schools in the Greater

	SBHC plus PCAU group		PCAU group		Total	
	Number of events	Number of participants (%)	Number of events	Number of participants (%)	Number of events	Number of participants (%)
Serious adverse events						
Suicidal intent	5	4 (2%)	1	1 (<1%)	6	5 (3%)
Other	0	0 (0%)	1	1 (<1%)	1	1 (<1%)
Total	5	4 (2%)	2	2 (1%)	7	6 (4%)
Non-serious adverse events						
School exclusion	6	6 (4%)	1	1 (<1%)	7	7 (4%)
Significant increase in emotional difficulties	3	3 (2%)	3	3 (2%)	6	6 (4%)
Significant deterioration in behaviour	3	3 (2%)	0	0 (0%)	3	3 (2%)
Significant decrease in school attendance	2	2 (1%)	0	0 (0%)	2	2 (1%)
Self-harm	1	1 (<1%)	2	2 (1%)	3	3 (<1%)
Complaint made against the counsellor	1	1 (<1%)	0	0 (0%)	1	1 (4%)
Other	9	9 (5%)	2	2 (1%)	11	11 (3%)
Total	25	22 (13%)	8	8 (5%)	33	30 (18%)

Number of participants do not sum to total number of events as participants might have had more than one type of event. SBHC=school-based humanistic counselling. PCAU=pastoral care as usual.

Table 3: **Adverse events**

London area of the UK. All schools were state funded: 11 academies, six community schools, and one foundation school. The mean number of pupils per school was 900 (SD 226·1, range 445–1489). Five of the schools were faith schools (Church of England), and five were single-sex schools (three all female, two all male). Seven (39%) of the schools were in the most deprived Index of Multiple Deprivation quintile, with a further three (17%) in the second lowest quintile. The mean percentage of children receiving free school meals (made available by the state to individuals from the lowest income families) was 32% (SD 22%, range 7–80%). The mean percentage of children from Black and ethnic minorities, on the basis of data provided by 11 of the 18 schools, was 47% (29%, 3–89%).

The study ran from April 1, 2016, to Feb 28, 2019. We did 596 eligibility assessments and, in 330 cases (58%), enrolled the young person into the trial (figure 1). However, in one case, a young person had been erroneously referred for assessments and randomly assigned into the trial twice, giving 329 participants in total (table 1). The primary reason for ineligibility at assessment was a SDQ Emotional Symptoms score of less than 5 (221 participants). Of the 329 eligible participants, 167 (51%) were allocated to the SBHC plus PCAU group and 162 (49%) to the PCAU group. The overall retention rate was 98% (321 participants) at 6 weeks, 96% (315 participants) at 12 weeks, and 93% (306 participants) at 24 weeks. Testers reported unmasking in approximately 15% (136) of instances (appendix p 1). On average, young people in the SBHC plus PCAU group attended 7·80 sessions of counselling (SD 2·70, range 0–11; appendix p 2).

At baseline, the mean YP-CORE scores for the two groups were similar (table 2). Based on the last observation carried forward approach, the 12 week scores were 16·41 (7·59) for the SBHC plus PCAU group and 18·34 (7·84) for the PCAU group. The primary analysis indicated a difference between groups of 1·87 YP-CORE points (95% CI 0·37–3·36) in favour of SBHC plus PCAU (p=0·015). The effect size was 0·25 (0·03–0·47). In the mixed-effect model analysis, the effect of school on outcome was not significant. The parameter estimate for the intraclass correlation coefficient was $3·37\times10^{-10}$ (SE $3·35\times10^{-7}$).

Results from most secondary analyses supported the primary analysis (table 2). The significant reductions in psychological distress brought about by SBHC were maintained at 24 weeks follow-up. SBHC brought about medium to large improvements in both goal attainment (Goal-Based Outcome Record Sheet) and self-esteem (Rosenberg Self-esteem Scale) across all time points, and small improvements in wellbeing (Warwick-Edinburgh Mental Wellbeing Scale) and psychological difficulties (SDQ) at 12 weeks only. The intervention had no significant effect on levels of anxiety and depression (Revised Children's Anxiety and Depression Scale), externalised difficulties (SDQ), or engagement with school (Behavioural Engagement sub-scale of the Student Engagement Scale). Similarly, there were no significant effects on school and educational outcomes.

Seven serious adverse events occurred during the trial, five for four participants (2%) in the SBHC plus PCAU group and two for two participants (1%) in the PCAU group. A serious adverse event was defined as any adverse event that is life-threatening, or results in death. Five of these serious adverse events were attempted drug overdoses, three of which led to hospitalisation. One further serious adverse event involved suicidal intent (without suicidal attempt or hospitalisation). Two of the attempted drug overdoses, both for the same participant in the SBHC plus PCAU group, were assessed by the Chief Investigator as being causally related to involvement in the trial. In these instances, the young person had become severely distressed following meetings with an assessor or tester. Additionally, eight non-serious adverse events were recorded across eight participants (5%) in the PCAU group and 25 non-serious adverse events for 22 participants (13%) in the SBHC plus PCAU group (table 3). Most commonly, this type of event was school exclusion (seven participants [2%]) and significant increases in emotional difficulties (six participants). An independent review was commissioned by the project management team to investigate the serious adverse events and adverse events further. The review concluded that trial procedures were appropriate and recommended the ongoing monitoring and investigation of adverse events.

	Baseline					24 weeks				
	SBHC plus PCAU (n=147)		PCAU (n=150)		p value	SBHC plus PCAU (n=147)		PCAU (n=150)		p value
	Mean (SD)	Cost range (£)	Mean (SD)	Cost range (£)		Mean (SD)	Cost range (£)	Mean (SD)	Cost range (£)	
SBHC intervention	N/A	N/A	N/A	N/A	N/A	393·90 (128·65)	29·10–640·20	2·17 (26·53)*	0·0–325·5*	<0·0001
Pastoral care	232·34 (360·85)	0·0–1850·0	274·50 (426·38)	0·0–1890·0	0·513	363·43 (583·42)	0·0–3580·0	392·76 (1118·57)	0·0–13128·0	0·92
Other school-based services	23·34 (89·40)	0·0–730·0	22·14 (90·09)	0·0–730·0	0·888	72·31 (217·92)	0·0–1825·0	60·52 (248·74)	0·0–2533·2	0·26
Physical health and mental health services	158·08 (308·30)	0·0–2436·0	107·07 (163·43)	0·0–876·0	0·057	131·23 (214·00)	0·0–1313·0	124·11 (219·01)	0·0–1405·8	0·97
Medication	0·23 (1·20)	0·0–13·9	0·11 (0·33)	0·0–2·3	0·793	0·13 (0·43)	0·0–2·3	0·12 (0·35)	0·0–2·3	0·87
Other services	34·83 (86·88)	0·0–601·2	30·90 (93·97)	0·0–917·0	0·476	34·19 (93·23)	0·0–601·8	33·21 (100·05)	0·0–904·2	0·95
Total cost	448·82 (541·30)	0·0–3196·1	434·73 (505·82)	0·0–2336·0	0·65	995·20 (769·86)	34·0–4328·2	612·89 (1224·56)	0·0–13410·6	0·0015

PCAU=pastoral care as usual. SBHC=school-based humanistic counselling. *Cost in PCAU group is for the participant who was erroneously allocated to SBHC plus PCAU group.

Table 4: **Economic costs (£) associated with service use for SBHC plus PCAU versus PCAU**

The sample for the cost-effectiveness analysis consisted of participants with data on both service use and outcome measures at baseline and at follow-up (SBHC plus PCAU group: 147 participants [88%]; PCAU group: 150 participants [93%]). The cost of the SBHC intervention was estimated to be £53·28 per session. There was little difference in the use of services across conditions, at baseline and at 24 weeks (table 4; appendix p 4). Consequently, we found no significant differences in any cost category other than total costs at 24 weeks, driven by the cost of the intervention (unadjusted difference for total costs £382·31, 95% CI £148·18–616·44; p=0·0015). The cost-effectiveness analysis suggests that SBHC is unlikely to be considered cost-effective if the decision maker's willingness to pay for a 1-point improvement on the YP-CORE, over and above the improvement seen in the PCAU group, is below £390, in which the probability of cost-effectiveness reaches 80% (figure 2). The probability that the intervention will be considered cost-effective compared with PCAU exceeds 50% at a willingness to pay of £222, and exceeds 90% at a willingness to pay of £630.

For the primary outcome, the results of the sensitivity analyses (appendix p 6) all indicated significantly greater improvements for SBHC plus PCAU, except for the comparison between worse case for SBHC plus PCAU scenario and best case for PCAU scenario. Between-group differences ranged from 1·45 points in favour of SBHC (effect size 0·19; p=0·091) to 2·99 points in favour of SBHC (effect size 0·38; p=0·00016).

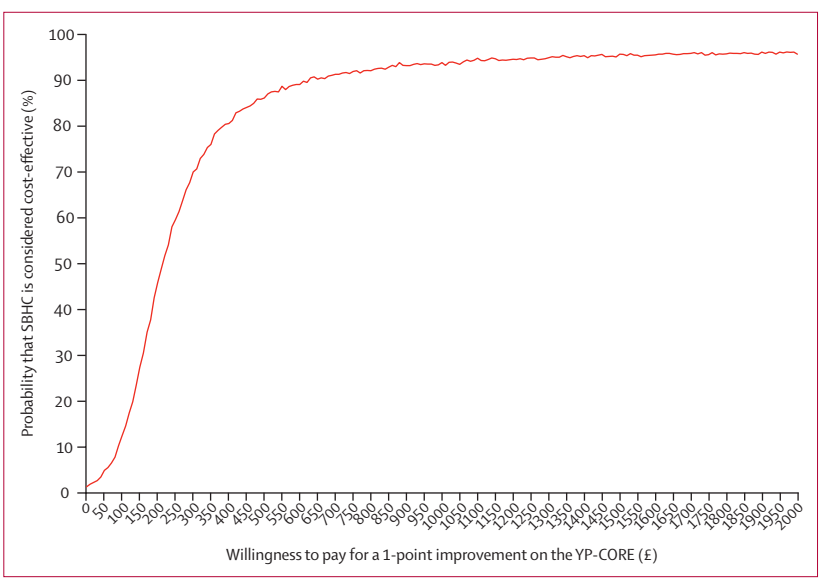

Figure 2: **Cost-effectiveness acceptability curve**
SBHC=school-based humanistic counselling. YP-CORE=Young Person's Clinical Outcomes in Routine Evaluation.

Discussion

Finding effective ways of managing adolescent mental health problems remains a policy priority. Decisions about service delivery should be based on rigorous evidence. SBHC is widely delivered; however, to date, only pilot data have supported this approach. We found that the addition of up to ten weekly sessions of SBHC to PCAU led to a small but significant reduction in psychological distress in adolescents with moderate and severe emotional symptoms on our primary outcome measure, the YP-CORE, sustained at 6 month follow-up. These benefits were achieved across a range of state-funded schools. However, the benefits were associated with increased costs, and were not found on our secondary outcome measures of distress, the SDQ, and Revised Children's Anxiety and Depression Scale.

Our study was designed to balance internal and external validity. Allocation was concealed and assessors were masked. Counsellors delivered a replicable intervention. Training, support, and assessment procedures assured competence and fidelity, while allowing variation in

delivery to better reflect routine practice. Retention rates were high, and the likelihood of bias in the main comparison is small. The participating schools had relatively high levels of social deprivation and ethnic diversity. However, poor school attenders were excluded from the study, as were young people at risk of serious harm to self or others, and those already receiving psychological interventions. Therefore, the results might be not be generalisable to adolescents with the most severe mental health problems. Our ability to generalise is also limited by an absence of precise data on the numbers excluded at pre-screening. This number includes cases where parental consent could not be obtained (approximately 11% of prospective participants). Measures were predominantly self-reported and those that were not did not show significant effects. As with all trials of psychological interventions, masking of participants to condition was not possible. There was considerable variability in the amount and type of pastoral care provided, but the overall levels of service care provision (and costs) in the two groups were similar. Furthermore, because no active control was used, we cannot disentangle the effects of humanistic counselling from generic counselling provision or other forms of attentional control.

There are complexities associated with the size of the effect that we found. There is no consensus on the magnitude that represents clinically significant benefits in young people, and we showed that the benefits of counselling persisted at 24 weeks. Nevertheless, our observed effect size (0·25) was less than that used to guide the sample size calculation (0·50), and did not generalise to all secondary, validated measures of psychological distress. The effect size in this study was also lower than that found in previous trials of SBHC, and in a recent meta-analysis of controlled studies of person-centred and experiential psychological therapies for children and adolescents (0·48, 95% CI 0·38–0·58).[37] A large meta-analytic study of school-based counselling and psychotherapy interventions also found greater effects (0·45, 0·37–0·53) than those found in our study.[38] However, sample sizes in these previous studies have generally been much lower than in the present study: in the large meta-analysis of school-based interventions, only 19 (15%) of 132 interventions were tested in trials with more than 100 participants. Attenuation of intervention effects is not unusual in large trials, which could reflect greater variation in participants and interventions in larger, more pragmatic trials in routine care settings compared with smaller exploratory trials done in a more restricted number of selected care settings.[39] Our observed effect for SBHC was also smaller than for other manualised treatments for young people, such as CBT and interpersonal therapy for depression, in which standardised mean differences ranged from 0·47 to 0·96 against controls.[40] However, these interventions are yet to be tested in UK school settings. To date, evaluations of mental health interventions in UK schools have tended to show mixed results, with economic analyses either absent or indicating that the intervention is unlikely to be considered cost-effective.[41] The lowered levels of change before and after the intervention in this study, across both conditions, might also be related to the sample's relatively high levels of deprivation, which might be associated with increased chronicity of distress.

There is no one agreed measure of quality-adjusted life years (QALY) in child mental health that would allow assessment of value against consensus thresholds (eg, £15 000 per QALY, which underpins National Institute for Health and Care Excellence decision making). Our analysis would suggest that SBHC does not reduce use of other services, thus leading to an increase in costs. Nevertheless, the intervention does not result in an increase in use of external mental health services and, therefore, does not add to pressure on already stretched services. Assuming that the estimated increase in costs associated with SBHC (£382) is the maximum willingness to pay for a commissioner, and considering the effect size of SBHC on the primary outcome, the chance that SBHC would be considered cost-effective is only 52%, similar to flipping a coin. The economic data alone do not provide strong support for a decision to provide or expand SBHC. However, although making efficient use of resources is important, evidence on cost-effectiveness might not be the sole decision-making criterion for commissioners. Other factors that might influence the decision include the effect on secondary outcomes, user experience, accessibility, and local policies formulated to support young people's mental health.

The mixed results raise important questions for policy makers and commissioners, given the strategy to centre development of mental health support in schools. SBHC is a viable option for meeting policy goals that are likely to deliver benefits for some young people, as one of a range of interventions. The benefits of SBHC could potentially be enhanced through increased training and supervision, or improved targeting of psychological therapies (to particular subgroups of young people, or as part of a stepped care system). Alternatively, cost reductions might be sought through efficiencies in delivery. Further research on such issues should be a priority.

There is an urgent need for equally rigorous evaluations of alternative interventions. Evidence from outside of UK schools suggests that CBT and interpersonal therapy might be effective, but evidence within UK schools is scarce. In principle, digital therapy and universal preventative interventions (eg, the Promoting Alternative Thinking Strategies curriculum) could improve access and efficiency, but are yet to prove clear advantages in this setting.[42] Understanding how these different services can be organised to provide seamless coverage, appropriate to the individual needs of children and young people, remains a crucial task.

Our ETHOS study has shown that schools are an excellent environment for high-quality research in mental health. There is an urgent need for these alternative models (eg, CBT) to have rigorous assessment in the context of schools in the UK, as the Department for Education's INSPIRE and AWARE trials are doing, to support decisions about the right mix of services to meet the pressing challenge of addressing children and young people's mental health.

Contributors

MC, JB, MB, PB, KC, CD, and PP designed the study and were responsible for its conduct. MC was Chief Investigator and oversaw all aspects of the study. MRS and KC managed the delivery of the trial, with support from TR. PP was Clinical Lead for the study. GR coordinated the assessment of adherence. DS analysed the clinical outcomes. JB and E-MB developed and conducted the economic analysis. DS, E-MB, and MC analysed, checked, and examined the data files. Data verification processes were conducted by the Manchester Clinical Trials Unit. All authors had access to the data, contributed to writing and editing of the manuscript, and approved the final version.

Declaration of interests

All authors report grants from Economic and Social Research Council, during the conduct of the study. CD and GR report personal fees from British Association for Counselling and Psychotherapy, outside of the submitted work. MB was a member of the research group that developed the YP-CORE measure.

Data sharing

Quantitative, participant-level data for the ETHOS study (with data dictionary), and related documents (eg, parental consent form), are available from Feb 1, 2021, via the ReShare UK Data Service (reshare.ukdataservice.ac.uk/853764/). Access requires ReShare registration.

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References

1 Blakemore S-J. Adolescence and mental health. *Lancet* 2019; **393:** 2030–31.

2 Sadler K, Vizard T, Ford T, et al. Mental health of children and young people in England, 2017: summary of key findings. London: National Health Service Digital, 2018.

3 Chen H, Cohen P, Crawford TN, Kasen S, Johnson JG, Berenson K. Relative impact of young adult personality disorders on subsequent quality of life: findings of a community-based longitudinal study. *J Pers Disord* 2006; **20:** 510–23.

4 Snell T, Knapp M, Healey A, et al. Economic impact of childhood psychiatric disorder on public sector services in Britain: estimates from national survey data. *J Child Psychol Psychiatry* 2013; **54:** 977–85.

5 Department of Health, Department for Education. Transforming children and young people's mental health provision: green paper. London: Department of Health and Department for Education, 2017.

6 Werner-Seidler A, Perry Y, Calear AL, Newby JM, Christensen H. School-based depression and anxiety prevention programs for young people: a systematic review and meta-analysis. *Clin Psychol Rev* 2017; **51:** 30–47.

7 Kaplan DW, Calonge BN, Guernsey BP, Hanrahan MB. Managed care and school-based health centers. Use of health services. *Arch Pediatr Adolesc Med* 1998; **152:** 25–33.

8 Knopf JA, Finnie RKC, Peng Y, et al. School-based health centers to advance health equity: a community guide systematic review. *Am J Prev Med* 2016; **51:** 114–26.

9 Cooper M. School-based counselling in UK secondary schools: a review and critical evaluation. Lutterworth: British Association for Counselling and Psychotherapy and Counselling MindEd, 2013.

10 Harris B. International school-based counselling. Lutterworth: British Association for Counselling and Psychotherapy and Counselling MindEd, 2013.

11 Harland J, Dawson A, Rabiasz A, Sims D. NFER teacher voice omnibus: questions for the Department for Education–June 2015. London: The National Foundation for Education Research, 2015.

12 Hill A, Roth A, Cooper M. The competences required to deliver effective humanistic counselling for young people. Lutterworth: British Association for Counselling and Psychotherapy, 2013.

13 Cooper M, Rowland N, McArthur K, Pattison S, Cromarty K, Richards K. Randomised controlled trial of school-based humanistic counselling for emotional distress in young people: feasibility study and preliminary indications of efficacy. *Child Adolesc Psychiatry Ment Health* 2010; **4:** 12.

14 McArthur K, Cooper M, Berdondini L. School-based humanistic counseling for psychological distress in young people: pilot randomized controlled trial. *Psychother Res* 2013; **23:** 355–65.

15 Pearce P, Sewell R, Cooper M, Osman S, Fugard AJB, Pybis J. Effectiveness of school-based humanistic counselling for psychological distress in young people: pilot randomized controlled trial with follow-up in an ethnically diverse sample. *Psychol Psychother* 2017; **90:** 138–55.

16 Pybis J, Cooper M, Hill A, et al. Pilot randomised controlled trial of school-based humanistic counselling for psychological distress in young people: outcomes and methodological reflections. *Couns Psychother Res* 2015; **15:** 241–50.

17 Beecham J, Pearce P, Sewell R, Osman S. Support and costs for students with emotional problems referred to school-based counselling: findings from the ALIGN study. *Brit J Guid Couns* 2018; **47:** 460–71.

18 Stafford MR, Cooper M, Barkham M, et al. Effectiveness and cost-effectiveness of humanistic counselling in schools for young people with emotional distress (ETHOS): study protocol for a randomised controlled trial. *Trials* 2018; **19:** 175.

19 Sellars E, Pavarini G, Michelson D, Creswell C, Fazel M. Young people's advisory groups in health research: scoping review and mapping of practices. Arch Dis Child 2020; published online Nov 18. https://doi.org/10.1136/archdischild-2020-320452.

20 Goodman R. Psychometric properties of the strengths and difficulties questionnaire. *J Am Acad Child Adolesc Psychiatry* 2001; **40:** 1337–45.

21 Miller SD, Duncan B, Brown J, Sparks J, Claud D. The Outcome Rating Scale: a preliminary study of the reliability, validity, and feasibility of a brief visual analog measure. *J Brief Ther* 2003; **2:** 91–100.

22 University of Roehampton. The effectiveness and cost-effectiveness trial of humanistic counselling in schools (ETHOS). https://www.roehampton.ac.uk/research-centres/centre-for-research-in-social-and-psychological-transformation/ethos/ (accessed Dec 5, 2020).

23 Freire E, Elliott R, Westwell G. Person-Centred and Experiential Psychotherapy Scale: development and reliability of an adherence/competence measure for person-centred and experiential psychotherapies. *Counsell Psychother Res J* 2014; **14:** 220–26.

24 Twigg E, Cooper M, Evans C, et al. Acceptability, reliability, referential distributions and sensitivity to change in the Young Person's Clinical Outcomes in Routine Evaluation (YP-CORE) outcome measure: replication and refinement. *Child Adolesc Ment Health* 2016; **21:** 115–23.

25 Ebesutani C, Reise SP, Chorpita BF, et al. The Revised Child Anxiety and Depression Scale-Short Version: scale reduction via exploratory bifactor modeling of the broad anxiety factor. *Psychol Assess* 2012; **24:** 833–45.

26 Rosenberg M. Society and the adolescent self-image. Princeton, NJ: Princeton University Press, 1965.

27 Lam SF, Jimerson S, Wong BPH, et al. Understanding and measuring student engagement in school: the results of an international study from 12 countries. *Sch Psychol Q* 2014; **29:** 213–32.

28 Tennant R, Hiller L, Fishwick R, et al. The Warwick-Edinburgh mental well-being scale (WEMWBS): development and UK validation. *Health Qual Life Outcomes* 2007; **5:** 63.

29 Law D, Jacob J. Goals and Goal Based Outcomes (GBOs): some useful information. London: Child and Adolescent Mental Health Services Press at Evidence Based Practice Unit, 2015.

30 Attride-Stirling J. Development of methods to capture users' views of child and adolescent mental health services in clinical governance reviews. https://www.corc.uk.net/media/1215/chi_projectevaluationreport.pdf (accessed Dec 19, 2020).

31 Beecham J, Knapp M. Costing psychiatric interventions. In: Thornicroft G, ed. Measuring mental health needs. London: Gaskell, 2001: 200–24.

32 Department of Health. NHS reference costs 2016–17. London: Department of Health, 2017.

33 Curtis L, Burns A. Unit costs of health and social care, 2017. Canterbury: Personal Social Services Research Unit, University of Kent, 2017.

34 Beecham JK. Unit costs–not exactly child's play: a guide to estimating unit costs for children's social care. UK: Department of Health, Dartington Social Research Unit, and Personal Social Services Research Unit, 2000.

35 Stinnett AA, Mullahy J. Net health benefits: a new framework for the analysis of uncertainty in cost-effectiveness analysis. *Med Decis Making* 1998; **18** (suppl)**:** S68–80.

36 van Hout BA, Al MJ, Gordon GS, Rutten FFH. Costs, effects and C/E-ratios alongside a clinical trial. *Health Econ* 1994; **3:** 309–19.

37 Nuding D. Effects of person-centered and experiential psychotherapy and counseling with children and young people: review and meta-analysis. Cologne: GwG-Verlag, 2017.

38 Baskin TW, Slaten CD, Crosby NR, Pufahl T, Schneller CL, Ladell M. Efficacy of counseling and psychotherapy in schools: a meta-analytic review of treatment outcome studies. *Couns Psychol* 2010; **38:** 878–903.

39 Dechartres A, Trinquart L, Boutron I, Ravaud P. Influence of trial sample size on treatment effect estimates: meta-epidemiological study. *BMJ* 2013; **346:** f2304.

40 Zhou X, Hetrick SE, Cuijpers P, et al. Comparative efficacy and acceptability of psychotherapies for depression in children and adolescents: a systematic review and network meta-analysis. *World Psychiatry* 2015; **14:** 207–22.

41 Caldwell DM, Davies SR, Hetrick SE, et al. School-based interventions to prevent anxiety and depression in children and young people: a systematic review and network meta-analysis. *Lancet Psychiatry* 2019; **6:** 1011–20.

42 Humphrey N, Barlow A, Wigelsworth M, et al. A cluster randomized controlled trial of the Promoting Alternative Thinking Strategies (PATHS) curriculum. *J Sch Psychol* 2016; **58:** 73–89.