The effectiveness of a low-intensity, lay counsellor-delivered, problem-solving intervention for common mental health problems in school-based adolescents in New Delhi, India: the PRIDE randomized controlled trial – Statistical Analysis Plan

Version 2

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1. Purpose and scope

The purpose of this document is to describe procedures and considerations for analysis of data from the PRIDE trial in India, in accordance with the published study protocol. This analysis plan does not cover the embedded recruitment trial, for which a separate analysis plan will be developed.

2. Description of the trial

The goal of this trial is to evaluate the effectiveness of a low-intensity, lay counsellor-delivered, problem-solving intervention for adolescents with common mental health problems attending Government-run secondary schools in New Delhi, India. Details are given in the protocol publication.[1]

The two-arm, parallel-design, individually randomised controlled trial will be conducted in six Government-run secondary schools from the National Capital Territory of Delhi, India. The schools were purposively selected in consultation with the Department of Education, Government of New Delhi, India. This includes five same-sex schools (three boys' schools and two girls' schools) and one mixed school.

2.1 Principal research objectives

The primary objective of the trial is to evaluate the effectiveness of a low-intensity, problem-solving intervention (intervention arm) in reducing adolescent-reported mental health symptoms and idiographic problems for adolescents with common mental health problems in Government-run secondary schools in New Delhi, India (see **Box 1** for eligibility criteria);

Secondary objectives are:

- To evaluate the effectiveness of the intervention on adolescent-reported distress/functional impairment, perceived stress, and mental wellbeing; and on caregiver-reported adolescent mental health symptoms and their impact.

- To explore whether a theoretically-informed a priori factor (perceived stress at 6 weeks) mediates the effects of the intervention on symptoms of mental health difficulties and idiographic problems at 12 weeks

- To evaluate the intervention delivery processes to assist in the interpretation of the trial results and to inform potential implementation of the PRIDE intervention on a wider scale

- To estimate the costs and cost-effectiveness of implementing the PRIDE interventions.

The primary hypothesis is that the intervention will be superior to an Enhanced Usual Care (EUC) control condition in reducing the severity of adolescent-reported mental health symptoms and idiographic problems at six weeks post-randomisation.

The secondary hypotheses are that the intervention will be superior to the control condition with respect to the following outcomes, over a 12-week period post-randomisation

1. Reducing self-reported adolescent mental health symptoms and idiographic problems;
2. Reducing self-reported distress/functional impairment;
3. Reducing self-reported perceived stress;
4. Improving self-reported adolescent wellbeing
5. Improving remission, derived from the 'crossing clinical threshold' method applied to self-

reported adolescent mental health symptoms and associated distress/functional impairment
6. Reducing caregiver-reported adolescent mental health symptoms and their impact

Tables 1-3 provides a summary of primary, secondary, and exploratory outcomes.

Box 1 Trial eligibility criteria

Eligible adolescent participants will be:

i) enrolled as a student in Grades 9-12;
ii) aged 13-20 years;
iii) experiencing elevated mental health symptoms, based on response in the borderline or abnormal range of the self-report SDQ Total Difficulties Score ≥19 for boys and ≥20 for girls (derived from a normative reference sample of 1087 students (M age=16.4 years) from urban India)
iv) experiencing significant distress and/or functional impairment, based on response in the abnormal range (>=2) on the self-reported Impact Supplement of the SDQ;
v) experiencing difficulties for >1 month, based on response to the self-reported chronicity item of the Impact supplement of the SDQ.
vi) able to provide informed consent (or assent if under 18 years, supported by parental consent) to participate.

Eligible caregiver participants will be:

i) a primary parental caregiver or guardian for the index adolescent; and
ii) able to provide informed consent for their and index adolescent's participation (if under 18 years);
iii) if adolescent age 18 or more years, caregiver involvement is in turn subject to the index adolescent's preference.

Table 1 Primary outcomes

Measures	Description	Primary outcomes at 6 weeks post-randomisation
Strengths and Difficulties Questionnaire (SDQ) Total difficulties score	25-item self-report measure of youth mental health difficulties (Goodman et al., 2000). A Total Difficulties scale score is derived by summing items from four problem subscales (Emotional, Conduct, Hyperactivity/inattention, and Peer relationship), while a fifth subscale measures prosocial functioning and does not contribute to the overall severity score. Individual problem scale items are scored from 0-2 (with higher scores indicating greater problem severity), giving a range of 0-40 for Total Difficulties.	Self-reported total difficulties score
Youth Top Problems (YTP)	The Youth Top Problems (YTP) is a brief, idiographic measure which identifies, prioritizes and scores respondents' three main problems (Weisz et al., 2011). Each nominated problem is scored from 0 ('not a problem') to 10 ('huge problem'). A mean severity score is calculated by summing individual problem scores and then dividing by the number of nominated problems.	YTP severity score

Table 2 Secondary outcomes

Measures	Description	Secondary outcomes over a 12 week period post-randomisation[a]
Strengths and Difficulties Questionnaire (SDQ) Total difficulties score	(see Table 1)	Self-reported total difficulties score
Youth Top Problems (YTP)	(see Table 1)	YTP severity score
SDQ Impact Supplement	The SDQ Impact Supplement measures distress and functional impairment associated with index mental health difficulties identified on the main SDQ scale (Goodman et al., 2000). One item on overall distress and four items on domain-specific functional impairment (home life, friendships, classroom learning, leisure activities) are individually scored from 0-2 (with higher scores indicating greater impact), generating a total impact score from 0 to 10.	Self-reported total impact score
SDQ internalising subscale	Peer and emotional sub-scales	Self-reported score
SDQ externalising subscale	Conduct and hyperactivity sub-scales	Self-reported score

Perceived Stress Scale-4-item version (PSS-4)	The PSS-4 will be used to measure the perception of stress, reflecting the degree to which situations are appraised as stressful during the preceding month (Cohen et al., 1983). This brief instrument uses a five-point scale (0=never, 1=almost never, 2 sometimes, 3=fairly often, 4=very often) to assess how often the respondent has experienced primary appraisals of events as stressful. The total score ranges between 0 and 16, with higher scores indicating a stronger tendency towards stressful appraisals.	Self-reported total score
Short Warwick-Edinburgh Mental Wellbeing Scale (SWEMWBS)	The SWEMWBS will be used to measure mental wellbeing (Stewart-Brown et al., 2009). The SWEMWBS is a unidimensional scale that comprises 7 items scored on a five-point scale (1=None of the time, 2=Rarely, 3=Some of the time, 4=Often, and 5=All of the time), with a total range from 7-35 and where higher scores indicate more positive mental wellbeing.	Self-reported total score
Remission [a]	Remission is defined as falling below baseline eligibility cut-offs on both reported SDQ Total Difficulties score (i.e. < 19 for boys & < 20 for girls) and SDQ Impact score (< 2).	Self-reported (based on SDQ)

[a] Repeated measures analysis of 6-week and 12-week endpoints, adjusting for baseline values (see section 5.1.2)

Table 3 Exploratory outcomes

Measures	**Description**	**Secondary outcomes over a 12 week period post-randomisation[a]**
Strengths and Difficulties Questionnaire (SDQ) Total difficulties score	(see Table 1)	Caregiver-reported total difficulties score
SDQ Impact Supplement	(see Table 2)	Caregiver-reported total impact score
SDQ internalising subscale	Peer and emotional sub-scales	Caregiver-reported score
SDQ externalising subscale	Conduct and hyperactivity sub-scales	Caregiver-reported score
SDQ prosocial subscale		Self-reported score

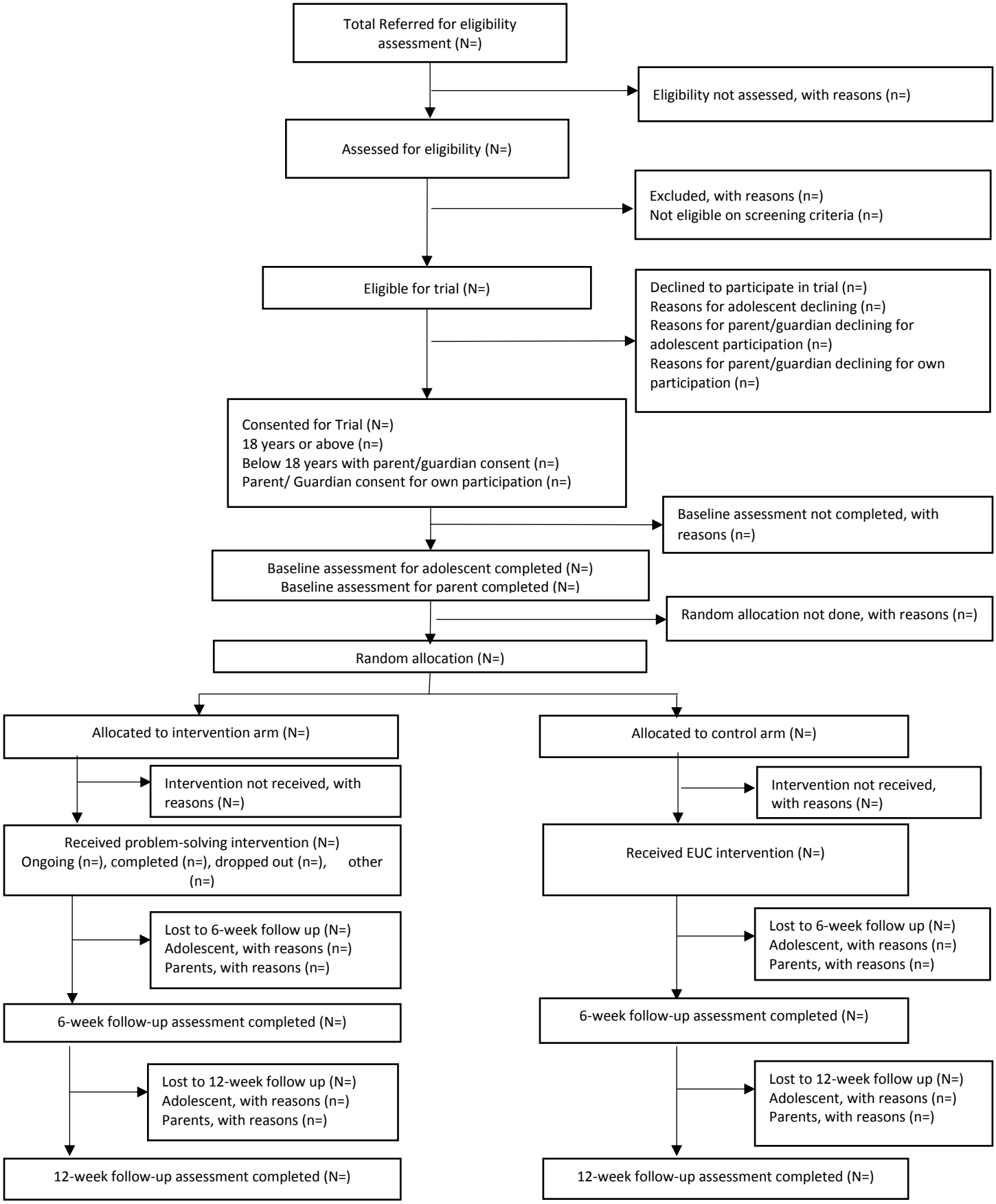
[a] Repeated measures analysis of 6-week and 12-week endpoints, adjusting for baseline values (see section 5.1.2)

2.2 Trial design

The PRIDE problem-solving intervention will be evaluated in a two-armed, parallel-design, individually randomised controlled trial. Individual randomisation of each participant will be carried out after the respective baseline outcome assessments are completed.

The flow chart (Figure 1) shows the process of participant recruitment and follow-up.

Figure 1: PRIDE trial flow chart



2.3 Randomisation and allocation concealment

The randomisation list will be stratified by school (and gender for the co-educational school) using randomly sized blocks of four or six. This will be generated by a statistician independent of the trial at the London School of Hygiene and Tropical Medicine, UK. The randomisation code will be concealed using sequentially numbered opaque sealed envelopes additionally secured by tapes to maximize allocation concealment,[2] prepared by the data manager in India. Inside there will be a plain piece of card folded in two, containing a sticker denoting the participant ID number and allocation. Randomisation will be completed following informed consent procedures and baseline assessment. Baseline assessment and randomisation will take place an estimated 2 days (maximum 5 days) after the student is deemed to be eligible. Errors in randomisation will be recorded and reported.

We will maximise allocation concealment by:

- A daily check by the data manager to evaluate if allocations done were consistent with the randomisation code.

Trial PI, site coordinators, trial statistician and members of the Trial Steering Committee will remain blind to the allocation status throughout the trial and until the final analyses.

Unplanned incidents of unblinding of the interviewers /outcome assessors to the intervention arm will be summarised based on overall prevalence and the point during the interview that the interviewer was unblinded.

2.4 Sample size calculation

Sample size estimations were produced for two co-primary outcomes: mental health symptoms (SDQ Total Difficulties score) and idiographic problems (YTP score). First, we obtained uncontrolled effect sizes (ES=difference in means/SD) for both co-primary outcomes from a group of 52 adolescents who completed the problem-solving intervention during pilot work in the six secondary schools in New Delhi. Among these participant, all of whom met the same baseline eligibility criteria as intended for the current trial, the mean SDQ Total Difficulties scores changed from 23.4 (SD 3.4) at baseline to 16.1 (SD 5.9) at the end of the intervention (ES=1.4). The mean YTP scores for the same group changed from 5.6 (SD 2.0) at baseline to 2.9 (SD 2.6) at the end of the intervention (ES=0.9). Second, we obtained a paired effect size on the SDQ Total Difficulties score from another cohort of 47 adolescents participating in a later phase of piloting, including 29 participants who received the problem-solving intervention and 18 waitlisted controls (ES=1.03). YTP data were unavailable for this second cohort.

We assumed a 1:1 allocation ratio of individual participants within each of the six schools, loss to follow up of 15% over 6 weeks (based on piloting), and a Bonferroni correction to adjust for multiple primary outcomes. Based on these assumptions, we determined a recruitment target of N=240 in total. This sample size provided 90% power to detect an ES of 0.5 on both co-primary outcomes and 80% power to detect an ES of 0.44

2.5 The interventions

A problem-solving intervention will be delivered to individual participants across 4-5 face-to-face sessions spread over three weeks. Each session will last for up to 30 minutes (aligned with the usual duration of school periods) and will be delivered in the local language (Hindi). The sessions will be conducted on school premises, in private rooms or, where private rooms are not available, behind screens and curtains. Session 1 focuses on fostering engagement, understanding the participant's difficulties, and introducing the structure and process of the intervention. Over the next three sessions, the participant is helped to learn and apply a structured problem-solving strategy involving three steps, each with its own specific goals (following the acronym "POD"): (1) to identify and prioritize distressing/impairing problems ("**P**roblem Identification"); (2) to generate and select coping options for modifying the identified problem directly (problem-focused strategies) and/or to modify the associated stress response (emotion-focused strategies) ("**O**ption Generation"); and (3) to implement and evaluate the outcome of this strategy ("**D**o it"). The intervention may be concluded after four sessions or else extended to a fifth session, depending on the adolescent's preferences and logistical barriers to intervention completion such as exam breaks and holidays. The concluding session will focus on consolidating learning and generalizing problem-solving skills across different contexts. With permission, all sessions will be audio-recorded for office-based quality and fidelity assessments. Adolescents will be encouraged to practice problem-solving skills between the sessions, aided by a set of three "POD booklets" which explain problem-solving using illustrated vignettes and describe corresponding between-session practice exercises. Each booklet covers one of the steps of problem-solving and they are distributed sequentially over the first three intervention sessions. At the end of intervention, the adolescents are handed a full-colour POD poster that summarises the three steps of problem-solving.

Each school will have one or two counsellors, depending on demand. The counsellors will be Hindi-speaking college graduates aged 18 years or above, with no formal training or qualifications related to psychotherapy or mental health. They will be recruited through online job portals commonly used in the NGO/public sector in India. Selection will be based on reasoning capacity (assessed by written test) and interpersonal skills (assessed by structured role-plays and interview). Selected candidates will receive a structured manual and complete one week of classroom-based training involving a combination of lectures, demonstrations and role-plays. This will be followed by a 6-week period of field training in which counsellors will carry out casework (with at least four cases) under the supervision of psychologists. Trainees' performance will be evaluated using structured role-plays at the end of classroom-based training, as well as supervisors' ratings of audio-recorded intervention sessions.

Counsellors will participate in weekly peer group supervision meetings, based on an approach tested in the PREMIUM trials, where it was found to be an acceptable, effective and scalable supervision model for lay counsellors in low-resource settings[3]. Each 2-hour meeting will be facilitated by one of the counsellors in rotation and overseen by a supervisor. Counsellors will review and discuss one or two audio-recorded sessions in each meeting. Audio-recordings will be rated by all group members using a therapy quality rating scale that incorporates elements from two established scales [4,5] and assesses skills specific to problem-solving as well as non-specific therapeutic skills (e.g. empathic understanding). Recurrent skills deficits noted by supervisors will be addressed through supplementary training workshops held on a monthly basis. The supervision schedule will ensure a representative selection of audio-recorded sessions; with the intention that all counsellors will receive equal opportunities to discuss their cases. In addition, supervisors will undertake weekly telephone calls (20-30 minutes) with each counsellor in order to monitor the progress of their caseload, and identify and manage risks. The counsellors will be able to initiate ad hoc calls if immediate help is needed with any case.

Control arm: There were previously no mental health services in the participating schools. A standardized control arm was therefore devised. Participants allocated to this arm will receive the same printed problem-solving materials used in the intervention arm but without any counsellor contact. Immediately following random allocation to this condition, a researcher will provide a set of POD booklets and explain their purpose and contents using a standardized script. Participants will be encouraged to read through the booklets in sequence, and complete the specified practice exercises. No further guidance will be provided.

2.6 Time of outcome assessment

Outcome data will be collected at 6 weeks and 12 weeks post randomisation. **The 6-week outcome is the primary endpoint** as the intervention will be completed by then and we would expect the optimal effect of the intervention. With the assumption that the intervention has a constant effect at both time points, we will estimate the effect of the intervention over the 12-week follow-up period to evaluate the sustainability of the effect of the intervention.

2.7 Visit windows

The protocol defines the primary outcome assessment to be at a scheduled visit 6 weeks after randomisation. A 2- week period will be allowed for the outcome assessment at 6 weeks (i.e. from 6 weeks after the date of delivery, to 14 days after the scheduled visit date) to enable follow-up of hard-to-reach participants. A similar window was allowed at the 12-week follow-up. For each scheduled contact, researchers will make up to four approaches, including first physical contact at the adolescent's home and subsequent telephonic contacts to fix appointments for the assessments.

The median and interquartile range of the timing of the 6 week and 12 week visits relative to the date of randomisation will be reported, along with the number and proportion of participants who were visited outside of the protocol-defined windows. We will conduct primary and sensitivity analyses as follows:

Table 4. Analysis windows to be used for the trial

Definition	6 week follow up	12 week follow up
Primary analysis	Planned at 6 weeks or 42 days, [0 week before, 2 weeks or 14 days after planned follow-up]	Planned at 12 weeks or 84 days, [0 week before, 2 weeks or 14 days after planned follow-up]
Sensitivity analysis	Planned at 6 weeks or 42 days, [0 week before, 1 week or 7 days after planned follow-up]	Planned at 12 weeks or 84 days, [0 week before, 1 week or 7 days after planned follow-up]

All times relate to time after randomisation. If there was more than one visit within a window then we will refer to the visit closest to the nominal visit, with preference for earlier. For analysis, we will perform calculations in days.

The primary analysis windows were chosen to be as inclusive (wide) as possible, but without overlap between the windows permitted for the 6 and 12 week visits. Note that the primary analysis windows cover those defined by the trial protocol. The same width of window will be applied for the 6 and 12 week visits (namely, 0 weeks before and 2 weeks after).

The sensitivity analysis windows will be more restrictive. These windows will cover those defined by the trial protocols. The same width of window will be applied for the 6 and 12 week visits (namely, 0 weeks before and 1 week after).

Follow-up assessments will not take place if the trial participant is lost to follow-up or withdraws from the trial and explicitly asks not to be followed-up for outcome assessment.

2.8 Serious Adverse Events (SAEs)

SAEs include death, life-threatening event, clinical deterioration requiring hospitalization or other specialist intervention, victimization, sexual abuse, and chronic absenteeism and/or drop-out from school. Immediate safeguarding actions will prioritize the safety of participants. This may involve suicide risk assessment, informing stakeholders, facilitating intervention with specialists, and statutory
reporting in line with relevant legislation, such as the Protection of Children from Sexual Offences Act 2012 and the Juvenile Justice (Care and Protection) Act 2000 (last amended in 2015).

SAEs will be reported spontaneously by adolescents/caregivers and may also be picked up by researchers or intervention providers at any contact with the participant. If a SAE is suspected, participants will be referred to a supervisor who completes a standard form. Each potential SAE will also be assessed for causality by two clinically qualified co-investigators (KM, DM) and classified as unrelated, unlikely, possible, probable or definitely related to trial participation. In the event that consensus is not reached, a third clinical psychologist (independent of the trial) will review the SAE report. Where causality is deemed to be anything other than unrelated to trial participation, the DSMC will advise on further actions such as withdrawal of individual participants, modifications to the trial protocol, continuing without modifications, or suspending/terminating the trial.

2.9 Data management

Four types of quantitative data will be collected: eligibility/baseline, intervention process, and 6- and 12-week outcome assessments. While referral information will be recorded on paper forms, all the measures, with the exception of the YTP and the clinical case records completed by the counsellors during the sessions, will be administered via a tablet computer. Time stamps for all recruitment and outcome assessment processes will be recorded to monitor the progress of the research.

These data will be remotely uploaded as comma-separated values (CSV) files on the main data server using the customized STAR software program (OPSPL, 2013), which is compliant with Good Clinical Practice (including date and time stamps for original data entry, and an audit trail documenting any subsequent changes). The paper-based data for YTP will be entered using Epi-info database. Participant contact details and assent/consent information will be collected using paper forms and will be marked with the appropriate trial ID before being filed in separate locked cabinets. Intervention process data will be collected in paper form; these will be manually entered and stored as CSV files.

Range and consistency checks were performed at weekly intervals separately for each data source, with all inconsistencies logged to maintain an audit trail. Identified queries were resolved promptly by the Trial Management Committee, and the database updated accordingly. All data were kept in separate databases and only merged into a master database after data collection had been completed and each individual database has been locked. All data were backed-up on external hard disks on a daily basis. Access to pre-locked data was password-protected at multiple levels and no member of the trial team apart from the data manager and independent statistician had access to these passwords. After the dataset was locked, it remained password-protected and trial investigators had access to the datasets. Consent procedure, baseline and follow up assessments and intervention

sessions were audio recorded. Audio recordings were linked with the trial ID and stored in a secure, password-protected folder. For all data, a separate file linking names and trial IDs was kept and password-protected.

3. Variables

3.1 Screening variables

Full codebooks have been developed. Key variables are listed below.

Eligibility for screening

Inclusion criteria

Eligible adolescent participants will be:

vii) enrolled as a student in Grades 9-12;
viii) aged 13-20 years;
ix) self-report SDQ Total Difficulties Score ≥19 for boys and ≥20 for girls
x) self-reported Impact Supplement of the SDQ >=2
xi) experiencing difficulties for >1 month, based on response to the self-reported chronicity item of the Impact supplement of the SDQ.
xii) able to provide informed consent (or assent if under 18 years, supported by caregiver consent) to participate.

Eligible caregiver participants will be:

iv) a primary parental caregiver or guardian for the index adolescent; and
v) able to provide informed consent for their and index adolescent's participation (if under 18 years);
vi) if adolescent age 18 or more years, parental involvement is in turn subject to the index adolescent's preference.

Exclusion criteria

- Participants who need immediate inpatient care for any reason (medical or psychiatric).

3.2 Baseline variables

From refusers (restricted to those who signed consent, underwent baseline assessment but who did not proceed to randomisation):

- Age
- Gender
- Class
- YTP, PSS-4, SWEMWBS
- SDQ, SDQ-impact (from eligibility screening)
- Reason for refusal

From Caregivers of refusers (restricted to those who signed consent, underwent baseline assessment but whose ward did not proceed to randomisation):

- Caregiver's Age
- Caregiver's Gender
- Caregiver's education
- Caregiver's occupation

- Caregiver-reported SDQ

From randomised participants:
- Age
- Gender
- Class
- YTP, PSS-4, SWEMWBS
- SDQ, SDQ-impact (from eligibility screening)

From caregivers of randomised participants:
- Caregiver's Age
- Caregiver's Gender
- Caregiver education
- Caregiver occupation
- Caregiver-reported SDQ

3.3 Outcome variables

These are listed in Tables 1-3 and below:

Primary (at 6-weeks post randomisation; adolescent-reported)
- SDQ total difficulties score
- YTP severity score

Secondary (over 12 weeks of follow-up post randomisation; adolescent-reported)
- SDQ total difficulties score
- SDQ impact
- SDQ internalising subscale
- SDQ externalising subscale
- YTP severity score
- PSS-4
- SWEMWBS
- Remission

Exploratory (over 12 weeks of follow-up post randomisation; caregiver- and/or adolescent-reported)
- SDQ total difficulties (caregiver-reported)
- SDQ impact (caregiver-reported)
- SDQ internalising subscale (caregiver-reported)
- SDQ externalising subscale (caregiver-reported)
- SDQ prosocial subscale (adolescent-reported)

3.4 Intervention process variables (aggregated for the intervention arm)

Intervention arm
- Mean number of sessions completed (counsellor-completed session record forms)
- Mean session length (counsellor-completed session record forms)
- Mean intervention duration (days between first and last session) (counsellor-completed session record forms)

- Number/proportion of participants who attended session on time (counsellor-completed session record forms)
- Number/proportion of participants who (i) read the POD booklets between sessions, (ii) completed the POD exercises between sessions (iii) brought the POD booklets to the sessions (iv) demonstrated understanding of POD booklets and session content (counsellor-completed session record forms) (v) implemented the POD plan (counsellor-completed session record forms for session 4 and 5)
- Number/proportion of participants who completed the intervention and had a planned discharge (counsellor completed end of treatment form)
- Mean therapy quality of audio-recorded sessions as independently assessed by an expert on a random selection of 10% of all sessions in PRIDE (using 18-item Therapy Quality Scale)[6]

Both Intervention and EUC arms

- Frequency of POD booklet use at home (Adolescent reports at 6 week, 12 week)
- Helpfulness of POD booklets in the preceding 6 weeks (Adolescent reports at 6 week, 12 week)

3.4a Intervention process variables (per participant)

- Total number of sessions completed (counsellor-completed session record forms)
- Frequency with which the participants (i) read the POD booklets between sessions, (ii) completed the POD exercises between sessions (iii) brought the POD booklets to the sessions (iv) implemented the POD plan (counsellor-completed end of treatment form)

3.5 Serious Adverse Events (SAEs)

- Death of the participant
- Life-threatening event
- Clinical deterioration requiring hospitalization or other specialist treatment
- Victimization (reported violence against the participant)
- Sexual abuse
- Chronic absenteeism and/or dropping out from school

3.6 Potential effect moderators

- Baseline chronicity of mental health difficulties (from eligibility screening; <=12 months, >12 months)
- Baseline severity of mental health difficulties (from eligibility screening; borderline or abnormal)
- YTP type (symptomatic, social, both)
- SDQ caseness profile (elevated internalising sub scale; elevated externalising subscale; elevated internalising AND externalising subscales; neither subscale elevated)

3.7 Potential effect-mediators

- Perceived stress (measured at 6 weeks)

4. Data analysis plan

Analyses will follow CONSORT guidelines for parallel-group randomised trials.[7] Analyses will be conducted in Stata version 15. Analysis programs ("do-files") will be prepared based on blinded data, and unblinding will not take place until after analysis and interpretation of blinded results has taken place. Analyses will only be conducted after finalisation of the data analysis plan.

4.1 Recruitment and representativeness of recruited participants and participants who completed follow up

The trial flowchart will include the number of students referred, screened, eligible, randomised and analysed for the primary and secondary outcomes at the 6- and 12-week endpoints respectively. The number refusing or excluded (with reasons), actively withdrawing, and passively lost to follow-up will be shown by arm. These will be summarised by means (standard deviation), medians (interquartile range) or numbers and proportions as appropriate by key relevant subgroups (defined by gender, baseline severity of mental health difficulties, baseline chronicity of mental health difficulties, YTP type). For continuous outcomes, histograms within each arm will be plotted to assess normality and whether transformation is required.

Initial analyses will compare baseline characteristics of i) participants who did and did not complete outcome assessments at 6 weeks, and ii) participants who did and did not complete outcome assessments at 12 weeks, compared using Mann-Whitney tests or t-tests for continuous variables and chi2 tests for categorical variables, appropriately categorised as necessary. The variables that will be summarised are as shown in tables 1-2 of section 7.1.

4.2 Baseline comparability of randomised groups

Baseline characteristics of enrolled participants will be compared between intervention arms and also reported overall, summarised using mean and standard deviation, median and interquartile range or numbers and proportions as appropriate. No significance testing will be done as any differences are due to chance if randomisation was correctly applied. For continuous outcomes, histograms will also be plotted within each arm to assess normality, and whether any transformation is required.

The variables that will be summarised are as shown in table 3 of section 7.1.

4.3 Adherence to allocated intervention and intervention fidelity

The following intervention fidelity variables will be summarized in the intervention arm. The quantity/coverage of the active intervention (PRIDE) will be described, as indicated by number of sessions. In addition, we will summarise:

- mean therapy quality of sessions as independently assessed by an independent expert on a random selection of 10% of all sessions in PRIDE arm.

4.4 Loss to follow-up and other missing data

The numbers and proportions actively withdrawing from the trials and passively lost to follow-up will be reported overall and by arm at 6 weeks and 12 weeks. The reasons for withdrawal from the trials will be summarised.

4.5 Adverse event reporting

SAEs will be reported as the number and proportion of individuals with each type of SAE (as described above), and for any SAE, by arm. If there are a sufficient number of these, the risks and 95% CIs will be estimated and compared between intervention arms. Other (non-SAE) AEs will be reported similarly.

4.6 Description of therapists

The counsellors will be described in terms of age, education, area of residence (rural/urban) and caseload.

5. Outcome analysis

The primary analyses will be on an intention-to-treat basis at the 6-week end-point, adjusted for baseline values of the outcome measure, school (as a fixed effect in the analysis) to allow for within-school clustering, counsellor variation (as a random effect), and variables for which randomisation did not achieve reasonable balance between the arms at baseline, or those associated with missing outcome data [8]. Analyses of outcomes will be conducted using linear mixed-effects regression models for continuous outcomes with normally-distributed errors (e.g. SDQ Total Difficulties score) and generalized (logistic) mixed-effects regression models for binary outcomes (e.g. remission). Intervention effects will be presented as adjusted mean differences and effect sizes (ES), defined as standardized mean differences, with 95% confidence intervals (CIs) for continuous outcomes, and adjusted odds ratios with 95% CIs for binary outcomes.

Repeated measures analysis will be used to analyse the two follow-up time points (6 and 12 weeks). Initial models will include an interaction effect between arm and time to allow for differential effects at the two end-points. This will be retained if there is evidence of effect modification by time. No interim analyses of outcomes will be undertaken.

5.1 Main analysis of intervention differences

The outcome measures will be summarized at baseline and the 6- and 12- week follow-ups by arm, summarized by means (standard deviation), medians (interquartile range) or numbers and proportions as appropriate. For continuous outcomes, histograms within each arm will be plotted to assess how closely the scales follow a normal distribution to determine how to describe the outcomes and choice of inferential analysis method.

5.1.1 Analysis of primary outcomes at 6 weeks

The intervention effect on SDQ total score and YTP score will be reported as standardized mean differences (SMD; effect size), with 95% confidence intervals (CI). Linear mixed-effects regression will be used, adjusting for baseline SDQ score, school as a fixed effect, and counsellor variation as a random effect. Adjustments will also be made for variables for which randomisation did not achieve reasonable balance between arms at baseline, or those associated with missing outcome data.

5.1.2 Analysis of secondary outcomes over 12 weeks

The analysis of secondary outcomes will use similar methods to those for the primary outcomes for continuous variables. For the binary outcome (remission), the intervention effect will be reported as the odds ratio. Generalized (linear or logistic) random-effects regression models will be used, adjusting for baseline outcome score and clustering, and other baseline variables as above. For outcomes to be examined over the 12 week follow-up period (other than remission), regression models will include a variable to represent 'time' to indicate whether the data was collected at the 6 or 12 week time point. To assess whether the intervention effect varies over time, a intervention x time interaction term will be fitted to allow for a different intervention effect at 6 vs 12 months, although this will not be highly powered.

5.2 Statistical considerations

Adjustment for multiple outcomes and reporting p-values

No p-value adjustment will be conducted. Interpretation of the intervention effect will be based on the strength of evidence of effect size and consistency of results for related outcomes.

Missing baseline and outcome data
The number (%) of participants with complete data will be reported. If scales have recommended methods for dealing with missing data, these will be applied. As outlined above, primary analyses will be complete case, with adjustments made for variables associated with missingness, to account for missing data. If necessary, in sensitivity analyses, we will apply appropriate methods to impute missing outcome data (see below).

Model assumption checks
For continuous outcomes, model residuals will also be plotted to check for normality and inspected for outliers. If substantial departures from normality occur, transformations will be considered. If a suitable transformation cannot be found, a non-parametric analysis will be considered.

5.3 Adherence analysis

As we expect a proportion of our participants to have poor adherence to PRIDE, we will in addition estimate intervention effects using a Complier Average Causal Effect (CACE) structural equation mixture model.[9,10] This model estimates the effect of the intervention on the participants who completed intervention as intended by the original randomisation.[11] Intervention completion for those in the PRIDE arm is defined as participation in at least 4 PRIDE sessions. We will summarise the intervention received by arm, including numbers not treated, receiving incomplete intervention (1-3 PRIDE sessions) and numbers completing intervention. Not treated is defined as those who were randomised to PRIDE but did not have any sessions. We will summarise the numbers of participants randomised to control but who received PRIDE.

5.4 Process evaluation

Process evaluation. We will undertake descriptive statistical analysis of quantitative process data in order to explore the differential implementation of intervention procedures. This would include analysis within the intervention arm level to describe the intervention delivery with a focus on fidelity (number of sessions, quality of therapy etc). At the individual participant level, we will explore associations between intervention engagement (e.g. completion of POD booklet exercises, frequency of implementation of POD plan), and dose (e.g. number of sessions) with outcomes. In addition, thematic content analysis will be used to code and organise qualitative interview data on intervention expectancies (assessed prior to enrolment in the trial) and qualitative written feedback on intervention satisfaction (assessed at 12-week follow-up). Findings from the various data sources will be triangulated and used to develop explanatory hypotheses about potential differences in intervention delivery and participation across schools, subgroups of participants and providers. The process evaluation findings will be used to facilitate interpretation of the main trial results. The trial statisticians may conduct further analyses to test hypotheses generated from integration of the process evaluation and trial outcome data.

5.5 Cost-effectiveness analysis

We will carry out cost effectiveness analysis according to the protocol developed separately in consultation with Giulia Greco (Health Economist).

An economic evaluation will be conducted to estimate the costs and incremental cost-effectiveness of the PRIDE intervention. A combination of top-down and ingredients-based costing approaches will be used to generate cost estimates for the whole package, and for each package component (e.g.

counselling sessions and POD booklet), in the intervention (and control) groups. All costing will be estimated from the provider's perspective (the schools, and the implementing partner) and financial and economic costs will be calculated for all inputs (e.g. materials, training, supervision, staff time, overheads). The results of cost analysis will assess the costs of setting up and running the interventions, describe the distribution of costs across different forms of inputs, the unit cost per student/adolescent reached, the cost per additional case remitted, the cost of delivering all activities in intervention schools and the cost per unit of measure for selected primary and secondary outcomes (e.g. youth mental health difficulties (SDQ) and youth top problems (YTP) summary scores). We will estimate the incremental cost effectiveness of the intervention relative to the status quo (enhanced usual care represented by the control schools). The cost-effectiveness measure proposed here will be compared to similar school programmes in the region and it will inform programme replication, scalability and financial sustainability.

Results will be plotted on a cost-effectiveness plane and presented as cost-effectiveness acceptability curves to show the probability of the intervention being cost-effective at a range of willingness-to-pay threshold levels. A sensitivity analysis will be conducted to take account of uncertainty and imprecision in the measurements.

5.6 Planned sub-group (moderator) analyses

A moderator analysis will be conducted to investigate for whom, and under what circumstances, the problem-solving intervention is effective. We will assess modification of intervention effect by *a-priori* defined modifiers (i.e. chronicity of mental health difficulties (<=12 months, > 12 months), severity of mental health difficulties (borderline, abnormal), YTP type (symptomatic, social, both), SDQ caseness profile (internalizing; externalizing; both internalizing and externalizing; neither), by fitting appropriate interaction terms and testing for heterogeneity of intervention effects in regression models.

5.7 Additional secondary/mediation analyses

Additional secondary analyses will be conducted to answer exploratory questions related to potential intervention mechanisms and mediation where data is available. A mediation analysis will be conducted to examine whether the theoretically-driven a priori factor (perceived stress at 6 weeks) mediates the effects of the intervention on mental health symptoms and idiographic problems at 12 weeks. All analyses will control for potential confounders including baseline primary outcome and mediator scores following the approaches used for the main trial analyses. Using conditions stated by MacKinnon[12,13] and the Monte Carlo method for assessing mediation[14], we will examine associations between the intervention and the potential mediator (perceived stress at 6 weeks), the mediator and the outcomes, and the intervention and the outcomes.

6. References

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7. Appendix I: Dummy tables

Table 1 Baseline characteristics of completers of outcome evaluation and participants lost to follow-up at 6 week time point (LTFU)

	Lost before 6 week evaluation* (n=)	**Completed 6 week outcome evaluation (n=)**	**p-value [1]**
Gender (n [%]) Female Male			
Age (years) (mean [SD])			
Class (n [%]) 9th Class 10th Class 11th Class 12th Class			
School (n [%]) GBSSS, Mahipalpur. GBSSS, Badarpur. SBV, Badarpur. GGSSS, Badarpur. ASMS-SKV, Mahipalpur. SarvodayaV Co-Ed, Vasant Vihar.			
Week of enrolment (n [%])			
Primary Caregiver (n [%]) Mother & Father Mother Father Grandmother Aunt/Uncle			
Primary caregiver age (years) (mean [SD])			
Primary caregiver gender (n [%])			

Caregiver Education No formal education Completed primary Completed secondary school and above Data Not Available			
Caregiver Occupation Unemployed/ Homemaker Unskilled manual work Skilled manual work Professional Data Not Available			
SDQ Total Difficultly Score (mean [SD])			
SDQ Impact score (mean [SD])			
SDQ Internalising subscale (mean [SD])			
SDQ Externalising subscale (mean [SD])			
SDQ prosocial subscale (mean [SD])			
SDQ Chronicity (n [%]) 1-5 Months 6-12 Months Over a Year			
YTP severity score (mean [SD])			
PSS-4 score			
SWEMWBS score			
Caregiver reported SDQ Total Difficulty score (mean [SD])			
Caregiver reported SDQ Impact score (mean [SD])			
Caregiver reported SDQ internalising subscale (mean [SD])			
Caregiver reported SDQ externalising subscale (mean [SD])			

*Were deemed eligible, underwent baseline assessment but for whom 6 week outcomes are not available

[1] By Mann-Whitney test where medians are reported, by t-test where means are reported, and by chi2 test for categorical variables.

Table 2. Baseline characteristics of completers of outcome evaluation and participants lost to follow-up at 12-week time point (LTFU)

	Lost before 12 week evaluation* (n=)	**Completed 12 week outcome evaluation (n=)**	**p-value [1]**
Gender (n [%]) Female Male			
Age (years) (mean [SD])			
Class (n [%]) 9th Class 10th Class 11th Class 12th Class			
School (n [%]) GBSSS, Mahipalpur. GBSSS, Badarpur. SBV, Badarpur. GGSSS, Badarpur. ASMS-SKV, Mahipalpur. SarvodayaV Co-Ed, Vasant Vihar.			
Week of enrolment (n [%])			
Primary Caregiver (n [%]) Mother & Father Mother Father Grandmother Aunt/Uncle			
Primary caregiver age (years) (mean [SD])			
Primary caregiver gender (n [%])			

Caregiver Education No formal education Completed primary Completed secondary school and above Data Not Available			
Caregiver Occupation Unemployed/ Homemaker Unskilled manual work Skilled manual work Professional Data Not Available			
SDQ Total Difficultly Score (mean [SD])			
SDQ Impact score (mean [SD])			
SDQ Internalising subscale (mean [SD])			
SDQ Externalising subscale (mean [SD])			
SDQ prosocial subscale (mean [SD])			
SDQ Chronicity (n [%]) 1-5 Months 6-12 Months Over a Year			
YTP severity score (mean [SD])			
PSS-4 score			
SWEMWBS score			
Caregiver reported SDQ Total Difficulty score (mean [SD])			
Caregiver reported SDQ Impact score (mean [SD])			
Caregiver reported SDQ Internalising subscale (mean [SD])			
Caregiver reported SDQ Externalising subscale (mean [SD])			

*Were deemed eligible, underwent baseline assessment but for whom 12 week outcomes are not available

[1] By Mann-Whitney test where medians are reported, by t-test where means are reported, and by chi2 test for categorical variables.

Table 3. Baseline characteristics of trial participants by arm (primary analysis group)

	PRIDE (n=)	**EUC (n=)**
Gender (n [%]) Female Male		
Age (years) (mean [SD])		
Class (n [%]) 9th Class 10th Class 11th Class 12th Class		
School (n [%]) GBSSS, Mahipalpur. GBSSS, Badarpur. SBV, Badarpur. GGSSS, Badarpur. ASMS-SKV, Mahipalpur. SarvodayaV Co-Ed, Vasant Vihar.		
Week of enrolment (n [%])		
Primary Caregiver (n [%]) Mother & Father (?) Mother Father Grandmother Aunt/Uncle etc….		
Primary caregiver age (years) (mean [SD])		
Primary caregiver gender (n [%])		

Caregiver Education No formal education Completed primary Completed secondary school and above Data Not Available		
Caregiver Occupation Unemployed/ Homemaker Unskilled manual work Skilled manual work Professional Data Not Available		
SDQ Total Difficultly Score (mean [SD])		
SDQ Impact score (mean [SD])		
SDQ Internalising subscale (mean [SD])		
SDQ Externalising subscale (mean [SD])		
SDQ prosocial subscale		
SDQ Chronicity (n [%]) 1-5 Months 6-12 Months Over a Year		
YTP severity score (mean [SD])		
PSS-4 score		
SWEMWBS score		
Caregiver reported SDQ Total Difficulty score (mean [SD])		
Caregiver reported SDQ Impact score (mean [SD])		
Caregiver reported SDQ Internalising subscale (mean [SD])		
Caregiver reported SDQ Externalising subscale (mean [SD])		

Table 4. Process indicators for trial participants in the PRIDE arm

Process indicator	**Total** (n [%])	
Participants who entered PRIDE arm		
Mean therapy quality of sessions as independently assessed by an independent expert on a random selection of 10% of all sessions in PRIDE arm		
Participants who read the POD booklets between sessions (counsellor-completed session record forms)		
Participants who completed the POD exercises between sessions (counsellor-completed session record forms)		
Participants who brought POD booklets to the sessions (counsellor-completed session record forms)		
Participants who demonstrated understanding of POD booklets and session content (counsellor-completed session record forms)		
Participants who implemented the POD plan (counsellor-completed session record forms for sessions 4 and 5)		
Participants who attended session on time (counsellor-completed session record forms)		
Intervention Dosage (Number of PRIDE sessions received (n=))	Completers* (n=)	Non-completers (n=)
0 sessions 1 session 2 sessions 3 sessions 4 sessions 5 sessions		
Mean number of sessions completed (SD)		
Mean session length		

*Intervention completion defined as attending at least 4 sessions and had a planned discharge

Table 5. Process indicators for trial participants in the PRIDE and EUC arm

	PRIDE (n=)	**EUC (n=)**
Frequency of POD booklet use at home- participant report at 6 weeks (mean score)		
Frequency of POD booklet use at home- participant report at 12 weeks (mean score)		
Helpfulness of POD booklets in the preceding 6 weeks- participant report at 6 weeks (mean score)		
Helpfulness of POD booklets in the preceding 12 weeks- participant report at 6 weeks (mean score)		

Table 6: Primary and secondary outcomes at 6 week and 12 weeks[1]

Outcome	PRIDE arm (n=X)	EUC arm (n=X)	Adjusted mean difference or prevalence ratio (95% CI)	p-value
Primary outcomes				
Mean self-reported SDQ Total difficulties score at 6 weeks (SD)				
Mean self-reported YTP severity score at 6 weeks (SD)				
Secondary outcomes				
Mean self-reported SDQ Total difficulties score over 12 weeks (SD)				
Mean self-reported YTP severity score over 12 weeks (SD)				
Mean self-reported SDQ Impact score over 12 weeks (SD)				
Mean self-reported SDQ internalising subscale score over 12 weeks (SD)				
Mean self-reported SDQ externalising subscale score over 12 weeks (SD)				
Mean self-reported Perceived Stress Scale-4-item version (PSS-4) total score over 12 weeks (SD)				
Mean self-reported SWEMWBS score over 12 weeks (SD)				
Remission based on self-reported SDQ Total difficulties score over 12 weeks(%)				
Exploratory outcomes				
Mean caregiver-reported SDQ Total difficulties score over 12 weeks (SD)				
Mean caregiver-reported SDQ Impact score over 12 weeks (SD)				
Mean caregiver-reported SDQ internalising subscale score over 12 weeks (SD)				
Mean caregiver-reported SDQ externalising subscale score over 12 weeks (SD)				
Mean self-reported SDQ prosocial subscale score (SD) over 12 weeks				

[1] This table assumes no effect modification by time – if there is effect modification, results will be shown separately at 6 and 12 weeks.

Table 7. Primary Outcome by potential effect modifiers: adjusted* SDQ total difficulties scores at 6 weeks

	PRIDE (mean [SD])	**EUC (mean [SD])**	**Intervention effect: adjusted mean difference [95% CI]**	**P value for effect modification**
YTP type				
Symptomatic				
Social				
Both				
SDQ caseness				
Elevated internalising				
Elevated externalising				
Both internalising and externalising				
Neither				
Chronicity of mental health difficulties (SDQ Impact score)				
<= 12 months				
>12 months				
Baseline severity of mental health difficulties (SDQ Total difficulties score)				
Borderline				
Abnormal				
*Adjusted as for the primary analyses (see main text)				

Table 8. Primary Outcome by potential effect modifiers: adjusted* YTP scores at 6 weeks

	PRIDE (mean [SD])	**EUC (mean [SD])**	**Intervention effect: adjusted mean difference [95% CI]**	**P value for effect modification**
YTP type				
Symptomatic				
Social				
Both				
SDQ caseness				
Elevated internalising				
Elevated externalising				
Both internalising and externalising				
Neither				
Chronicity of mental health difficulties (SDQ Impact score)				
<= 12 months				
>12 months				
Baseline severity of mental health difficulties (SDQ Total difficulties score)				
Borderline				
Abnormal				
*Adjusted as for the primary analyses (see main text)				

Table 9: Mediation effect of Perceived stress measured at 6 weeks (parameter estimates and standard errors)

Effect	**Estimate**	**SE**	**95%Bootstrap**
SDQ Total difficulties score			
(c) Intervention → SDQ Total score (12 weeks)			
(a) Intervention arm → PSS-4 score (6 weeks)			
(b) PSS-4 score (6 weeks) → SDQ Total score (12 weeks)			
axb			
YTP score			
(c) Intervention → YTP score (12 weeks)			
(a) Intervention arm → PSS-4 score (6 weeks)			
(b) PSS-4 score (6 weeks) → YTP score (12 weeks)			
axb			

8. Appendix II: Modifications made to the PRIDE trial protocol

Here we report changes made to the trial outcomes and/or analysis plan during the course of the trial.

8.1 Table 1: Amendments to outcomes (PRIDE)

Wording in previous versions	Changes in revised updated version
PRIDE Protocol **PRIDE_TrialProtocol_V3_12June2018**	**PRIDE Analysis plan**
Trial Protocol Section **Background, Objectives** The secondary hypotheses are that the intervention will be superior to the control condition with respect to: • reduced self-reported adolescent mental health symptoms and idiographic problems at 12 weeks post-randomization; • reduced parent-reported adolescent mental health symptoms at six and 12 weeks post-randomization; • reduced self- and parent-reported distress/functional impairment for adolescents at six and 12 weeks post-randomization; • reduced self-reported perceived stress for adolescents at six and 12 weeks post-randomization; improved self-reported adolescent wellbeing at six and 12 weeks post-randomization; and • improved remission, derived from the 'crossing clinical threshold' method applied to self-reported adolescent mental health symptoms and associated distress/functional impairment at six and 12 weeks post-randomization.	**Trial Analysis plan** **Section 2.1** The secondary hypotheses are that the intervention will be superior to the control condition with respect to the following outcomes, over a 12-week period post-randomisation 1. Reducing self-reported adolescent mental health symptoms and idiographic problems; 2. Reducing self-reported distress/functional impairment; 3. Reducing self-reported perceived stress; 4. Improving self-reported adolescent wellbeing 5. Improving remission, derived from the 'crossing clinical threshold' method applied to self-reported adolescent mental health symptoms and associated distress/functional impairment 6. Reducing caregiver-reported adolescent mental health symptoms and their impact

8.2 Table 2: Amendments to protocol for clarification of the analysis plan

Wording in previous versions	**Changes in revised versions**
PRIDE_TrialProtocol_V3_12June2018	**PRIDE Analysis plan**
Analyses *Moderator analyses*: We will explore potential moderators of intervention effects, with respect to a priori defined modifiers (i.e. age, gender, chronicity of mental health difficulties, severity of mental health difficulties). We will fit relevant interaction terms and test for heterogeneity of intervention effects in regression models.	5.6 **Planned sub-group (moderator) analyses** A moderator analysis will be conducted to investigate for whom, and under what circumstances, the problem-solving intervention is effective. We will assess modification of treatment effect by *a-priori* defined modifiers (i.e. chronicity of mental health difficulties (<=12 months, > 12 months), severity of mental health difficulties (borderline, abnormal), YTP type (symptomatic, social, both), SDQ caseness profile (internalizing; externalizing; both internalizing and externalizing; neither), by fitting appropriate interaction terms and testing for heterogeneity of treatment effects in regression models.