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Title

Early intervention for depression and anxiety in 16-18-year-olds: Protocol for a feasibility cluster randomised controlled trial of open-access psychological workshops in schools (DISCOVER)

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ABSTRACT

Adolescence is a vulnerable period for the development of mental health problems. The DISCOVER intervention aims to provide accessible, acceptable and cost-effective psychological support for stressed adolescents in inner-city secondary schools. The intervention uses age-appropriate cognitive-behavioural therapy (CBT) methods and materials, delivered in an interactive 1-day workshop with additional telephone support. An open-access entry route allows students to self-refer. This protocol describes a feasibility cluster randomised controlled trial (RCT) comparing DISCOVER with a waitlist control condition. The study will run across 10 clusters (secondary schools) in the inner London Boroughs of Southwark and Lambeth. Participants are students aged over 16 years who are seeking help with anxiety and/or depressive symptoms. Key feasibility parameters relate to the proportion of students willing to participate in the research following publicity events; the proportion of students who complete the intervention; and response rates for outcome measures. Outcome variance estimates and intra-cluster correlations will be obtained for future power calculations. Qualitative methods will be used to explore the acceptability of the intervention and research procedures for students and school staff. The feasibility of an economic evaluation will also be examined. The results will (i) determine the appropriateness of proceeding to a definitive full-scale trial; and (ii) inform the development of an optimised version of the DISCOVER intervention that can be tested within feasible parameters.

Trial registration

ISRCTN88636606 (registered with ISRCTN 15 January 2015).

Keywords

Adolescents, anxiety, CBT, depression, schools

Abbreviations

BME – black and minority ethnic.

CAMHS – child and adolescent mental health services.

CBT – cognitive behavioural therapy.

CSQ-8 – Client Satisfaction Questionnaire – 8.

CSRI – Client Service Receipt Inventory.

EQ-5D – EuroQol – 5D.

MFQ – Mood and Feelings Questionnaire.

NHS – National Health Service.

PQ-LES-Q – Pediatric Quality of Life Enjoyment and Satisfaction Questionnaire.

QALY – quality-adjusted life years.

RCADS – Revised Children’s Anxiety and Depression Scale.

RCT – randomised controlled trial.

TAG – Teenage Advisory Group.

WEMWBS – Warwick Edinburgh Mental Wellbeing Scale.

1. INTRODUCTION

More than half of mental health problems in adult life start by adolescence [1, 2]. Emotional disorders of anxiety and depression are especially common in the adolescent years, causing marked distress and daily interference for 5% of teenagers at any given time [3, 4]. Anxious and depressed young people are more likely to suffer from poor social, educational and occupational outcomes [5-7]. They are also vulnerable to substance abuse, early sexual activity and self-harm [8, 9]. Even subthreshold emotional symptoms - which affect up to one-third of adolescents [10] - increase risk for long-term functional impairment and suicidal behaviours [11, 12].

Despite this significant burden, less than one quarter of anxious and depressed youth are in contact with specialist child and adolescent mental health (CAMHS) services in the UK [13]. Many young people choose

not to disclose problems due to concerns about stigma and confidentiality [14, 15]. Access is also restricted by inconvenient appointment times, transportation difficulties, long waiting lists and high thresholds for specialist referral [16, 17]. Even when young people do appear at mental health clinics, there is limited provision of cognitive-behavioural therapy (CBT) and other recommended psychological therapies [18].

‘DISCOVER’ has been developed in the UK to provide more accessible, acceptable and cost-effective early intervention for 16-18-year-olds with emotional difficulties. The content and delivery methods have been adapted from an established ‘well-being workshop’ model for working age adults [19, 20]. Key elements of the adult workshops are: (i) use of evidence-based CBT materials; (ii) group delivery at community sites; (iii) brief, one-day duration; and (iv) an open-access referral pathway. These features were reviewed by a Teenage Advisory Group and refined in an initial proof-of-concept study [21]. The latest iteration of DISCOVER incorporates new age-appropriate video material, a more interactive presentational style and additional methods for personalisation and telephone follow-up. DISCOVER also uses a teacher-assisted, open-access referral pathway in schools. In this way, teachers can encourage vulnerable students to access help, but the final decision is made by the student.

The current study will accomplish the critical next phase of development and testing, in line with the *MRC Framework for Complex Interventions* [22]. The overall aim is to assess the feasibility of a cluster randomised controlled trial of DISCOVER in secondary schools.

Primary objectives are:

1. To recruit, consent and randomise N=150 student participants from 10 schools
2. To assess participant attendance at DISCOVER workshops
3. To assess data collection rates at baseline and 3-month follow-up
4. To obtain outcome variance estimates and intra-cluster correlations required for sample size calculations in a full-scale trial
5. To produce a protocol for a full-scale trial (if supported by this feasibility trial)

Secondary objectives are:

1. To assess student attendance rates at DISCOVER publicity meetings
2. To explore factors affecting students' participation in the study
3. To explore accessibility of DISCOVER by examining participation rates of students who are clinically anxious and depressed; from black and minority ethnic backgrounds; and have not previously accessed CAMHS or school counselling
4. To explore acceptability of DISCOVER and associated trial procedures, using feedback from students and teachers at research sites
5. To explore the feasibility of collecting resource use and outcome data required for cost-utility and cost-effectiveness analyses
6. To explore the likely ranges for candidate outcomes by obtaining intervention effect estimates and confidence intervals

2. MATERIALS AND METHODS

2.1 Design

This is a school-based feasibility cluster randomised controlled trial with two parallel arms: (i) a structured 1-day CBT workshop with personalised telephone follow-up (DISCOVER); and (ii) a waitlist control condition. The unit of randomisation will be the school, thereby minimising contamination between intervention and control arms. Outcomes will be measured in both arms at baseline and 3-month follow-up. Three qualitative sub-studies will examine factors affecting students' willingness to participate in the research following an initial information meeting (sub-study 1); and acceptability of DISCOVER and associated trial procedures as perceived by student participants (sub-study 2) and school staff (sub-study 3).

2.2 Setting

The study will run across 10 secondary schools in Lambeth and Southwark. These inner London Boroughs are two of the most socially deprived and ethnically diverse local authorities in England [23, 24].

Approximately 80% of pupils from Lambeth schools and two thirds of pupils from Southwark schools are from black and minority ethnic (BME) backgrounds [24, 25].

2.3 Eligibility criteria

Participant eligibility criteria for the main trial are: (i) enrolled as a student in Year 12 or 13 at one of the collaborating schools; (ii) aged at least 16 years; (iii) fluent in English; (iv) wanting psychological help for emotional difficulties; (v) willing and able to attend a 1-day psychological workshop on school premises; and (vi) able to provide informed written consent to participate.

Exclusion criteria are: (i) presenting with acute risk of harm to self or others (see section 2.9 below); and (ii) severe learning difficulties. The latter will rule out young people with pervasive developmental difficulties who would be unlikely to benefit from the workshop. Our assessment of this criterion will be based on teacher report. As such, we will follow the convention of UK education services, where the term ‘severe learning difficulties’ relates to general learning impairments of varying severity [40]. We will not exclude students with ‘specific learning difficulties’, for example dyslexia, who are not judged to have a significant general impairment of intelligence. In addition, we will not exclude students who are older than the intended 16-18 years age range, provided that they are currently enrolled in Year 12 or 13.

2.4 Interventions

2.4.1 Intervention arm. Students in the intervention arm will participate in a DISCOVER workshop shortly after randomisation.

Delivery methods: The intervention uses a group workshop format with material organised into short sections delivered in a single day (6 hours). It is run during school hours in a quiet room at a host school. Permission for participating students to miss scheduled classes is obtained in advance from school staff. Each workshop is co-facilitated by two clinical psychologists according to a detailed manual. The minimum number of permitted student participants is four, and the maximum is fifteen.

Core content: Each workshop begins with introductions and icebreakers. Psychoeducational content then focuses on a basic cognitive-behavioural model of emotional problems. Video clips involving teenage actors and group discussion are used to normalise young people's experiences. Particular attention is given to personal, relationship and academic stresses typical for the age group. CBT techniques for managing anxiety and mood problems are then introduced and practised, supported by role-plays, video demonstrations and printed handouts. Behavioural strategies include problem-solving and time management. Cognitive strategies include identification and challenging of negative thoughts.

Personalised follow-up: Participants are encouraged to set personal goals at the end of the workshop. After one week, participants are followed up individually by one of the workshop leaders in a 20-30 minute telephone call. The purpose of this 'telephone goal review' is to monitor progress and support generalisation of CBT skills into real-life situations. If needed, participants are given the option of receiving further telephone goal reviews within the 12-week post-workshop period, and before the administration of repeated outcome measures. It is expected that most participants will require 1-3 telephone consultations in order to refine their original goal(s) and/or address unforeseen barriers. A workshop leader will send text messages to each participant in advance of making an initial call. Further calls will be arranged to suit the participant's schedule. If a participant cannot be reached by telephone after four consecutive attempts, s/he will be texted and asked to opt in for any further contact. All of the telephone calls, successful and unsuccessful, will be documented.

Control arm. Students in the waiting list control arm will participate in a DISCOVER workshop approximately 3 months later than the intervention group (i.e. in the following academic term). During this period, they will be able to access usual support that is available to students in or outside schools.

2.4.2 Concomitant interventions. Medication and other treatments are permitted in both arms of the trial, and these will be noted by researchers using the Client Service Receipt Inventory.

2.5 Measures

2.5.1. Outcomes. Primary outcomes (anxiety and depression) and secondary outcomes (quality of life and mental well-being) will be assessed using four validated adolescent-reported questionnaires. These will be collected at baseline (prior to randomisation) and at 3-month follow-up. The Mood and Feelings Questionnaire (MFQ) is a 33-item self-reported measure of depressive symptoms [26]. Items (in the form of first-person statements) are rated on a 3-point Likert scale from 0 ('not true' in previous two weeks) to 2 (mostly 'true' in previous two weeks). Scores range from 0-66 with higher scores representing more severe depression. The clinical cut-off is 26. The validity and reliability of the measure have been established in diverse clinical and non-clinical samples [42, 43]. It is also recommended for routine outcome monitoring in the UK's national clinical guidelines on adolescent depression [44].

The Revised Child Anxiety and Depression Scale (RCADS) is a 47-item self-reported measure of emotional symptoms, including separate subscales for separation anxiety disorder, social phobia, generalized anxiety disorder, panic disorder, obsessive compulsive disorder and major depressive disorder [27]. It also yields a Total Anxiety Scale (sum of the 5 anxiety subscales) and a Total Internalizing Scale (sum of all 6 subscales). Items are rated on a 4-point Likert-scale from 0 (symptom 'never' occurs) to 3 (symptom 'always' occurs). Raw scores are converted into standardised T-scores, with a clinical cut-off (T-score) of 70. The measure's convergent validity, internal consistency and sensitivity to change have been demonstrated in school-based [45] and clinical samples [46].

The Pediatric Quality of Life Enjoyment and Satisfaction Form (PQ-LES-Q) is a 15-item self-reported measure of quality of life [28]. Items are scored on a 5-point Likert scale from 1 ('very poor' satisfaction with QoL item) to 5 ('very good' satisfaction with QoL item). Higher scores indicate better subjective quality of life. The reliability and validity of the scale have been reported with adolescent patients [47].

The Warwick-Edinburgh Mental Well-Being Scale (WEMWBS) is a 14-item self-reported measure of

mental well-being [29]. It consists of 14 positively worded items with five response categories ranging from 1 ('none of the time') to 5 ('all of the time'). Higher scores indicate more positive mental well-being. The measure's validity and reliability have been established in diverse populations, including secondary school pupils in the UK [48].

2.5.2. Economic evaluation. The following will be collected at baseline and 3-month follow-up.

The Client Service Receipt Inventory (CSRI) is a self-reported measure of service use [30]. An abridged version covering a retrospective 3-month period will be specially developed and adapted for use with this group of students. Respondents will be asked to provide information about contacts with physical and mental health services, charities and education support, as well as informal help received from carers and friends.

The EQ-5D is a measure of health-related quality of life that allows for the calculation of quality-adjusted life years (QALYs) [31]. It is scored on five dimensions: mobility, self-care, usual activities, pain discomfort and anxiety/depression.

In addition, a Service Information Schedule will be developed to collect information on staff salaries, on-costs, overheads, training costs, materials and travel time associated with DISCOVER. This will be used to calculate a comprehensive unit cost for the intervention.

2.5.3 Process and feasibility measures

Participant demographics. Participant age, gender and ethnicity will be obtained at baseline using a structured, self-reported form.

Feasibility parameters. Rates of information meeting attendance, informed consent, baseline assessment, intervention attendance and follow-up assessment will be documented using structured record sheets.

Relevant fields will be completed prospectively by research workers and workshop leaders, as appropriate.

User satisfaction. Participants' experiences of DISCOVER will be assessed using a structured feedback measure immediately following the workshop. This will incorporate the Client Satisfaction Questionnaire (CSQ-8), an 8-item self-reported measure of service satisfaction [32]. Supplementary questions will elicit open-ended qualitative feedback on the most helpful aspects of DISCOVER and suggested improvements.

2.5.4 Qualitative interviews

Sub-study 1: reasons for non-participation. Semi-structured interviews will be conducted with students who attended an information meeting about the research but did not subsequently participate in the trial. The interview will explore initial perceptions of DISCOVER and associated research procedures; factors affecting non-participation (e.g. potential stigma, competing demands); and availability of other sources of psychological help and support.

Sub-study 2: young people's experiences of DISCOVER and research procedures. Semi-structured interviews will be conducted with a sample of students who attended a DISCOVER workshop in the intervention arm of the trial. The interview topic guide will be developed in consultation with a Teenage Advisory Group to ensure that it is user-friendly and relevant to young people's concerns. Topics will include motivations for taking part; experiences of recruitment and assessment procedures; perceived impacts of DISCOVER; and compatibility with other sources of help and support.

Sub-study 3: schools' experiences of DISCOVER and research procedures. Semi-structured interviews will be conducted with a sample of school staff drawn from sites in the intervention arm of the trial. The interview will explore barriers and facilitators to participant recruitment and retention; the feasibility of DISCOVER as a school-based intervention; and perceived impacts.

2.6 Timeline

The research will be publicised from the start of the academic year. Prospective trial participants will be invited to provide informed consent prior to randomisation of schools. Baseline measures will be collected in the two weeks prior to randomisation; follow-up measures will be obtained approximately three months later in both arms of the trial. Participants in the waiting list control group will be able to attend a DISCOVER workshop during the subsequent academic term. Interviews for sub-study 1 will be completed within 1 month of randomisation. Qualitative interviews for sub-studies 2 and 3 will be completed after the 3-month outcome assessment.

2.7 Sample size

2.7.1 Main trial. The primary endpoints of this feasibility trial are factors that affect successful trial conduct, rather than measures of intervention effects. Hence, power analyses for intervention outcomes were not undertaken in advance [41]. However, a minimum of 5 clusters per arm, i.e. 10 schools, will be included in order to estimate the between-group variance and intra-cluster correlation within each arm. Based on pilot work in schools, we are expecting to recruit approximately $n=15$ participants at each site, providing a potential sample size of $N=150$. Assuming a follow-up rate of $\geq 75\%$, a two-sided confidence interval for this key feasibility parameter will extend no more than 7.5% from the observed proportion (adjusted Wald method) [33]. A total sample size of $N=150$ will also be sufficient to obtain stable estimates of population variances for future power calculations [34].

2.7.2 Sub-study 1. $N=10$ students who attended a school-based information meeting but did not subsequently participate in the research will be purposively sampled from both arms of the trial, with the aim to include students from all school sites and across age, gender and ethnic groups.

2.7.3 Sub-study 2. $N=15$ students will be interviewed from sites in the intervention arm (approximately $n=3$ per school). We predict that this will be sufficient to capture the range of participant experiences [35]. Participants will be purposively sampled to ensure representation from BME students and those who have not previously sought help, as we have particular interests in the suitability of DISCOVER for these groups.

2.7.4 Sub-study 3. N=10 school staff will be interviewed from sites in the intervention arm (n=2 per school). Participants will be selected according to their involvement in setting up the study and/or identifying potential participants.

2.8 Recruitment and consent procedures

Targeted communications, augmented by posters and flyers, will be used to publicise the study at 10 schools. In the first instance, students will be informed about the study's aims and methods in a joint presentation by a senior teacher and workshop leaders at a school assembly. All students within the eligible academic cohort (Years 12 and 13) will also receive written information, circulated through school email lists. Students will be invited to register their initial interest by sending their name and preferred contact details to a nominated teacher or directly to workshop leaders. Teachers will also be invited to facilitate referrals, following a three-stage process that involves: (i) identifying students with elevated emotional symptoms, based on written guidance and consultation from workshop leaders; (ii) approaching potentially anxious/depressed students, in confidence, about the rationale and methods of DISCOVER; and (iii) offering sensitive, non-coercive encouragement to attend a subsequent research information meeting.

The research information meeting will be offered during a lunchtime session at each school. Text and email reminders will be sent to students in advance. The session will be run jointly by workshop leaders and research staff. Students will be provided with detailed information about the DISCOVER intervention and associated study procedures, supported by a written Participant Information Sheet. There will also be opportunities for students to ask questions. Students who are unable to attend the group information meeting will be offered an individual meeting with a researcher.

Students will have at least 48 hours after the information meeting to decide whether or not to proceed further. This will be confirmed by a researcher using text message or email. Where indicated, an individual meeting will be arranged to obtain informed written consent to participate. Parents will only be informed

about this decision when specifically requested by the young person.

Further consent will be obtained from participants in the qualitative sub-studies, supported by separate Participant Information Sheets. In sub-study 1, students who provide their contact details at the information meeting - but do not participate in the main trial - will be approached by email or telephone. In sub-study 2, workshop attenders will be invited to participate in qualitative interviews after completing follow-up outcome measures. School staff in sub-study 3 will also be provided with a Participant Information Sheet and asked to sign a consent form before undertaking an interview.

2.9 Risk assessment and management procedures

Research workers and workshop leaders will monitor for potential harm during data collection sessions, workshop delivery and telephone contacts. A standard risk assessment and management protocol will consider: (i) indications of significant mood disturbance, suggested by MFQ scores above 26 and/or objective signs of agitation or markedly flat affect; (ii) indications of self-harm, suggested by spontaneous disclosure and/or endorsement of suicidality items on the MFQ; and (iii) other indications of harm (e.g. disclosure of bullying related to research participation). Such indications will be referred to the Chief Investigator, DISCOVER service lead and school safeguarding lead, as appropriate. If the risk is judged to be 'acute' (i.e. in need of immediate safeguarding actions, as per usual clinical and school procedures), then the young person in question will be excluded from further study procedures.

2.10 Allocation

Schools will be randomly allocated to experimental or control arms in a 1:1 ratio after consent and baseline assessment procedures are completed. Allocation will be performed using an online randomisation system, managed by an independent Clinical Trials Unit at King's College London. Cluster allocation will be communicated to the DISCOVER service lead (IS), who will then inform schools. If the number of participants at any one school exceeds $n=15$, we will use a random number generator to divide the cohort into smaller groups of equal or nearly equal size. This second stage of randomisation will be performed by

the blinded trial statistician (DS).

Research workers who are directly involved in data collection will also remain blind to cluster allocation. Several steps will be taken to preserve blinding. First, blinded research workers will have minimal contact with workshop leaders prior to follow-up data collection. Second, unblinded members of the research team will liaise with research sites and participants to confirm practical arrangements for data collection, thereby minimising contact between blinded researchers and schools. Third, blinded research workers will use a standardised script during data collection to remind students not to disclose their allocation status. The blinded research workers will also deploy badges and signs, containing similar reminders, during visits to schools.

2.11 Data collection

2.11.1 Procedures. Cumulative data on key feasibility parameters will be logged prospectively by research workers and workshop leaders. Additional quantitative data will be collected directly from participating students by a team of research workers during visits to research sites. Demographic and clinical outcome data will be assessed using self-reported questionnaires. Printed copies of these measures will be posted to any participants who are unable to complete assessments in person.

Economic data will be collected from structured interviews using the CSRI and EQ-5D. A self-reported service satisfaction measure will also be collected from all participants who attend DISCOVER workshops; this will be administered by workshop leaders.

Qualitative data will be collected from individual semi-structured interviews in three sub-studies. Face-to-face interviews will be conducted if possible, with an option to conduct interviews by telephone if necessary. All interviews will be audio-recorded and transcribed verbatim.

2.11.2 Strategies for promoting participant retention and completing follow-up. Participants will receive a

series of reminders from workshop leaders, research workers and school staff about the timing of follow-up assessments. Participants (intervention arm only) will receive a text message immediately following the workshop to acknowledge their attendance and mention the next steps (i.e. telephone goal review and 3-month assessment). Further reminders will be provided during telephone goal reviews. Text messages will also be sent to participants from both arms in the week prior to the 3-month assessment. Given the possibility that schools may forget about the 3 months follow-up, a non-blinded researcher will visit the schools prior to the 3 month assessment to make practical arrangements for the interviews (e.g. dates, rooms, appointments) and to keep teachers informed about the study arrangements. Text messages will also be used to remind consenting participants in sub-studies 1 and 2 about scheduled interviews. Participants in these interviews will be reimbursed for their time with a £10 voucher.

2.11.3 Data management. Personal data in the form of manual files (e.g. self-report questionnaires, demographic measures and consent forms) will be stored in a locked cabinet within a secure research office at King's College London. Data will entered into a secure electronic database by two research workers; 20% of all data will be independently checked for accuracy.

2.12 Analysis plan

2.12.1 Statistical methods. Statistical analyses will be mainly descriptive in nature, aiming to provide estimates of key feasibility parameters and to inform power calculations for a future definitive trial. A description of the sample will be presented using means and standard deviations for continuous data. Frequencies and proportions will be used to analyse categorical variables. Feasibility of trial procedures will be examined using proportions and exact Clopper Pearson 95% confidence intervals [49] for rates of information meeting attendance, consent and DISCOVER workshop attendance. Reasons for non-attendance will be examined where information is available. Descriptive sub-analyses (chi-squared and Fisher's exact tests) will be used to explore participation rates among students who are clinically anxious and depressed; from BME backgrounds; and have not previously accessed CAMHS or school counselling. In addition, completion rates for demographic, clinical and health economic measures will be assessed at baseline and

follow-up. The amount of missing data for individual items and entire measures will be examined to determine the suitability of instruments and level of burden for a future full-scale trial.

We will analyse clinical outcomes on an intention-to-treat basis using multi-level models (with school as a random factor) to estimate the likely range of intervention effects at 3-month follow-up; baseline outcome measures will be used as a covariate (ANCOVA approach) [50]. The emphasis will be on confidence intervals of effect size estimations, rather than hypothesis testing. This will allow us to explore the imprecision around effect sizes. We will also estimate the intra-cluster correlation, a measure of the dependency of the observation within a cluster. Estimates of population variances for future power calculations will use the upper 80th nonparametric bootstrap percentile of confidence intervals around the estimates [34].

2.12.2 Economic analyses. We will explore whether an appropriate CSRI can be developed for the definitive trial, and whether completion rates are satisfactory. We will also scrutinise whether the EQ-5D is sensitive to changes in mental wellbeing resulting from the intervention, with a view to its use in future cost-utility analyses. A comprehensive unit cost for the workshops will be calculated based on the Service Information Schedule. Indicative costs associated with other service use will be calculated by attaching a unit cost to each instance of service use. We will obtain cost differences and standard deviations to inform a power calculation for a definitive RCT.

2.12.3 Qualitative methods. Interview data will be analysed within Nvivo software using thematic analysis [35]. Analysis will focus on reasons for, and experiences of, participation and non-participation in the DISCOVER intervention. We will consider acceptability and feasibility from three perspectives: participants, non-participants and school staff. Commonalities and variations within and between these sub-groups will be explored. In order to enhance validity, analyses will be conducted using a collaborative approach supervised by the lead qualitative researcher (NM) and including two other members of the research team.

2.13 Trial governance

The research will be led by the Chief Investigator (JB) who will be accountable for all project objectives and milestones. An Operational Research Team will meet monthly as an internal working group to plan, implement and review operational procedures in accordance with the trial protocol and good clinical practice. Membership will include JB, another senior investigator (DM) and the DISCOVER service lead (IS). A Project Management Group (comprising all co-investigators) will meet on a six-monthly basis to monitor progress, review emergent findings and outputs, and formulate actions required to meet project milestones.

A Teenage Advisory Group (TAG) will also be established to offer feedback and advice on the relevance, feasibility and impacts of the research for young people. TAG activities will include co-production of participant information resources and research publicity materials; development of qualitative interview schedules; drafting lay summaries; and advising on other dissemination strategies for public audiences. The TAG will meet quarterly (facilitated by a DISCOVER workshop leader) and include students recruited from schools that are in the same locality but not included in the trial. Practical support and expenses will be provided in accordance with good practice guidelines from INVOLVE [36].

2.14 Ethics, consent and permissions

2.14.1 Research ethics approval. Ethics approval was obtained from Camberwell St Giles National Research Ethics Service (Reference: 14/LO/1416).

Monitoring. Given the relatively small size of the trial and feasibility design, we will not constitute a separate Data Monitoring Committee. Instead, the Chief Investigator will continuously monitor trial progress and potentially serious adverse events through regular reports from research workers and workshop leaders. The Chief Investigator will consult with the Project Management Group and independent Research Ethics Service before making recommendations on further study conduct. Recommendations could include

continuing with or without modifications to the trial protocol; unblinding; or stopping the trial. Any such decisions will be communicated in writing to other relevant parties (e.g. sponsor, funder, schools, trial registries).

The key stopping guidelines will be (i) insufficient numbers of research sites (< 10 schools); (ii) insufficient participant recruitment at each site (< 4 participants); and (iii) a serious adverse event that is directly related to the administration of research procedures. The latter will be defined as an untoward occurrence that: (i) results in death; (ii) is life-threatening; (iii) requires hospitalisation; (iv) results in persistent or significant disability or incapacity; or (v) is otherwise considered a significant harm by the Chief Investigator.

2.14.2 Consent and confidentiality. All participants will provide informed written consent prior to their enrollment in the research; this will be obtained separately for the main trial and qualitative sub-studies, as described earlier. All personally identifiable information such as names and contact details for participants will be removed from completed research measures. An anonymous code will be assigned to each participant to identify the research measures. Pseudonyms will be used in interview transcripts where participants mention names, places or any other information that could be used to identify them. All data will be anonymised in research reports. Confidentiality will also be maintained within schools, to the extent that only senior staff with direct teaching/pastoral responsibility will be informed about students' participation in the trial. School staff will have no access to the DISCOVER workshop and will not be informed about students' responses on the research measures.

Access to data. The Chief Investigator (JB) will act as custodian of the data in accordance with legislation and the terms of the research sponsor (King's College London) and funder (National Institute for Health Research, UK).

3. DISCUSSION

DISCOVER addresses a crucial need for accessible, age-appropriate and cost-effective early intervention for 16-18-year-olds who are vulnerable to anxiety and depression. Previous research has highlighted the lack of school-based programmes aimed at older adolescents who present with distinct developmental needs, mental health concerns and help-seeking preferences [37, 38]. It is also notable that most school-based psychological interventions have been studied with relatively affluent and predominantly white student populations, with scant evidence for effectiveness in disadvantaged and BME groups [39].

By the end of the study (May 2016), we will be in a stronger position to assess the feasibility, reach and potential impacts of DISCOVER when delivered for stressed older adolescents in ethnically diverse, inner-city secondary schools. We will share findings with the participating schools and young people, other local stakeholders (e.g. CAMHS), and wider professional and academic networks. If the findings of this feasibility trial are positive, then it will also be important to extend the research and (i) undertake a multi-centre trial in other parts of the UK, particularly outside of London; (ii) examine long-term outcomes in comparison with an active control (e.g. usual care); (iii) examine mediators and moderators of change; and (iv) complete a formal health economic evaluation. Future evidence on cost-effectiveness will help to determine whether DISCOVER offers a viable service model that can be scaled up to achieve significant public health impacts within the older adolescent age group.

COMPETING INTERESTS

The authors declare that they have no competing interests.

AUTHORS' CONTRIBUTIONS

JB (Chief Investigator), DM and IS conceived the study. DM led on protocol development and manuscript writing, with input from JB and IS. DS, EB and NM contributed to the design of the study, protocol development and writing of this manuscript. All authors read and approved the manuscript.

AUTHORS' INFORMATION

DM is a principal clinical psychologist and researcher in child and adolescent mental health services. He has expertise in clinical trials methodology and user involvement in intervention design/evaluation. JB is a senior lecturer in clinical psychology who developed the original well-being workshop model for adults; this was adapted for adolescents to produce DISCOVER. IS is a consultant clinical psychologist in child and adolescent mental health services who led the development of DISCOVER and wrote the intervention manual. IS is responsible for co-facilitating and supervising delivery of DISCOVER in the trial. DS is a senior lecturer in biostatistics with expertise in statistical analysis of clinical trials. EB and NM are researchers with expertise in health economics and qualitative methods respectively.

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