

Clinical effectiveness and cost-effectiveness of a brief accessible cognitive behavioural therapy programme for stress in school-aged adolescents (BESST): a cluster randomised controlled trial in the UK

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Summary

Background Depression and anxiety are increasingly prevalent in adolescents. The Brief Educational Workshops in Secondary Schools Trial investigated the effectiveness of a brief accessible stress workshop programme for 16–18-year-olds. We aimed to investigate the clinical effectiveness and cost-effectiveness of the DISCOVER cognitive behavioural therapy (CBT) workshop on symptoms of depression in 16–18-year-olds at 6 months compared with treatment-as-usual.

Methods We conducted a multicentre, cluster randomised controlled trial in UK schools or colleges with sixth forms to evaluate clinical effectiveness and cost-effectiveness of a brief CBT workshop (DISCOVER) compared with treatment-as-usual. We planned to enrol 60 schools and 900 adolescents, using a self-referral system to recruit participants. Schools were randomised in a 1:1 ratio for participants to receive either the DISCOVER workshop or treatment-as-usual, stratified by site and balanced on school size and index of multiple deprivation. Participants were included if they were 16–18 years old, attending for the full school year, seeking help for stress, and fluent in English and able to provide written informed consent. The outcome assessors, senior health economist, senior statistician, and chief investigator were masked. People with lived experience were involved in the study. The primary outcome was depression symptoms measured with the Mood and Feelings Questionnaire (MFQ) at 6-month follow-up, in the intention-to-treat population of all participants with full covariate data. The trial was registered with the ISRCTN registry (ISRCTN90912799).

Findings 111 schools were invited to participate in the study, seven were deemed ineligible, and 47 did not provide consent. Between Oct 4, 2021, and Nov 10, 2022, 933 students at 57 schools were screened for eligibility, seven were not eligible for inclusion, and 26 did not attend the baseline meeting and assessment, resulting in 900 adolescents participating in the study. The DISCOVER group included 443 participants (295 [67%] female and 136 [31%] male) and the treatment-as-usual group included 457 participants (346 [76%] female and 92 [20%] male). 468 (52%) of the 900 participants were White, and the overall age of the participants was 17·2 years (SD 0·6). 873 (97%) adolescents were followed up in the intention-to-treat population. The primary intention-to-treat analysis ($n=854$) found an adjusted mean difference in MFQ of $-2\cdot06$ (95% CI $-3\cdot35$ to $-0\cdot76$; Cohen's $d=-0\cdot17$; $p=0\cdot0019$) at the 6-month follow-up, indicating a clinical improvement in the DISCOVER group. The probability that DISCOVER is cost-effective compared with treatment-as-usual ranged from 61% to 78% at a £20 000 to £30 000 per quality-adjusted life-year threshold. Nine adverse events (two of which were classified as serious) were reported in the DISCOVER group and 14 (two of which were classified as serious) were reported in the treatment-as-usual group.

Interpretation Our findings indicate that the DISCOVER intervention is modestly clinically effective and economically viable and could be a promising early intervention in schools. Given the importance of addressing mental health needs early in this adolescent population, additional research is warranted to explore this intervention.

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Introduction

More than half of adult mental health conditions have first onset before the age of 15 years, and almost three-quarters by the age of 18 years.¹ Emotional disorders of anxiety and depression are especially common in the adolescent years, causing marked distress and daily interference for about

one in 12 (8%) young people in England,² with an increased risk of self-harm and suicidality among those with mental health conditions. The most recent government report on mental health of children and young people in England showed that the proportion of those aged 17–19 years with a probable mental health condition increased from 17·4%

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Research in context

Evidence before this study

Past meta-analyses have shown conflicting findings on the overall effectiveness of school-based interventions targeting depression and anxiety. A previously published systematic review and meta-analysis (Zhang et al, 2023) searched three databases up to June, 2021 (Education Resources Information Center, PsycINFO, and Google Scholar) with the following MeSH terms “education*” OR “education program” OR “health education” OR “health literacy” OR “education intervention” OR “school-based” OR “K-12”, “psychological well-being” OR “mental health” OR “anxiety” OR “mental illness” OR “emotional” OR “mental disease” OR “depression” OR “depressive symptoms” OR “internalizing problems” OR “clinical symptoms”, “randomized controlled trials” OR “RCT” OR “random assignment”. This review of papers identified 29 studies. School-based interventions showed positive results for anxiety (effect size 0.44; $p=0.001$); however, no significant results were obtained for depression ($p=0.04$, $p=0.723$). The interaction analyses showed improved outcomes for cognitive behavioural therapy (CBT), delivered by clinicians, especially for targeted populations. Effectiveness was greater in secondary school populations. Few cost-effectiveness evaluations have been carried out in school-based studies.

Added value of this study

This study demonstrates that school-based interventions for older adolescents can be effective in reducing depressive symptoms when following the factors identified in the literature as important to achieving effective outcomes (CBT,

delivered by clinicians in secondary school populations). To our knowledge, this is the first study in secondary schools that has involved intervention delivery by a new group of clinicians based in schools (Mental Health Support Teams) in England. The self-referral recruitment system used is a novel approach and has demonstrated it could be a valuable method to reach young people reluctant to seek help via other recruitment channels. The cost-effectiveness evaluation is novel and important in indicating the potential cost-effectiveness of these workshops for adolescents with elevated depressive symptoms.

Implications of all the available evidence

This study on a brief day-long intervention offers comparable results to other group interventions. Mental Health Support Teams have been implemented in schools across England, in an attempt to improve accessibility to mental health resources for young people. Effective, age-appropriate deliverable resources for these teams are essential. The positive results obtained from newly introduced Mental Health Support Teams in this study are notable and reinforce UK Government policy of introducing them to bridge the gap between schools and specialist services. Previous universally offered interventions have shown weak or no effects when delivered in schools, whereas targeted interventions can have issues with stigma and reach. Few studies have used self-referral as a way of recruiting participants. 80% of students in our study had not previously sought help, which suggests this approach merits further investigation as a way to reach those who do not engage with more formal routes to care.

to 25.7% between 2021 and 2022.³ Although data are not available specifically for 16–18-year-olds, it is estimated that 60% of children and young people with a diagnosable mental health condition do not receive any care through specialist child and adolescent mental health services (CAMHS) in the UK.⁴ Barriers to accessing formal support for young people include concerns about stigma and confidentiality⁵ and the limited capacity (and stringent eligibility criteria) of specialist mental health services, restricting access to effective evidence-based therapies. Consequently, there is a pressing need for scalable, accessible, and evidence-based interventions.

Patel and colleagues⁶ have suggested that given the aforementioned problems, a staged approach to more formal services could help, with the first stage being accessible interventions in more youth-friendly settings such as schools. The latest review of school-based interventions⁷ reported a small effect size for depression and anxiety, indicating that interventions that were cognitive behavioural therapy (CBT)-based and delivered in secondary schools by clinicians were more likely to be effective. Furthermore, specific interventions for older adolescents are probably needed as substantial brain

maturation and marked differences in sleep and coping mechanisms (as well as social changes—eg, increased autonomy) occur at this age.⁸ There has only been one small trial with 21 participants of a school-based intervention in adolescents age 16 years and older.⁹

To help address these problems, in England, Mental Health Support Teams have been recently introduced to support adolescents' mental health and bridge the gap between schools and CAMHS.¹⁰ Mental Health Support Teams staff are master's or postgraduate diploma level therapists or junior therapists.

How school-based interventions should be offered is unclear. Although researcher-led targeted approaches demonstrate greater effectiveness, participants report feeling stigmatised by this approach.¹¹ Conversely, universal approaches, which deliver the intervention to all adolescents, are less stigmatising, but tend to be less effective or reach students who do not require support.¹²

Participant-initiated self-referral systems, where the individuals decide if they want to be involved by referring themselves, have rarely been used in trials.¹³ The self-referral process is part of the PLACES model¹⁴ which describes methods to increase accessibility, including

using colloquial terms (eg, stress) rather than medical terms (eg, depression or anxiety) to reduce stigma. Self-referral itself has several advantages: it has the potential to reduce stigma,¹³ emphasises autonomy (which is valued by adolescents¹⁵), and allows more efficient use of resources. In previous research, this approach has led to high engagement by students who have not previously sought help and has also led to high follow-up rates of more than 90%.¹⁶

Furthermore, the self-referral system has been shown to facilitate a higher proportion of people from ethnic minority groups to engage in interventions,¹⁷ an important issue in diverse communities such as those in England. Minority ethnic groups have been consistently identified as underserved in mental health treatment and research because of problems with access to services.¹⁷

The DISCOVER workshop programme is based on an adult stress workshop model using a self-referral system¹⁸ and has been adapted to provide an accessible and acceptable intervention for adolescents.¹⁹ Key elements of the workshops are as follows: (1) use of CBT materials; (2) brief, 1-day duration delivered within a community setting; and (3) a self-referral pathway. Additional elements of the adolescent model are greater interaction between students and clinicians and the use of more visual materials such as videos and games. Although not powered to evaluate outcomes, a feasibility study of the DISCOVER workshop programme found a reduction in depression ($d=0.27$) and anxiety ($d=0.25$) 3 months post-intervention and was shown to be acceptable to students.¹²

The primary objective of the Brief Educational Workshops in Secondary Schools Trial (BESST) was to investigate the clinical effectiveness and cost-effectiveness of DISCOVER workshops on symptoms of depression in 16–18-year-olds at 6 months compared with treatment-as-usual. Secondary objectives were to assess symptoms of anxiety, wellbeing, sleep, and resilience. We also aimed to assess the accessibility of the workshops for underserved populations and the acceptability of the intervention when delivered by Mental Health Support Teams. Finally, we aimed to conduct a process evaluation of contextual factors affecting the intervention, which will be reported in a separate publication.

Methods

Study design and participants

The BESST study was a multicentre two-arm parallel cluster randomised controlled trial in England, with embedded health economic assessment. Outcomes were measured at baseline and at the 3 month and 6 month follow-up. Schools included in the study were either school sixth forms or dedicated sixth-form colleges with 70 or more students enrolled, state-funded, with sufficient resources available to host the trial. Timings were planned to fit around the school year, with enrolment, baseline assessment, and allocation planned

for the autumn term. The full recruitment and data collection process was repeated with different sixth forms across two school years: 2021–22 and 2022–23. For participation, consent was required from an appropriate school staff member on behalf of the school.

The participants were students aged 16–18 years; attending for the full school year; seeking psychological help for stress, worry, or low mood; fluent in English and able to provide written informed consent; and available to attend and participate in the workshop. Participants were excluded if they were identified as actively suicidal, had severe learning difficulties or psychosis, or were actively receiving psychological therapy for anxiety or depression through CAMHS. Participation was limited to 19 students per school during the 2022–23 school year (for practical reasons in implementing the DISCOVER workshop), with students who had provided written informed consent invited to take part through random selection (appendix p 3).

Gender data were collected via self-report questionnaires, with options male, female, other, or prefer not to say. Ethnicity data were also collected via self-report questionnaires. The options available to select from were: White British, White Irish, any other White background; Mixed: White and Black Caribbean, Mixed: White and Black African, Mixed: White and Asian, any other Mixed background; Asian or Asian British: Indian Asian or Asian British, Pakistani Asian or Asian British, Bangladeshi, any other Asian background; Black or Black British: Caribbean, Black or Black British: African, other Black background; Chinese; other ethnic group; or do not wish to say. Index of multiple deprivation decile for each school was calculated using the school postcode, and for each participant using their home postcode.

Ethical approval was obtained from King's College London PNM Research Ethics Subcommittee (HR–20/21–17758). The protocol has been published in full,²⁰ and was registered with ISRCTN (ISRCTN90912799) on May 28, 2020.

Randomisation and masking

Following baseline assessments, schools were randomised in a 1:1 ratio for their participants to receive either the DISCOVER workshop intervention or treatment-as-usual, using a covariate minimisation algorithm, stratified by site and balanced on school size and index of multiple deprivation.²¹ The allocation sequence was generated by an unmasked statistician who was not part of the study team and the arm allocations were released as A and B to the trial manager who was also unmasked after all adolescents were enrolled at baseline. The outcome assessors were masked and reminded the students at the start and during the follow-up not to divulge whether they received the workshop or not. The chief investigator, senior health economist, and senior statistician were masked until database lock.

See Online for appendix

For more information on the English Indices of Deprivation see https://assets.publishing.service.gov.uk/media/5d8e26f6ed915d5570c6cc55/10D2019_Statistical_Release.pdf

Procedures

Following consent from participating schools and colleges to host the trial, an assembly presentation introduced the trial and intervention to potential participants. Students were informed that they could choose whether or not to participate and were invited to hear more about the trial at a lunchbreak a few days later, where they were given the participant information sheet and consent form.

For students who consented, a baseline assessment took place in a private room at the school, during school hours, which was organised at times appropriate for the students with the help of a school administrator. The masked research assistant, who conducted the assessments at each timepoint, went through the inclusion and exclusion criteria with each participant. If they met the criteria, the participants then completed the demographic information and baseline assessments. Following the baseline timepoint, participants in sixth forms allocated to the treatment-as-usual group received usual school care as well as a signposting information sheet that was provided to all trial participants. Participants in sixth forms randomly allocated to the DISCOVER group were invited to attend the workshop programme delivered at their sixth form.

DISCOVER is a brief, accessible workshop-based stress management programme for 16–18-year-olds, to which they can self-refer. The workshop is considered accessible because of the self-referral system where students are invited at the assembly to refer themselves as well as the use of non-diagnostic terms, such as stress, in describing the programme. The programme was co-designed with a Teenage Advisory Group of 31 16–18-year-olds, with the aim of improving engagement, offering effective treatment, and maintaining participants' motivation and improvement to reduce relapse.¹⁹ The workshop programme includes CBT coping techniques for managing mood, anxiety, and stress, delivered in non-medicalised language and with images and materials featuring students from diverse groups.

A 2-day DISCOVER training programme was offered to Mental Health Support Team staff from National Health Service (NHS) trusts. Members of the Mental Health Support Teams were trained to deliver the intervention in accordance with the DISCOVER manual and trial protocol.²⁰ The 2-day training session, and one supervision session per Mental Health Support Team, were led by IS, who was a co-applicant on BESST. Each workshop programme was co-facilitated by three staff: one senior therapist and two junior therapists. The workshop delivery teams were recruited into the trial solely for workshop delivery.

The workshop was a day-long, face-to-face group event, which took place at the school or college in a private classroom (without school staff present) over a single school day. Permission for students to attend and miss curricular activities was obtained from staff in advance, and the students' usual breaks and lunch were adhered to.

In the days before attending the workshop, each student met individually with a workshop leader in a private space, for approximately 30 min. During this session they discussed their personal goals, which they would set at the end of the workshop day.

Core workshop content was as follows. Each workshop began with introductions and icebreakers. A CBT-informed model of emotional problems was then provided to explain and normalise young people's experiences, including video clips of teenage actors and group discussions. Particular attention was given to personal, relationship, and academic stresses typical for the age group. CBT techniques for managing anxiety and mood problems were taught and practised, supported by scripted role-plays, video demonstrations, and printed handouts. Behavioural strategies used included problem-solving, sleep advice, and time management. Cognitive strategies included identification of and challenging negative thoughts. Participants were provided with a workbook to keep, which provided all the covered material and space to make notes throughout the workshop, and record their personal goals. Content of the workshop in digital form was also provided in a smartphone app.

After 1 week, participants were followed up individually by one of the workshop leaders, with the participants receiving a 15–30 min telephone goal review to monitor progress and support incorporation of CBT skills into real-life situations. Participants were given the option of receiving two further telephone goal reviews within the 12-week post-workshop period. Further details are provided in the published protocol.²⁰

To assess treatment fidelity, each member of the workshop delivery team completed a 9-item self-report fidelity checklist immediately following each workshop. An independent observer also attended one workshop per delivery team to assess treatment fidelity using the same checklist. The checklist was developed by the trial team, based on research literature²² and consultations with the DISCOVER workshop team. Fidelity was met if seven of the nine items were met (including four mandatory items). Fidelity scores were compiled at the end of the trial but were not used as a means to improve fidelity during the trial.

Treatment-as-usual is defined as the usual school care provided to students in their sixth form. Types of school provision offered across participating schools, and the percentage of schools offering each provision, are presented in the appendix (p 4).

Adolescent Patient and Public Involvement groups, some of whom had lived experience of mental illness, were consulted on recruitment approaches and participant materials. Patient and Public Involvement members advised on the content and delivery of participant recruitment presentations to provide optimal clarity of trial information, ensure appropriateness of materials for the target population, and maximise engagement of the presentations for the relevant students.

Outcomes

Follow-up assessment appointments were conducted approximately 3 months and 6 months post-randomisation date by a masked outcome assessor. Gift voucher incentives (£15 at baseline, £15 at 3 months, and £25 at 6 months for completing final assessment) were offered to participants following completion of each assessment.

The primary outcome (collected at baseline, 3-month, and 6-month follow-ups in all participants) was symptoms of depression, assessed using the Mood and Feelings Questionnaire (MFQ; higher scores indicate greater severity of depressive symptoms).²³

Secondary outcomes and their measures were anxiety, assessed using the anxiety sub-scale from the Revised Child Anxiety and Depression Scale (higher scores indicate greater severity of anxiety symptoms)—child version;²⁴ wellbeing, assessed using the Warwick–Edinburgh Mental Wellbeing Scale (higher scores indicate higher levels of general wellbeing);²⁵ sleep quality, assessed using the Sleep Condition Indicator (SCI; higher scores indicate better sleep);²⁶ and resilience, assessed using the Child and Youth Resilience Measure 12 (higher scores indicate greater resilience).²⁷ These measures were collected at baseline, 3-month, and 6-month follow-ups in all participants. Student satisfaction was measured in the intervention group only at the end of each workshop, assessed using the Client Satisfaction Questionnaire (CSQ-8; higher scores indicate greater satisfaction),²⁸ and prespecified additional assessments of the acceptability of the intervention using student feedback forms.

Health economic secondary outcomes were health-related quality of life, assessed using the EQ-5D-3L,²⁹ used to calculate quality-adjusted life-years (QALYs) for use in economic evaluation, and use of health and social care services, measured using the Child and Adolescent Service Use Schedule (CA-SUS). This was designed for, and successfully implemented in, multiple evaluations of interventions for children and young people with mental health conditions, including depression.^{12,30} These measures were collected at baseline, 3-month, and 6-month follow-ups in all participants.

Research assistants asked participants if they had experienced any adverse events, serious adverse events, or suspected adverse reactions (related to the intervention) at each follow-up assessment. Workshop facilitators recorded any adverse events or serious adverse events reported during the workshop and follow-up calls.

Choice of primary outcome measure

The MFQ is a 33-item self-report depression measure, which in the English version has shown good psychometric properties and is a widely used and validated instrument for adolescents. It has been used throughout the world and translated into several languages and is free to use for clients or research.

Scores range from 0 to 66, with a clinical cutoff of higher than 27 defining elevated symptoms of depression.

Statistical analysis

All outcomes reported were prespecified in the statistical analysis plan that was drafted and approved by a masked trial statistician and senior statistician (KJ, BC) following King's Clinical Trials Unit Standard operating procedures, and is presented in the appendix (p 10).

Assuming a two-sided type 1 error of 0.05 with 90% power, to detect an effect size of 0.28 with an intra-cluster correlation of 0.03, 760 participants were estimated to be required from 54 schools. After inflating for loss to follow-up of schools and participants, we planned to enrol 60 schools and 900 adolescents.

Descriptive data of the population were presented as means and SDs for continuous data, and as counts and percentages for categorical data.

The primary outcome of MFQ was analysed with a mixed-effect, multi-level linear model at 6 months adjusted using prespecified fixed effects of: baseline severity (MFQ score), aggregated level school deprivation, geographical area, school size, gender, ethnicity group, assessment timepoint, treatment, and treatment-by-time interaction. A random intercept was fitted for each school and student and the adjusted mean difference between the intervention and control score was estimated, alongside the 95% CI and p value. The associated Cohen's d standardised effect size (with 95% CI) was calculated using a pooled standard deviation. The intra-cluster correlation at 6 months was also calculated. Secondary outcomes were analysed in a similar way.

All participants with any follow-up data were included in the intention-to-treat population, and those with complete covariate data were included in the intention-to-treat analysis. Full details of handling missing data (observations and participants) are in the statistical analysis plan (appendix p 10). Prespecified subgroup analyses were planned for elevated baseline score (MFQ >27), gender, participant age, and school year. A per-protocol analysis, as specified in the statistical analysis plan, repeated the primary analysis but excluded participants who did not receive an acceptable dose of the intervention (less than 75% of the workshop or not setting a goal), had data collected outside of visit windows, or reported access to CAMHS.

The economic analyses followed a health economic analysis plan drafted by the trial health economist (JS), in line with the trial protocol, and approved by the senior health economist (SB; reproduced in the appendix p 48). The economic analysis was a cost-utility analysis at the 6-month follow-up with effectiveness measured in terms of QALYs estimated from the EQ-5D-3L measure of health-related quality of life.²⁹ The economic perspective taken was that preferred by the National Institute for Health and Care Excellence, which includes all national health services and all social care services (often referred

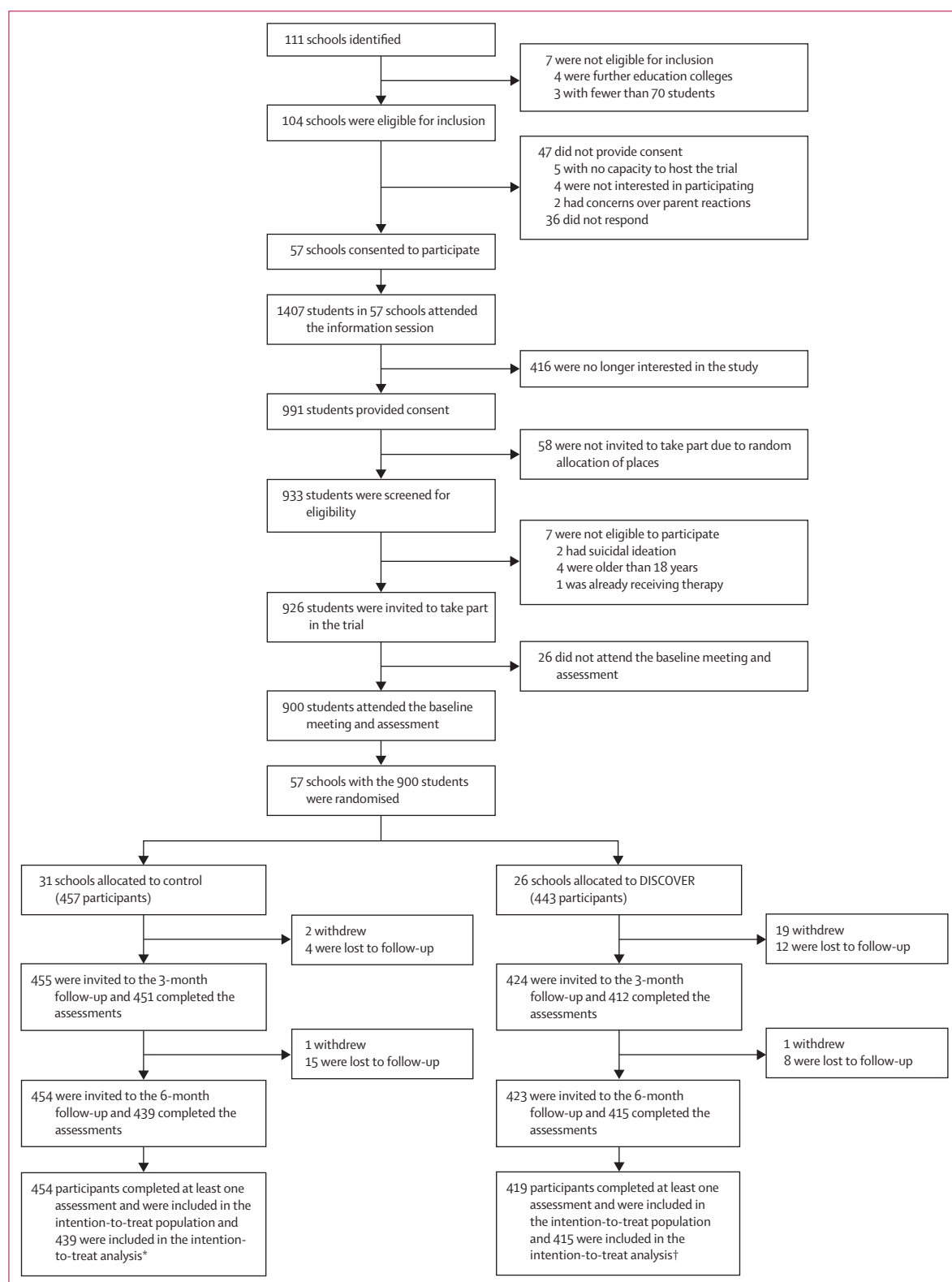


Figure 1: Trial profile

*15 participants were missing covariate data and were therefore not included in the intention-to-treat analysis of the primary outcome. †Four participants were missing covariate data and were therefore not included in the intention-to-treat analysis of the primary outcome.

to as the NHS and personal social services perspective). Use of health and social care services was measured using the CA-SUS, designed for children and young people with mental health conditions, including depression.^{12,30}

The DISCOVER intervention was directly costed using a micro-costing approach, detailed in full in the appendix (p 35). Nationally applicable unit costs were applied to all other health and social services used (appendix p 38).

Full details of the economic analyses are provided in the appendix (p 33). In summary, costs and QALYs adjusted for baseline, aggregated level school deprivation, geographical area, school size, gender, and ethnicity group, were compared between groups using generalised linear modelling (GLM) with the Gaussian family and identity link functions selected using the modified Park test³¹ and bootstrapped confidence intervals as recommended to account for the highly skewed nature of cost data.³² Cost-effectiveness was explored in terms of cost per QALY using incremental cost-effectiveness ratios with uncertainty represented by cost-effectiveness acceptability curves which show the probability that an intervention is cost-effective compared with control across a range of willingness to pay thresholds.³³ All economic analyses were adjusted for baseline severity (MFQ score), aggregated level school deprivation, geographical area, school size, gender, and ethnicity group, plus the variable of interest (cost or QALYs). Sensitivity analysis of cost-effectiveness results to outliers (prespecified) and GLM assumptions (post hoc) were carried out, as well as prespecified subgroup analysis (on participants with an MFQ score of higher than 27).

A Data Monitoring Committee was formed to review the ongoing safety profile of the intervention. The committee consisted of a clinical chair and independent statistician, and one additional independent member. The study has been reported consistent with the CONSORT statement for transparent reporting of trials. Stata 18 has been used throughout for statistical and economic analyses.

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.

Results

Over 2 school years (2021–22 and 2022–23), we screened 111 schools to participate, and seven were deemed ineligible and 47 did not provide consent. We then enrolled 57 schools or colleges with sixth forms in the study (appendix p 8). Between Oct 4, 2021, and Nov 10, 2022, 933 students were screened for eligibility, seven were not eligible for inclusion, and 26 did not attend the baseline meeting and assessment, resulting in 900 students randomly assigned to either of the two groups. 379 were enrolled during the

2021–22 intake and 521 during the 2022–23 intake, in 15 localities across four regions of England. 31 schools with 457 participants were randomly assigned to the treatment-as-usual group and 26 schools with 443 participants were randomly assigned to the DISCOVER workshop programme (figure 1). The study involved a total of 11 NHS trusts within which 15 Mental Health Support Teams delivered the intervention.

The overall index of multiple deprivation for the 57 schools was 4.9 (SD 3.0) which ranged from average

	Control group (n=457)	DISCOVER group (n=443)	Overall (N=900)
Age, years			
Mean (SD)	17.2 (0.6)	17.3 (0.6)	17.2 (0.6)
Gender			
Male	92 (20%)	136 (31%)	228 (25%)
Female	346 (76%)	295 (67%)	641 (71%)
Other	12 (3%)	9 (2%)	21 (2%)
Prefer not to say	7 (2%)	3 (<1%)	10 (1%)
Ethnicity			
White	239 (52%)	229 (52%)	468 (52%)
Mixed	28 (6%)	31 (7%)	59 (7%)
Asian	67 (15%)	88 (20%)	155 (17%)
Black	78 (17%)	63 (14%)	141 (16%)
Chinese	9 (2%)	6 (1%)	15 (2%)
Other	20 (4%)	21 (5%)	41 (5%)
Prefer not to say	3 (<1%)	1 (<1%)	4 (<1%)
Missing	13 (3%)	4 (<1%)	17 (2%)
Intake year			
2021–22	206 (45%)	173 (39%)	379 (42%)
2022–23	251 (55%)	270 (61%)	521 (58%)
Number of sixth forms enrolled			
2021–22	11/31 (35%)	8 (31%)	19/57 (33%)
2022–23	20/31 (65%)	18 (69%)	38 (67%)
Sixth-form year			
Year 12 (aged 16–17 years)	233 (51%)	210 (47%)	443 (49%)
Year 13 (aged 17–18 years)	221 (48%)	233 (53%)	454 (50%)
Missing	3 (<1%)	0	3 (<1%)
English as a first language			
No	61 (13%)	65 (15%)	126 (14%)
Yes	395 (86%)	378 (85%)	773 (86%)
Missing	1 (<1%)	0	1 (<1%)
Number of GCSEs passed			
Mean (SD)	8.7 (1.7)	8.7 (1.6)	8.7 (1.6)
Participant index of multiple deprivation			
Mean (SD)	4.6 (2.8)	4.6 (2.8)	4.6 (2.8)
Previously sought help from general practitioner for mental health			
No	371 (81%)	349 (79%)	720 (80%)
Yes	86 (19%)	93 (21%)	179 (20%)
Missing	0	1 (<1%)	1 (<1%)
Data are n (%) or mean (SD). GCSE= General Certificate of Secondary Education.			
Table 1: Baseline characteristics			

	Baseline			3 months			6 months		
	Control (n=457)	DISCOVER (n=443)	Overall (N=900)	Control (n=451)	DISCOVER (n=412)	Overall (N=863)	Control (n=439)	DISCOVER (n=415)	Overall (N=854)
Primary outcome									
MFQ									
Number of participants	455	443	898	451	412	863	439	415	854
Total score	24.2 (13.1)	22.7 (11.7)	23.4 (12.4)	21.9 (12.8)	18.9 (10.3)	20.5 (11.8)	21.3 (12.7)	18.4 (11.2)	19.9 (12.1)
Secondary outcomes									
RCADS Anxiety T-score									
Number of participants	435	429	864	433	401	834	421	404	825
Total score	55.4 (13.0)	55.6 (13.3)	55.5 (13.1)	52.7 (13.3)	51.0 (12.6)	51.9 (13.0)	51.4 (13.0)	49.5 (12.9)	50.5 (13.0)
WEMWBS									
Number of participants	451	439	890	452	411	863	437	415	852
Total score	40.7 (9.1)	41.8 (8.6)	41.2 (8.8)	42.4 (9.4)	44.0 (9.0)	43.2 (9.3)	42.6 (9.3)	45.0 (9.2)	43.8 (9.3)
SCI									
Number of participants	455	443	898	449	411	860	437	413	850
Total score	19.1 (6.8)	19.4 (6.6)	19.2 (6.7)	19.4 (7.4)	20.2 (6.7)	19.8 (7.1)	19.8 (7.5)	20.6 (6.9)	20.2 (7.2)
CYRM-12									
Number of participants	457	443	900	449	412	861	438	414	852
Total score	45.1 (7.9)	45.1 (7.4)	45.1 (7.7)	45.1 (8.1)	45.7 (8.0)	45.4 (8.0)	44.7 (8.0)	46.0 (7.9)	45.4 (7.9)

Data are n or mean (SD). MFQ=Mood and Feelings Questionnaire. RCADS Anxiety T-score=Revised Child Anxiety and Depression Scale, Anxiety T-score only. WEMWBS=Warwick-Edinburgh Mental Wellbeing Scale. SCI=Sleep Condition Indicator. CYRM-12=Child and Youth Resilience Measure 12.

Table 2: Primary and secondary outcome data

	Number of participants	Adjusted mean difference estimate (95% CI)	Cohen's d effect size (95% CI)	p value
Primary outcome				
MFQ	854	-2.06 (-3.35 to -0.76)	-0.17 (-0.27 to -0.06)	0.002
Secondary outcomes				
WEMWBS	847	1.77 (0.76 to 2.77)	0.20 (0.09 to 0.31)	0.0006
SCI	853	0.63 (-0.06 to 1.33)	0.09 (-0.01 to 0.20)	0.07
RCADS Anxiety T-score	822	-2.21 (-3.41 to -1.01)	-0.17 (-0.26 to -0.08)	0.0003
CYRM-12	856	1.23 (0.49 to 1.96)	0.16 (0.06 to 0.25)	0.001
Subgroup analyses				
MFQ >27 at baseline	298	-3.88 (-6.48 to -1.29)	-0.52 (-0.86 to -0.17)	0.003
MFQ males	216	-2.89 (-5.03 to -0.75)	-0.25 (-0.43 to -0.06)	0.008
MFQ females	609	-2.01 (-3.60 to -0.42)	-0.16 (-0.29 to -0.03)	0.013
MFQ Year 12 (aged 16-17 years)	421	-2.26 (-3.90 to -0.62)	-0.17 (-0.30 to -0.05)	0.007
MFQ Year 13 (aged 17-18 years)	430	-2.13 (-4.13 to -0.14)	-0.18 (-0.35 to -0.01)	0.036
MFQ year 2021-22	352	-1.42 (-3.29 to 0.45)	-0.11 (-0.26 to 0.04)	0.14
MFQ year 2022-23	502	-2.64 (-4.34 to -0.94)	-0.21 (-0.35 to -0.08)	0.002

MFQ=Mood and Feelings Questionnaire. WEMWBS=Warwick-Edinburgh Mental Wellbeing Scale. SCI=Sleep Condition Indicator. RCADS Anxiety T-score=Revised Child Anxiety and Depression Scale, Anxiety T-score only. CYRM-12=Child and Youth Resilience Measure 12.

Table 3: Standardised effect estimates for the primary, secondary, and subgroup analyses

scores of 2.8 in London to 8.8 in the southwest. The overall average school size in our sample was 244 students (SD 164.9).

Baseline characteristics for the population are presented in table 1. Participants were predominantly female (641 [71%] of 900 female, 228 [25%] male, 21 [2%] other, and ten [1%] preferred not to say) and White (468 [52%] of 900). The overall age of the participants was 17.2 years (SD 0.6). Only 20% (179 of 900) had previously sought help from their general practitioner for their mental health problems. There appeared approximate balance between the two arms for the baseline data collected. Of the 900 students, 873 (97%) were followed up and included in the intention-to-treat population, of whom 854 were included in the intention-to-treat analysis (439 in the control group and 415 in the DISCOVER group; table 2).

For the primary analysis of the MFQ at 6 months post randomisation (intention-to-treat analysis population), we estimated an adjusted mean difference of -2.06 (95% CI -3.35 to -0.76, Cohen's d -0.17; $p=0.0019$; intra-cluster correlation, 0.01; table 3; figure 2), showing a significant reduction in depressive symptoms in the DISCOVER group versus the control group. The intra-cluster correlation for the MFQ at 6 months was similar to that quoted in the sample size calculation (0.01 [95% CI 0.001 to 0.09]).

For the secondary outcomes, we found a significant improvement in the DISCOVER group versus treatment-as-usual for wellbeing (adjusted mean difference, 1.77 [95% CI 0.76 to 2.77]; Cohen's d=0.0006; $p=0.0006$);

anxiety (adjusted mean difference -2.21 [95% CI -3.41 to -1.01]; Cohen's $d=-0.17$; $p=0.0003$); and resilience (adjusted mean difference, 1.23 [95% CI 0.49 to 1.96]; Cohen's $d=0.16$; $p=0.0010$). No improvement on sleep (measured with the SCI) was seen (adjusted mean difference, 0.63 [95% CI -0.06 to 1.33]; Cohen's $d=0.09$; $p=0.072$; table 3).

The DISCOVER workshop was generally well attended with 88% of participants (392 of 443) attending 75% or more of the workshop. Satisfaction with workshops was good with a CSQ average score of 26.6 (SD 3.7). Follow-up calls were not as well used, with 214 participants using at least one call. Required fidelity was met across the workshops. The per-protocol analysis using the MFQ included 618 participants and showed a similar effect to that of the intention-to-treat population (Cohen's $d=-0.16$ [95% CI -0.28 to -0.04 ; $p=0.0092$).

Several prespecified subgroup analyses were carried out (table 3). When looking at only those participants who showed depressive symptoms at baseline (MFQ >27 ; $n=298$), we saw a larger adjusted mean difference (-3.88) equating to a Cohen's d of -0.52 (95% CI -0.86 to -0.17 ; $p=0.0033$). No difference was seen between effects for students in year 12 or year 13 of sixth form. A slightly larger effect was seen for males (Cohen's d of -0.25 [95% CI -0.43 to -0.06]; $p=0.0081$) than females (-0.16 [95% CI -0.29 to -0.03]; $p=0.0013$).

There were 23 adverse events reported, with nine (two serious adverse events) in the DISCOVER group compared with 14 (two serious adverse events) in the treatment-as-usual group. One participant experienced a mild adverse reaction from the treatment-as-usual group which might have been attributed to the study (table 4).

Service use at baseline and follow-up was broadly similar between groups (appendix pp 39–41). The cost of the DISCOVER intervention was estimated to be £108.87 per student (appendix p 35). Total costs per participant over the 6-month follow-up adjusted for baseline covariates were significantly higher in the DISCOVER group than in the treatment-as-usual group (adjusted mean difference, £147.57 [SE £94.80; 95% CI 9.48 to 310.58]; $p=0.037$; appendix p 42) and QALYs over the 6-month follow-up were significantly higher in the DISCOVER group than in the treatment-as-usual group (adjusted mean difference, 0.0095 [SE 0.0042 ; 95% CI 0.0004 – 0.0165]; $p=0.039$; appendix p 43). The point estimate of the ratio of the mean difference in costs and QALYs for DISCOVER compared with treatment-as-usual, referred to as the incremental cost-effectiveness ratio, was £15 387 per QALY, with additional effects generated by DISCOVER being associated with additional costs (appendix p 44). The cost-effectiveness acceptability curve shows that the probability that DISCOVER is cost-effective compared with treatment-as-usual ranged from 61% to 78% at the £20 000 to £30 000 per QALY threshold preferred by the National Institute for Health and Care Excellence (appendix p 45).³⁴ These probabilities were higher in

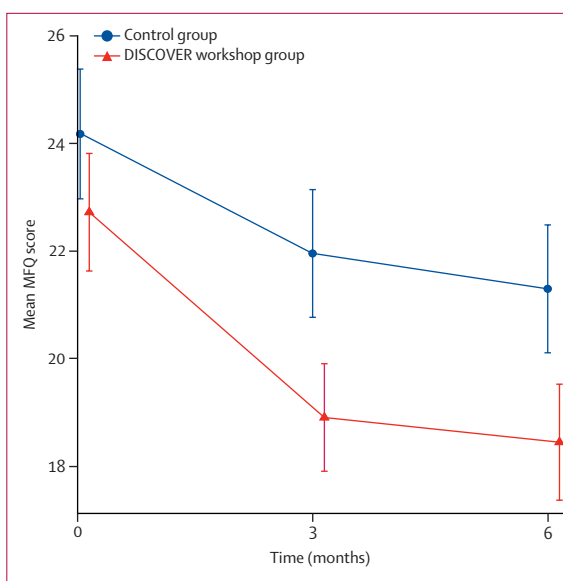


Figure 2: MFQ scores

MFQ=Mood and Feelings Questionnaire. Circles and triangles indicate mean score and upper and lower bars indicate 95% CIs for each treatment group.

	Control group (n=14)			DISCOVER group (n=9)			Overall (N=23)
	Female (n=8)	Male (n=5)	Other (n=1)	Female (n=8)	Male (n=1)	Other	
Is the event serious?							
No	7 (88%)	5 (100%)	0	6 (75%)	1 (100%)	0	19 (83)
Yes	1 (13%)	0	1 (100%)	2 (25%)	0	0	4 (17)
Serious adverse events (number of events; number of people)							
Psychological event (eg, panic attack)	1; 1	0	1; 1	0	0	0	2; 2
Physiological event (eg, injury)	0	0	0	2; 2	0	0	2; 2
Type of adverse event (including serious adverse events; number of events; number of people)							
Self-harm	0	1; 1	0	1; 1	0	0	2; 2
Disclosure of current abuse, emotional	1; 1	0	0	0	0	0	1; 1
Disclosure of current abuse, physical	1; 1	1; 1	0	0	0	0	2; 2
Participant became distressed	1; 1	1; 1	0	2; 2	1; 1	0	5; 5
Other psychological event (eg, panic attack)	2; 2	1; 1	1; 1	2; 2	0	0	6; 6
Other physiological event (eg, injury)	3; 3	1; 1	0	3; 3	0	0	7; 7
Relationship to study procedures							
Possibly related	1 (13%)	0	0	0	0	0	1 (4%)
Not related	7 (88%)	5 (100%)	1 (100%)	8 (100%)	1 (100%)	0	22 (96%)
Data are (%), unless otherwise indicated.							
Table 4: Adverse events							

Data are (%), unless otherwise indicated.

Table 4: Adverse events

sensitivity analyses (outliers removed 87–94%; GLM assumptions 77–87%) and the vulnerable subgroup analysis (91–95%; appendix p 46).

Discussion

The BESST study is a large, rigorous school-based study of an intervention aimed at reaching and addressing depression and anxiety among adolescents. Only a few such studies have been conducted in the UK. Our findings indicate that the DISCOVER intervention is clinically effective for the overall sample of students. Further, in the sample with elevated depressive symptoms at baseline, we found a moderate and clinically meaningful effect. The DISCOVER intervention also had a higher probability of being cost-effective than did treatment-as-usual with this group.

The DISCOVER intervention improved anxiety, wellbeing, and resilience scores. This aligns with our previous feasibility study¹⁶ and corroborates the efficacy of this workshop model, as evidenced in earlier studies involving adult participants.¹⁸

Our results resonate with the conclusions of a recent rigorous systematic review that advocated for interventions rooted in CBT, delivered by clinicians, and targeted at secondary school students.⁷

The success of the clinician-delivered CBT DISCOVER intervention is noteworthy, especially when juxtaposed against the outcomes of other school-based mental health initiatives. For example, a previous adolescent study, using classroom-based CBT via a universal approach, found no difference between intervention and usual school provision.³⁵ Similarly, the MYRIAD study,¹² a large-scale trial of 8376 students, of a school-based mindfulness training programme led by teachers and integrated into the school's socio-emotional curriculum, did not yield the same level of effectiveness. The authors of the MYRIAD study reported low engagement, as indicated by infrequent home practice at post intervention and follow-up, which might have been hindered by the impact of the COVID-19 pandemic. Acceptability of the MYRIAD intervention was very mixed. It is conceivable that either a more targeted or self-referral approach of students who needed or wanted the intervention could have led to more promising results.

The DISCOVER intervention was successfully delivered by a new professional group of clinicians (Mental Health Support Teams) based in schools.¹⁰ They have only been newly introduced and these positive outcome results show that, with good training, they were able to effectively deliver the workshops; with the workshops also being well received by participants.

The DISCOVER workshop is grounded in CBT. CBT is well researched, evidence based, and in DISCOVER was tailored to be applicable to the studied population and to be applied practically in their everyday lives. Workshops were delivered in secondary schools, specifically for 16–18-year-olds. Whereas previous trials were designed for a relatively wide age range of adolescents, the DISCOVER intervention was designed specifically for a narrower age range of 16–18 years and used age-appropriate topics, materials, and approaches.

One novel aspect of the DISCOVER intervention is its accessibility. The self-referral system is led by participants' decisions and aligns with adolescents' desire for autonomy.¹⁵ This approach is different to universal or targeted interventions in which enrolment is researcher or clinician led. The high proportion of those who had not previously sought help through formal routes (80%) underscores the value of this approach with this group who are not keen to consult professionals.⁵ This accessibility is very important to NHS England's patient care and policy.³⁶

Participants who self-refer are more likely to have elevated symptoms of depression and anxiety than the general population. In this study, the scores of self-referrers on the MFQ of 23.4 (SD 12.4) were higher than those of young people aged 12–18 years in the general population (17.98 [12.77]).³⁷ In a study of adults, 75% of self-referrers were found to have diagnosable mental health problems.³⁸ Self-referral does have some similarities to the targeted approach in reaching participants with mental health needs, but does not require the assessment system that participants who have reached the threshold have previously found stigmatising.¹¹

Despite these encouraging results, this self-referral approach might not have been an effective engagement tool for certain students. For example, we saw a significant number of students attend the information session but not sign up for the trial, and a smaller proportion of male students than female students. More work is required to understand for whom the self-referral approach is most suitable and how best to reach other individuals requiring help.

In comparing BESST to other studies, the fact that the intervention involves an element of self-nomination might boost the intervention effect, in that those enrolled by a researcher into a universal or targeted intervention might be less motivated to capitalise on the intervention.

Another strength was the multicentre design across rural and urban areas of England. Additionally, the study did allow for the participation of a high proportion (46%) of students from minoritised ethnic groups.

However, there are limitations. Assessments were based on unmasked participants and were self-reported rather than clinical evaluations. The control group was passive rather than active and the effect found in the sample was only modest. The sample was predominantly female.

Future studies should examine the long-term effects of this intervention to determine if it can prevent issues from arising in adulthood. A 2-year follow-up is presently being undertaken. In view of the newness of the approach, research using mixed methods is needed to compare self-referral with targeted ways of recruiting to discover who the self-referral approach is not reaching. Self-report and objective measures should be used. Co-designed interventions to improve engagement, developed with male students from different backgrounds, could be helpful.

A major consideration is the scalability of this intervention and its potential applicability across other regions of the UK and globally, which need to be tested. Given that implementation of evidence-based interventions is not easy,³⁹ issues about implementing this professionally trained and supervised intervention within the existing and planned infrastructure of school-based services will need considerable thought. Areas for further work include optimisation of the clinical follow-up calls (only 48% of students completed at least one follow-up telephone call), and the factors that led to schools accepting or declining involvement in the study.

In conclusion, BESST demonstrates that the brief CBT DISCOVER intervention was modestly clinically effective for reducing depressive and anxiety symptoms among adolescents. The self-referral model enhanced accessibility for those who would not normally seek help who might be hesitant to seek assistance when interventions are formally offered. This approach could serve as a clinically and economically viable early intervention tool for national health-care providers in schools, aiming to diminish the prevalence of mental health issues within this group of young people.

Contributors

The study concept was conceived by JB who was the chief investigator, and BC, CE, CD, JD, JB, IS, PF, PS, SB, and TW received funding. The study protocol was developed by BC, CD, CE, JD, JB, JY, KJ, IS, PF, PS, SB, SL, and TW, and the data collection was led by SL. DS, JD, JY, JB, and PS were regional site leads. The DISCOVER Programme training and supervision was led by IS. The trial statistician was KJ and senior statistician was BC. The trial health economist was JS and the senior health economist was SB. The study statistical analysis plan was approved by KJ and BC. The trial analysis was conducted by KJ and interpreted by BC and KJ. The health economics analysis was conducted by JS and interpreted by JS and SB. The qualitative analysis was planned and interpreted by TW. KJ and JS generated figures. The first draft of the manuscript was written by BC, JS, KJ, SB, SL, and JB, and approved by all coauthors. JB is the study guarantor. BC and SB verified the data. All authors confirm they had access to all the data and accept responsibility for the decision to submit for publication.

Declaration of interests

We declare no competing interests.

Data sharing

Authors wishing to access the data should contact the corresponding author providing a statistical analysis plan addressing a new research question. All requests will be discussed by the study trial management group.

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