Trials

STUDY PROTOCOL

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Study protocol for a pragmatic randomised multiple baseline trial evaluating Knowledge Insight Tools (KIT), a cognitive behavioural therapy-informed school-based counselling intervention for children and young people in UK secondary schools with low mood and anxiety

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Abstract

Background There is a pressing need to offer more accessible, evidence-based psychological interventions to secondary school students who are increasingly reporting difficulties with anxiety and low mood. The aim of this pragmatic randomised multiple baseline trial is to evaluate the efficacy of a school-based counselling intervention called Knowledge Insight Tools (KIT) for reducing anxiety and low mood in UK secondary school students. KIT is a flexible intervention delivered individually and informed by cognitive behavioural therapy (CBT).

Methods We will use a randomised multiple baseline design whereby young people will be randomly allocated to a baseline wait period of 3, 4, 5, 6, 7, or 8 weekly measurements, followed by receiving up to 10 weekly sessions of KIT delivered by trained, school-based practitioners. We aim to recruit 60 young people aged 11–18 who are primarily experiencing problems with low mood and/or anxiety from secondary schools across England and Scotland. We will assess child-reported anxiety, mood, and general psychological distress/coping with the Young Person's Clinical Outcomes in Routine Evaluation (YP-CORE), recorded at each session during the baseline and intervention phases. We will also assess child-reported anxiety and low mood with the Revised Children's Anxiety and Depression Scale (RCADS) at the beginning and end of treatment; practitioner-reported treatment fidelity with the KIT Fidelity Checklist; and practitioner-reported feasibility with an end-of-treatment Implementation Survey. We will analyse within-person and between-person change in YP-CORE scores across the baseline and intervention phases using visual analysis and piecewise multilevel growth curve models. We will also analyse pre-post changes in YP-CORE scores using randomisation tests, and reliable and clinically significant change using the RCADS scores.

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Discussion The KIT trial is a pragmatic, randomised multiple baseline trial aimed at evaluating a school-based, individual CBT counselling intervention for reducing anxiety and low mood in UK secondary school students. Results will directly inform the provision of KIT in school-based counselling services, as well as the growing evidence-base for school-based CBT interventions.

Trial registration ClinicalTrials.gov NCT06188962. Retrospectively registered on 02/01/24.

Keywords Randomised trial, Multiple baseline design, School-based counselling, Cognitive behavioural therapy, Anxiety, Depression, Low mood, Children, Young people

Administrative information

Title {1}	Study protocol for a pragmatic randomised multiple baseline trial evaluating Knowledge Insight Tools (KIT), a cognitive behavioural therapy-informed school-based counselling intervention for secondary school-aged children and young people with anxiety and low mood in the UK
Trial registration {2a and 2b}	NCT06188962 ClinicalTrials.gov
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Role of sponsor {5c}	As the study sponsor, UCL will conduct the trial's evaluation and uphold ethical practice and research governance

Introduction

Background and rationale {6a}

Mental health problems in secondary school-aged children and young people

Mental health problems appear to have risen in secondary school students over recent decades [1]. Large-scale analyses indicate that the school-based prevalence of emotional or behavioural problems in young people before the COVID-19 pandemic was as high as two in five children in England [2]. Various studies have documented a further increase in the rates of mental health difficulties in young people during the pandemic [3–7], which have remained high [8, 9]. These high rates of mental health problems in children and young people are concerning because they predict lower school achievement, difficulties in forming and maintaining relationships, nicotine and alcohol dependence, and suicide attempts [10]. Mental health problems in adolescence also predict future mental health problems in adulthood, as well as financial and social instability, criminal activity, and poorer physical health outcomes [11, 12].

The need for school-based psychological interventions

Despite the growing rates of mental health difficulties in secondary school students, specialist services like Child and Young People's Mental Health Services (CYPMHS) are struggling to meet the increase in demand [13]. Furthermore, there are several barriers to accessing specialist mental health services, including perceived stigma, not reaching diagnostic thresholds, and impracticalities like location and cost [14]. Recognising the need for more accessible forms of psychological support, the UK Government proposed an investment in schools to provide frontline mental health support via the development of Mental Health Support Teams, Senior Mental Health Leads, and prevention programmes [15]. However, these offer low-level support for mild mental health difficulties. The government has also called for more intensive interventions to meet the needs of more moderate and severe mental health difficulties [16], but the evidence base around what intensive school-based interventions work for alleviating anxiety and low mood in treatment-seeking secondary school students is lacking [17].

School-based psychological therapies

School-based counselling The main type of intensive psychological intervention offered in UK secondary schools is humanistic counselling [18]. School-based counselling typically involves one-to-one support where

the goal is for young people to learn to value their own experiences and develop insight into their difficulties through a counsellor's deep, empathic listening [19].

Early meta-analyses of uncontrolled studies evaluating school-based counselling in UK secondary schools showed large pre-post effect sizes [20, 21]. Nonetheless, the first pilot randomised controlled trial did not find a significant difference between school-based counselling and a waitlist control [22], but the school-based counselling intervention was briefer than usual (e.g. six sessions) and large post-treatment differences were still found in non-symptom-based measures (e.g. prosocial behaviour). Subsequent feasibility and pilot trials with 10–12-week counselling interventions have since shown high levels of superiority in reducing psychological distress in secondary school students compared to wait list controls ($d=1.14$ [23]) and usual school-based care ($d=0.86$ [24]). However, one trial [25] showed more modest treatment differences between school-based counselling and a wait list control, which were only significant at mid-treatment ($d=0.59$) rather than post-treatment ($d=0.39$). These mixed findings are likely a result of small sample sizes (e.g. each trial included around 30 young people) which can overestimate the treatment effect or produce noisy estimates.

In the first, large-scale randomised controlled trial of school-based counselling in the UK, the ETHOS trial, Cooper and colleagues [14] found that school-based counselling plus pastoral care was associated with significantly lower self-reported distress compared to pastoral care alone in 329 students attending 18 Greater London secondary schools. As expected, the effect size was more modest compared to the pilot trials ($d=0.25$), which, in addition to being a more rigorously powered study, might also be due to greater similarity between the intervention and control conditions (i.e. both included pastoral care). Furthermore, the school-based counselling arm showed a higher incidence of adverse and serious adverse events. Overall, the efficacy of school-based counselling might not be as pronounced as the initial evaluation and pilot studies indicated, at least compared to UK pastoral support.

Cognitive behavioural therapy School-based interventions have also been developed using the principles of cognitive behavioural therapy (CBT). CBT is a problem-focused intervention in which practitioners help clients recognise and challenge unhelpful thoughts and behaviours that inadvertently perpetuate their symptoms of depression and anxiety [26].

There have been several systematic reviews and meta-analyses supporting the moderate-to-large efficacy of school-based CBT interventions in reducing anxiety and low mood in at-risk students [27–33]. However, most interventions reviewed were group-based; brief or hyper-brief (e.g. 1–6 classroom sessions or workshops); delivered to selective and indicated samples; delivered to both primary and secondary school-aged children; and were conducted outside of the UK (e.g. Europe, North and South America, East Asia, Australasia, and the Middle East). The three UK-based trials evaluating school-based CBT interventions for secondary school students at risk of developing anxiety and low mood were brief, group-based, and reported minimal [34], small [35], or moderate [36] effect sizes.

Few studies have evaluated the efficacy of 'intensive' CBT interventions delivered individually to treatment-seeking students in secondary schools with anxiety and/or low mood. To address this gap, Ginsburg and colleagues [37] conducted what to our knowledge was the first pilot trial evaluating a school-based, individual, modular CBT intervention for anxiety in US secondary school students. In modular interventions, the core components and techniques of CBT are organised into flexibly delivered 'modules' determined by the child's needs [38]. Ginsburg et al. did not find a significant difference in anxiety disorder remission rates after 12 sessions of CBT compared to usual school-based treatment, which was a mix of supportive counselling, play and art therapy, and general emotional support [39]. However, they recruited a small ($N=32$) and relatively young sample (mean age = 10; range = 7–17); CBT-based interventions tend to be more effective for older students [29].

More recently, Ginsburg and colleagues [40] replicated their pilot findings in a similar but larger sample ($N=216$; mean age = 10; range = 6–18) in the School-Based Treatment for Anxiety Research Study (STARS) trial. Students who received school-based, individual, modular CBT showed similar rates of clinical improvement in anxiety severity compared to school-based treatment as usual described above. However, students who were older and showed higher baseline anxiety severity were more likely to show clinical improvement following CBT versus treatment as usual. These findings highlight how individual, modular CBT delivered in schools is at least as effective as supportive counselling and may be particularly beneficial for older children with more severe difficulties.

Whilst promising, the studies by Ginsburg and colleagues do not address whether intensive, school-based CBT is also efficacious for treating low mood in secondary school students. In their uncontrolled pilot study, Michael and colleagues [41] found that an individual, modular, school-based CBT intervention was linked to moderate-to-large pre-post reductions in depression symptoms (as well as anxiety and inattention symptoms)

in secondary school students. Similarly, Kirk and colleagues [42] found that most secondary school students reported a reliable improvement in general distress (which encompasses difficulties in low mood and anxiety) following an individual, modular, school-based CBT intervention, with a quicker rate of change for students with higher baseline distress scores (but slower rates of change in students with higher baseline depression scores on a separate measure).

These findings support the effectiveness of school-based CBT offered individually to secondary school students with symptoms of anxiety and depression but require replication in a UK-based sample using a randomised design. They also highlight the importance of modular interventions, where the core components of CBT can be delivered in a flexible way to meet the needs of students within a school setting. Knowledge Insight Tools (KIT) is a CBT-informed, one-to-one intervention for secondary school pupils who are struggling with low mood and/or anxiety. By being collaborative, goal-focused, and flexible, KIT was designed to suit the needs of secondary school students within a school setting. However, controlled studies are needed to evaluate KIT's efficacy before it can be offered as a treatment option in secondary schools.

Objectives {7}

Aims

The aim of this pragmatic randomised multiple baseline trial is to test the efficacy of KIT as a CBT-based model of one-to-one counselling for secondary school students in the UK. We ask the following research questions:

1) Do young people aged 11–18 who receive KIT in secondary schools show a statistically significant and clinically meaningful reduction in their anxiety and/or low mood compared to when they were not receiving KIT during a baseline wait period of a randomly varying length?
2) Do practitioners feel that KIT is feasible, suitable and helpful for young people receiving help in school-based settings?

Trial design {8}

We will use a randomised multiple baseline superiority design to investigate the efficacy of KIT in reducing anxiety and low mood in secondary school students. In single-case multiple baseline designs, each participant undergoes both the control and intervention conditions sequentially over time, i.e. each participant serves as their own control [43]. The current trial uses an A-B design, where all participants undergo a baseline wait period ('A') which varies randomly in length, followed by an intervention phase ('B'). If participants show similar changes in an outcome after the intervention is introduced, regardless of when it is introduced, then these changes are more likely to be due to the intervention rather than coincidental events [44]. Control for extraneous factors comes from randomly allocating participants to different baseline wait periods. This differs from standard randomised controlled parallel group designs, where each participant is compared to at least one other control participant who is matched on important characteristics except for the intervention. In parallel group designs, control for extraneous factors comes from randomly allocating participants to the intervention and control conditions. The benefit of multiple baseline designs is that both between-person *and* within-person change can be investigated, the latter being clinically informative in terms of examining individual responses to a treatment [43]. Repeated measurements also increase statistical power, meaning less participants are typically needed than parallel group designs to evaluate therapeutic efficacy [44].

Figure 1 in {13} displays our multiple baseline design. Our baseline 'A' phase will last 3–8 weeks, with participants randomly allocated to a baseline wait period of either 3, 4, 5, 6, 7, or 8 weeks (excluding school closures and non-avoidable absences) at a ratio of 1:1 (e.g. each participant serves as their own control, and we will aim for an equal number of wait period lengths). We will use a non-concurrent design, i.e. participants start their baseline phases on different start dates. The intervention 'B' phase will last for up to 10 weekly sessions of KIT. The length of the intervention will be jointly determined by young people and practitioners, with progress reviews on the fourth and seventh sessions. We will not specify a minimum treatment length but will consider the extent that interventions are complete for the analysis based whether they include all features and phases of KIT (assessed using the fidelity checklist). We will evaluate whether the intervention phase shows superiority to the baseline phase in a phase II trial.

Methods: participants, interventions and outcomes

Study setting {9}

The study will take place in Place2Be services located within 15–30 secondary schools and academies across England and Scotland**.** Place2Be is a charity that provides mental health support to primary and secondary schools in the UK. School-based practitioners (trained counsellors and therapists) offer one-to-one and group counselling in-house to children and young people who

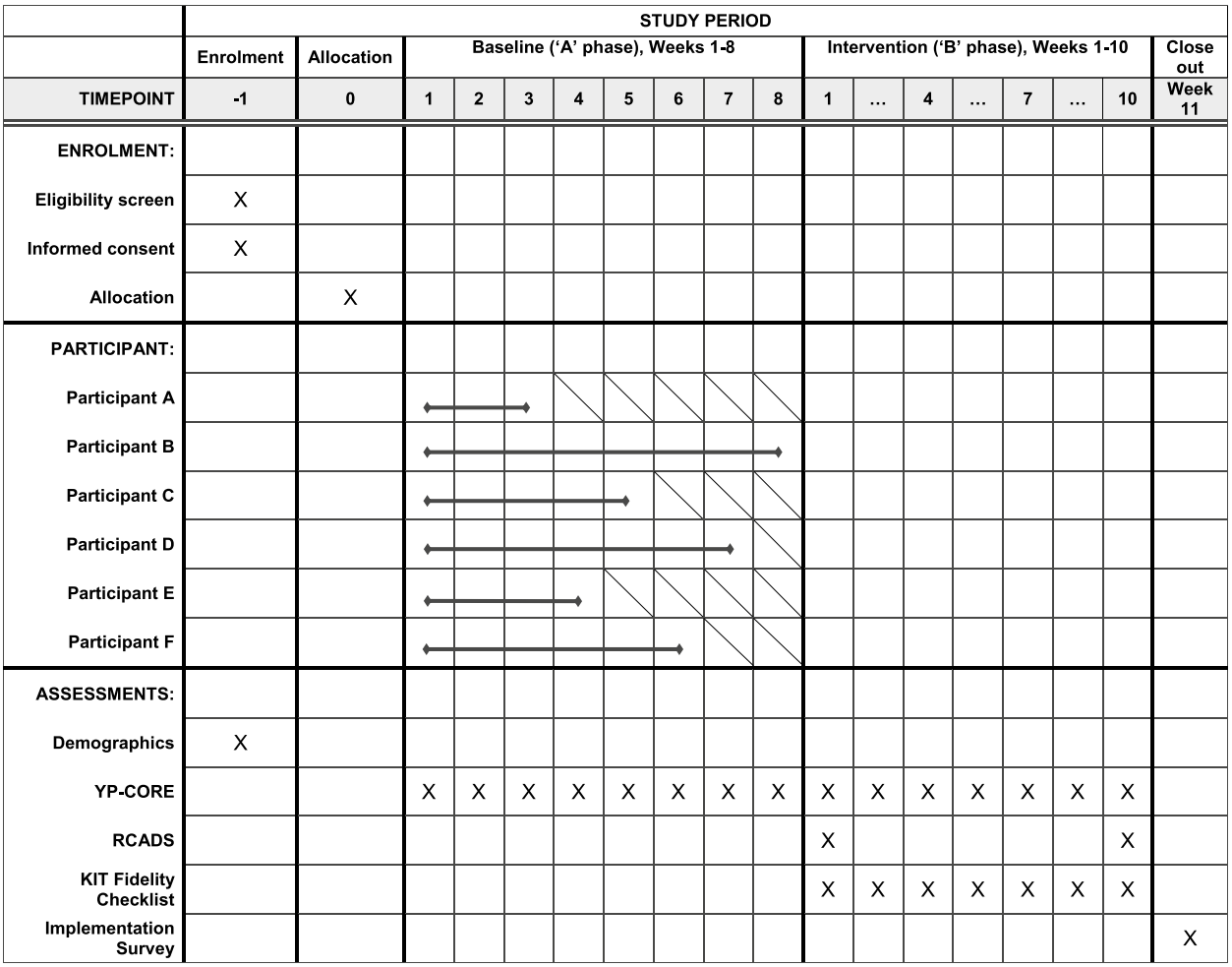

Fig. 1 Schedule of the enrolment, baseline, and intervention phases for the KIT trial's non-concurrent multiple baseline 'AB' design. KIT = Knowledge Insight Tools; RCADS = Revised Child Anxiety and Depression Scales (secondary outcome measure); YP-CORE = Young Person's Clinical Outcomes in Routine Evaluation Scale (primary outcome measure). *Note.* Example of six participants who are each randomly allocated to one of six baseline wait periods following a minimum of 3 weeks (e.g. Participant A) and a maximum of weeks (e.g. Participant B). Black horizontal lines in the 'Participant' rows reflect the length of each participant's baseline period, based on the number of weeks it spans (e.g. Participant E would wait for 4 weeks). Diagonally crossed baseline cells reflect weeks that are not included in a participant's baseline wait period. Note that participants do not start the baseline phase on the same absolute date; week 1in the baseline phase falls on a different date for each participant (as does week 1in the intervention phase). Furthermore, the figure shows 'allocated' baseline wait periods; participants randomised to a baseline period that ends on a school closure will start the intervention once schools re-open, which would reflect their 'actual' baseline period. The intervention lasts for up to10 weeks with weekly increments (e.g. week 1, 2, 3, etc.) but the intervention period is summarised every 3 weeks to condense the figure. The YP-CORE will be taken at the beginning of each baseline and intervention session; the KIT Fidelity Checklist after each intervention session; the RCADS on the first (week 1) and final (week 10) intervention sessions; and the Implementation Survey after all KIT interventions have been completed

are referred by school staff, parents/carers, or the child themselves. A list of study sites will be made available upon request.

Eligibility criteria {10}

The following criteria used to identify a KIT case are based on information triangulated from interviews and outcome measures completed by the young person, parents/carers, teachers, and school records and collected following a structured Assessment and Formulation protocol used in Place2Be services.

Inclusion criteria:

- Eleven to 18 years old.
- Attends a secondary school in England and Scotland.
- Experiences problems with low mood and/or anxiety that significantly impair day-to-day functioning.

Given the pragmatic nature of this trial, we have not specified a minimum/maximum symptom threshold for inclusion. Instead, we aim to recruit a representative sample of young people referred to school-based counselling services.

- Experiences problems that are at least in part within their control as opposed to the system being the problem (systems work/advocacy might be more relevant in these cases).
- Are seeking help and are motivated towards change.

Exclusion criteria:

- Pose a significant risk to themselves and/or others, e.g. where there is significant self-harm (e.g. self-harm that risks accidental death, such as cutting, self-strangulation, under/overusing medications, tablets or substances, and swallowing hazardous materials), suicidal ideation, suicidal intent, sexual/physical violence to/from others, hospitalisation due to alcohol/substance misuse/self-harm/psychiatric reasons.
- Primary difficulties are not related to anxiety/low mood, e.g. uncontrolled eating disorders, substance/alcohol dependence, psychotic disorders, body dysmorphia, antisociality, risk-taking problems, and personality disorders.
- Have significant special educational needs or learning difficulties.
- Are younger than 16 and for whom it would pose significant issues if their parents/carers were informed of their involvement with Place2Be services.

Eligible schools will have Place2Be services already set up within them. Practitioners will need to work for Place2Be, pass safety checks (e.g. up-to-date enhanced DBS), and have undergone KIT training with Place2Be.

Who will take informed consent? {26a}

Place2Be practitioners will first seek consent from head teachers to recruit schools that already house Place2Be services. Practitioners will send head teachers an information sheet and privacy notice on behalf of the research team that outlines what their school and pupils will be expected to do, how the data will be collected and stored securely and confidentially, and any risks associated with participating. Head teachers will have the option of discussing any questions with Place2Be researchers.

Within consenting schools, Place2Be practitioners will seek consent from young people who are deemed eligible for KIT based on a screening assessment that is standard practice in Place2Be services (see {10}). Young people will be given information sheets and a privacy notice, detailing what will be expected of them, what we will do with their data and how we will store it safely and confidentially, and how they can still access KIT or other forms of support from Place2Be without taking part in the trial or after withdrawing their participation. For eligible pupils younger than 16, practitioners will send parents/carers information sheets and the privacy agreement. Young people (and their parents/carers if young people are under 16) will have 2 weeks from the date they are sent the information sheets to decide whether they wish to participate and can discuss this decision with practitioners. Place2Be researchers—who are separate from Place2Be practitioners (see {5d})—will oversee the practicalities of the recruitment process, and UCL investigators at the Evidence-Based Practice Unit (EBPU) will oversee ethical conduct in the recruitment process.

Young people who wish to participate will date and sign a consent form which lists the main clauses of participation. Parents/carers of children under 16 do not need to submit any forms unless they wish to opt their child out of the study. In rare cases where young people wish to participate but their parents/carers opt-out, research participation will not be offered to young people, but support will still be offered by Place2Be services if the child is deemed Gillick competent and support is deemed helpful by Place2Be. Consent will never be assumed even after it is provided to practitioners by young people. The check-ins during the baseline and intervention sessions will provide information about whether young people wish to continue participating, based on verbal feedback as well as non-verbal behaviours reflecting their assent.

Additional consent provisions for collection and use of participant data and biological specimens {26b}

Not applicable, no biological samples were collected.

Interventions

Explanation for the choice of comparators {6b}

In single-case multiple baseline designs, each participant serves as their own control [43]. Therefore, the baseline wait period is the 'control condition' which all participants undergo before then completing the same intervention but at different times. Participants do not usually receive any form of treatment in the baseline phase, as the goal is to produce a stable estimate of their pre-treatment state.

Intervention description {11a}

Knowledge Insight Tools (KIT) is a CBT-informed, one-to-one intervention for secondary school pupils who are struggling with low mood and/or anxiety developed by Place2Be and Anna Freud. KIT incorporates key features of the general CBT model (e.g. agenda setting, guided discovery, collaborative case formulation), with therapeutic

techniques from disorder-specific models of anxiety and depression (e.g. behavioural experiments and behavioural activation), whilst being delivered in a creative way that matches the young person's needs and pace of learning. Whilst there is an emphasis on symptom reduction, the primary focus is on the young person's goals for living and co-producing an understanding of how symptoms can interfere with these goals. Practitioners can incorporate different therapeutic modalities (e.g. art, music, and play therapy) to increase engagement with the intervention. By being collaborative, goal-focused, and creative, KIT was designed to suit the needs of secondary school students within a school setting. However, controlled studies are needed to evaluate KIT's efficacy before it can be offered as a treatment option in secondary schools.

KIT is a non-manualised, semi-structured intervention that includes both 'fixed' and 'flex' components. Fixed components include 'what' needs to be done to count as a KIT intervention, including detailed written guidance on the core phases of CBT (e.g. assessment, formulation, intervention planning, intersession task planning and reviewing, and ending planning) and specific CBT skills and techniques (e.g. agenda setting, symptom reduction and goal setting, collaborative case formulation around maintenance cycles, and inter-session work involving behavioural experiments to target anxiety and/or behavioural activation to target low mood).

'Flex' components include 'how' things are done and offer practitioners flexibility in delivering KIT. For instance, practitioners can use their knowledge and skills from other modalities to creatively achieve the 'fixed' CBT-based tasks in a way that suits the young person's needs and learning styles. Like modular approaches to CBT delivery [38, 45], practitioners do not need to move through the fixed phases (or 'modules') of CBT sequentially; they can move back and forth between phases depending on the needs, strengths, and skills of the young person. However, certain phases naturally precede others (e.g. assessment before formulation), and certain tasks such as intervention planning are expected to be repeated in subsequent sessions once introduced.

KIT is delivered in approximately 10 weekly sessions, with progress reviews at weeks four and seven (or when the practitioner and/or young person feel it necessary). Young people can choose to have fewer or additional sessions depending on progress. KIT will be delivered by Place2Be practitioners working in secondary schools. Practitioners are qualified therapists and counsellors registered with a professional body (e.g. British Association for Counselling and Psychotherapy) with training in various modalities (e.g. counselling, psychotherapy, art therapy, play therapy, dance/movement therapy, music therapy). All practitioners will undergo KIT training consisting of five online, interactive modules covering the phases of KIT described above, and two modules focusing on anxiety and low mood. Practitioners will also partake in a 2-day experiential training, consolidation meetings, and six group sessions of KIT supervision.

Criteria for discontinuing or modifying allocated interventions {11b}

Young people can request to withdraw their participation from the trial at any time without giving a reason. This will not prevent them from receiving further support from Place2Be, including KIT, which will be made clear to them throughout the trial. They will simply stop contributing their outcomes to the trial and will no longer be required to wait until their randomly allocated baseline period is over to receive KIT or whatever intervention is suitable at the time.

Additionally, young people will be removed from the trial if they show a significant deterioration in their mental health which presents a significant risk to their personal and/or physical wellbeing. Verbal feedback from young people as well as their weekly YP-CORE scores will be monitored for deteriorations during the baseline check-in sessions and intervention sessions. Significant deteriorations in a young person's mental health are defined by any of the following:

- YP-CORE total scores increase by at least 7–8 points (i.e. reliable deterioration [46])
- YP-CORE question 4 ('I've thought of harming myself') increasing to 3 ('Often') or higher.
- The practitioner and/or young person feel there has been a significant decline in the young person's mental health such that they are no longer able to cope with daily activities.

Young people who experience adverse events (see {22}) that were likely a result of the trial protocol (e.g. the waiting period or the intervention itself) will be removed for safety reasons. Adverse events that are unlikely to be a result of the trial will not immediately preclude further participation. Instead, young people will be given the choice to continue following a risk assessment by Place2Be and any necessary involvement of Place2Be's safeguarding team. Place2Be services will still be available to any young person who discontinues the trial due to adverse events, but more intensive support from local services like Children and Young People's Mental Health Services (CYPMHS) will be sought if required.

Strategies to improve adherence to interventions {11c}

As described in {11a}, KIT is a semi-structured intervention: practitioners are expected to deliver 'fixed'

components of CBT, but there is flexibility or 'flex' in how they are delivered to young people. To improve adherence, practitioners will be provided with detailed written information about each phase of KIT and core CBT skills and techniques, which can be discussed in supervision sessions. Practitioners will also complete a fidelity checklist after each session, where they mark the session against a checklist of activities expected within each phase. The fidelity checklist will allow us to monitor adherence to KIT activities and phases. It can also be used as a reflective practice tool for practitioners to monitor progress in different phases which they can take to supervision.

Relevant concomitant care permitted or prohibited during the trial {11d}

Young people should not be receiving any other psychological intervention at any point during the trial. However, in more urgent cases, young people will have access to Place2Be's 'Place2Talk' service, a school-based counselling drop-in service for one-off support, as well as school support (e.g. pastoral care or learning mentors). We will record all young people who access additional support. If young people need further support, they can either start the Place2Be intervention sooner than their randomly allocated baseline wait period or be referred to local services—in both cases, trial participation will end.

Provisions for post-trial care {30}

The last phase of KIT involves preparing young people for life after therapy, tying together their learnings and reflecting on any difficulties faced during therapy. Place2Be's services will remain open to young people after the trial should they wish to be referred for further support. Young people who suffer any harms that likely result from the trial will be followed up by the research team and will have access to Place2Be services on a needs basis. Note that the main risk of harm is young people's mental health worsening during the baseline period. Should this occur, young people will be offered Place2Be services earlier than their randomly allocated baseline wait period and will no longer participate in the trial.

Outcomes {12}

Primary outcome

Young Person's Clinical Outcomes in Routine Evaluation Scale (YP-CORE [46]). The YP-CORE is a ten-item questionnaire assessing anxiety, depression, everyday coping and functioning, and risk to self. The YP-CORE is used as a screening tool and outcome measure in school-based counselling services and shows high levels of internal consistency, test–retest reliability, and sensitivity to change [46, 47]. Young people will complete the YP-CORE with their practitioners at the start of each baseline check-in session and intervention session. We will calculate total sum scores for each session and examine mean differences within and across young people between the baseline and intervention phases.

Secondary outcomes

Revised Child Anxiety and Depression Scales (RCADS [48]). The RCADS is a 47-item questionnaire assessing depression and anxiety disorder symptoms. RCADS is used as a routine outcome measure in CYPMHS [49] and shows high levels of internal reliability across populations (clinical and non-clinical), countries, and languages [49, 50]. Young people will complete the RCADS at the start and end of the intervention. They will also complete specific subscales relevant to their goals and presentation during the mid-point review sessions, but this data will not be analysed as part of the trial. We will calculate total and subscale sum scores and compare mean changes in scores averaged across the sample between the start and end of the intervention.

Treatment fidelity checklist Practitioners will complete a custom checklist after each session listing the features of KIT included in their session. Treatment fidelity measures are important for assessing whether the treatment delivered resembles the treatment that was developed. We will score each completed intervention for whether all phases of KIT were included (e.g. assessment, formulation, intervention planning, intersession task planning and reviewing, and ending planning), and whether a certain threshold of therapeutic tasks and activities were included within each phase. We may also develop other ways of scoring and analysing treatment fidelity (e.g. time-series analysis of treatment phase scores).

Implementation survey Practitioners will complete a custom survey once they have completed all their interventions with young people to assess how feasible, applicable, safe and effective they felt KIT was, and how confident they felt delivering it. We will calculate total scores and use them as covariates/moderators when analysing treatment effects.

Demographics We will collect records of young people's demographics at baseline, including their age (in years), sex, ethnicity (at the aggregated level, e.g. 'White British'), special educational needs status, and eligibility for free school meals, and use these measures as covariates/moderators when analysing treatment effects.

Participant timeline {13}

The participant timeline is shown in Fig. 1.

Sample size {14}

We will recruit 60 young people to observe a medium-to-large pre-post difference ($d = 0.7$) in YP-CORE scores between the baseline and intervention phases. We estimated this sample size using Samantha Bouwmeester's tool for a priori power analyses for randomisation tests [59, 51]. We estimated power at 90% using the following parameters:

- An alpha level/type 1 error rate of 0.05 (one-tailed, as the shape of the distribution for randomisation tests is unknown).
- A minimum of three baseline measurements (and a maximum of eight) to establish a stable baseline measurement.
- A maximum of six random baseline wait periods which produces 720 possible assignments within an ethical timescale. We used the Wampold and Worsham randomisation method (i.e. randomising to different wait periods) rather than alternative methods (i.e. randomising to different start dates within intervention start weeks) as the increase in power associated with alternative methods is small [52], and it would not be feasible to control for the start date within a pragmatic, school-based trial.
- A minimum of six intervention measurements (five excluding the first intervention start week), based on the average treatment length in weeks from Place2Be's pilot data.
- An autocorrelation of $r = 0.4$ between measurements, as weekly measurements tend to be moderately correlated.
- Thirty per cent missing data—we expect some missing data given the pragmatic nature of the trial.
- Four hundred permutations and 1000 simulated samples.

Recruitment {15}

We aim to recruit 20–40 Place2Be practitioners to deliver KIT to 60 young people. Within participating schools, we will recruit an opportunity sample of young people who have been referred for school-based counselling and screened by Place2Be practitioners for their suitability to KIT (see the "Eligibility criteria {10}" section). Eligible young people and their parents/carers (for young people under 16) will be invited to participate and asked to make an informed decision based on information sheets and any requested follow-up contact with researchers. We will host regular engagement meetings with Place2Be practitioners to address any issues with recruiting young people and delivering the intervention.

Assignment of interventions: allocation

Sequence generation {16a}

We will use the *blockrand* package [53] in *R* v 4.1.0 to generate a random, blocked sequence of baseline wait periods. We will use a block size of six which is equal to the total number of baseline wait periods, where wait periods are akin to intervention conditions (e.g. interventions will start after 3, 4, 5, 6, 7, or 8 weeks). This results in 720 possible sequences (or blocks) of baseline wait periods, e.g. 3–5–4–8–7–6, 7–5–4–3–2–8, 8–7–6–5–4–3, etc. We will randomly select 14 blocks to produce a list of equally balanced baseline periods for 84 participants (producing more allocations than our target sample size of 60 acts as a failsafe for participants who dropout after being assigned a baseline period). Due to the pragmatic nature of this trial, it is not possible to use stratification or block randomise by school (see {16c} for further details on the pragmatic nature of the study).

Concealment mechanism {16b}

We will ensure that the allocation sequence of baseline wait periods is concealed by separating out the team that generates the allocation sequence (Evidence-Based Practice Unit [EBPU], UCL) from both the team that communicates the assignment (Place2Be research team) to the team that undertakes the screening, enrolment, and treatment of young people (Place2Be school-based practitioners). Furthermore, the EBPU researchers who generate the blocked allocation sequence will not be involved in the analysis. We will use a central randomisation system to share the concealed allocations, whereby Place2Be research staff will send EBPU researchers a pseudonymised identifier for a young person who consents to participating in the trial and meets the eligibility criteria. EBPU researchers will respond with a random baseline period that they generated. Place2Be research staff will then calculate the baseline wait period and intervention start week and communicate this to Place2Be practitioners.

Implementation {16c}

See {16b}.

Assignment of interventions: blinding

Who will be blinded {17a}

Researchers from the EBPU who generate the random list of baseline wait periods will be blind to participants. Researchers from Place2Be who communicate the baseline wait periods to Place2Be school-based practitioners

cannot be blind to the allocated baseline period for practical reasons. It would not be ethical—nor would it be practically feasible—to blind young people or practitioners to young people's randomly allocated baseline wait period, as young people have the right to decide whether they wish to wait for their allocated baseline period to receive KIT. However, researchers from Place2Be who communicate the baseline wait periods to Place2Be school-based practitioners will be blind to the clinical characteristics of young people.

Procedure for unblinding if needed {17b}

Young people's allocated baseline wait period will be known to Place2Be research staff, who inform school-based practitioners of how many baseline measurements to undertake before starting the intervention. Since young people and practitioners will know which baseline wait period they have been allocated, and outcomes are self-reported, unblinding in this trial refers to (i) Place2Be research staff receiving clinical information about a young person and/or (ii) EBPU researchers learning the identity of a young person. Instances where this might arise are when a young person wishes to withdraw their participation and/or data from the trial or following a serious adverse event. In such instances, Place2Be research staff will request further details about the young person from school-based staff. Note that in most instances, EBPU researchers will not need personal information about the young person, even if they have been withdrawn from the trial.

Data collection and management

Plans for assessment and collection of outcomes {18a}

See {12} for a description of the study instruments and procedures around their use.

Plans to promote participant retention and complete follow-up {18b}

Young people who withdraw their participation will likely have a clinical reason for doing so (e.g. they may wish to start their treatment earlier than their baseline wait period or may need more intensive services). In such cases, we will respect young people's needs and prioritise safety and clinical care over participant retention. In cases where young people feel KIT is 'not working' or unsuitable for their needs, practitioners will arrange a review session to see if/how delivery of the intervention can be adapted to suit the young person's needs. For all young people, we will emphasise the value in completing routine outcomes as a tool for monitoring their wellbeing and needs (e.g. for further support).

At the time of submitting this protocol following revisions (June 2024), we were nearing the end of the first wave of data collection. We approached 31 young people in the first wave of recruitment. All 31 young people were randomly assigned to a baseline wait period. At the time of writing, 23 (74%) young people completed their baseline wait period and 16 are expected to have completed their intervention. Of the 8 (26%) young people who did not complete the baseline wait period and withdrew from the trial, four no longer wanted to wait for KIT under trial conditions, two were removed due to adverse events that predated the trial, one left the school, and one withdrew due to exam pressure. We plan to conduct the second wave of recruitment in August (Scotland) and September (England) in 2024 to recruit a further 30–40 young people.

Data management {19}

Data entry, coding and quality checks

Data entry and coding will be fully automated through an online data collection platform. Specifically, young people and practitioners will jointly complete the measures outlined in {12} using an online platform which uploads their pseudonymised, coded responses to a secure database. Place2Be research staff will check the data for values outside the expected ranges, missing values, incorrect coding, and completeness.

Security and storage

Clinical outcomes data will initially be stored on the secure servers of the data collection platform described above, which is UK-based, GDPR-compliant and uses ISO 27001 and ISO 9001 security. Data will be downloaded onto Place2Be's secure database, which is hosted on a Microsoft Azure cloud environment with UK servers that are ISO 27001 and ISO 9001 accredited, GDPR-compliant, and encrypted at rest. Place2Be will combine the clinical outcomes data with the demographic data, remove non-anonymised identifiers, and send the combined data via a secure link to EBPU researchers, who will store the pseudonymised data on secure UK-based servers that are GDPR-compliant. The data will be stored in folders that require authorised access, using work laptops that are encrypted at rest. After 2 years, the pseudonymised pupil IDs, school IDs and therapist IDs will be removed, and the anonymised data will be archived on a secure server for 10 years.

Confidentiality {27}

Identifiable information about young people, including their names, dates of birth, and personal demographic information (see the "Demographics" section in {12}) will be collected by Place2Be clinical services whilst screening young people for their suitability to KIT and

the research study. This information will be shared with Place2Be's research team, who will contact young people and their parents/carers (if younger than 16) with study information.

Place2Be researchers will generate a unique identifier code for all young people who enrol onto the study. This unique identifier code will be used in all communications with the EBPU to preserve young people's confidentiality. No identifying information will be sent to the EBPU, who do not have access to Place2Be's databases, offering two-layer pseudonymisation. Demographic information that is shared with the EBPU will be coded at the broadest level to minimise unintentional identification of young people with rare constellations of personal characteristics.

Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

Not applicable, no biological samples were collected.

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

Primary Outcome

To recap, the primary outcome is YP-CORE scores, assessed weekly throughout the baseline and intervention phases. We will analyse within-person and between-person change in YP-CORE scores using descriptive and inferential statistics suitable for multiple baseline designs.

Descriptive methods include summary statistics (e.g. measures of central tendency and dispersion) and visual analysis, where we will inspect time-series graphs of session-by-session scores for stability during the baseline phase, negative trends in the intervention phase, variability within and between phases, and the general degree of overlap between baseline and intervention scores using range lines [55].

Inferential methods include piecewise multilevel growth models to estimate within-person and between-person differences in average scores (i.e. levels) and the direction/rate of change in scores (i.e. slopes) between the baseline and intervention phases [56]. Multilevel models will include at least two levels, with repeated observations of YP-CORE scores at level 1 nested within each young person at level 2. We will include additional levels if there is significant variation associated with specific therapists, schools, or regions. We will estimate fixed effects, which include intercepts and slopes averaged across young people for both the baseline and intervention phases (see below for piecewise coding of separate phases). We will also estimate random effects, which include between-person variation in intercepts and slopes for the baseline and intervention phases.

Two dummy-coded variables each representing an intercept for the baseline phase and intervention phase will be included in the model at level one. Each intercept variable will be coded to reflect the individually varying break-points between baseline and intervention phases. Take, for instance, a young person with a 3-week baseline phase followed by a 4-week intervention phase. The baseline intercept variable for this young person would be coded as 1, 1, 1, 0, 0, 0, 0, and the intervention intercept variable as 0, 0, 0, 1, 1, 1, 1. This coding will produce estimates of the mean baseline and intervention YP-CORE scores averaged across young people with individually varying phase lengths. Baseline and intervention intercepts can then be compared using a two-tailed Wald test to estimate a treatment effect; mean YP-CORE scores during the intervention phase are predicted to be significantly lower than mean YP-CORE scores during the baseline phase.

Two more dummy-coded variables will be included at level one to estimate the slopes for the baseline and intervention phases. The baseline slope variable will be coded for the weeks until the first intervention session, whilst the intervention slope variable will be coded for the weeks since the first intervention session. Continuing the example above of a young person with a 3-week baseline phase and 4-week intervention phase, the baseline slope variable would be coded as $-3, -2, -1, 0, 0, 0, 0$, and the intervention slope variable would be coded as 0, 0, 0, 0, 1, 2, 3. Note that the first intervention session is coded as a '0' across baseline and intervention time variables because it serves as the pre-treatment baseline (since the YP-CORE will be administered at the beginning of the first intervention session, before the intervention starts). This coding will produce estimates of the mean slopes during the baseline and intervention phases averaged across young people with individually varying phase lengths. A group-level baseline slope not significantly different from zero, plus a significant negative intervention slope, would indicate a treatment effect. Furthermore, random intercepts and slopes will allow us to quantify stability and intraindividual variability in YP-CORE trajectories that would be observed in the visual analysis.

Between-person covariates, including the randomly allocated baseline wait period, recruitment wave, absolute time in weeks since the first participant was recruited, age, sex, ethnicity, free school-meal eligibility, and special education needs status, will be added to level two of the model to control for the confounding effects of method variables and demographics. We will also include interactions within time variables to investigate

non-linear trajectories in YP-CORE scores, and interactions between time and demographic variables to investigate whether demographics moderate the treatment effect (e.g. we might expect older students with more severe baseline scores to show steeper improvements in YP-CORE scores [40, 42]).

Multilevel models tend to be robust to deviations from their parametric assumptions [57]. However, we will explore non-parametric alternatives, like Simulation Modelling Analysis [58] if our data heavily violate these assumptions.

We will also estimate pre-post treatment effects and their effect size with standard approaches used in randomised controlled trials. For the pre-post treatment effect, we will use randomisation tests, which, unlike more common tests of repeated measures like paired *t*-tests, do not make distributional assumptions or assume homogeneous variances [59]. This is because the sampling distribution is based on random permutations of the observed data (i.e. a randomisation distribution). We will also calculate Shadish and colleagues' [60] adapted *d*-statistic for single-case designs or Tau-U if there are trends in the baseline phase [61].

Secondary outcomes

Secondary outcomes include the RCADS, KIT Fidelity Checklist, and Implementation Survey. The RCADS will be completed at the start and end of the intervention. We will use measures of central tendency and dispersion (e.g. means and standard deviations) to report group-level differences in scores between the start and end of the intervention. Furthermore, we will evaluate the statistical significance of the difference in group means using parametric tests (e.g. repeated *t*-test), non-parametric (e.g. Wilcoxon signed-rank test) tests, and regression models controlling for covariates, and quantify the size of the difference using the standardised mean difference (i.e. Cohen's *d*). Note that we cannot use the test statistics described above for randomisation tests because the RCADS will not be collected during the randomly allocated baseline phase.

We will also calculate Jacobson and Truax's [62] clinically significant and reliable change indices for the RCADS. Clinically significant change tells us the proportion of young people who start the intervention in the clinical range and finish the intervention in the non-clinical or recovery range. There are different methods for calculating the thresholds for the clinical and non-clinical ranges. We will use the RCADS' established clinical norms to determine the clinical range (e.g. T scores > 69) and non-clinical range (e.g. T scores < 65 [63]).

Reliable change refers to whether the changes observed in scale scores (both improvements and deteriorations) over the course of an intervention are greater than the changes expected due to measurement error alone [62]. We will calculate the proportion of young people who demonstrate reliable improvement, reliable deterioration, and no reliable change in the RCADS after receiving KIT. We will calculate reliable change indices from the sample data using Jacobson and Truax's formula for reliable change [62]. We will also compare our findings to previous reports of reliable change indices for the RCADS [63]. Finally, we will determine the proportion of young people who showed both clinically significant and reliable change, since one can show reliable improvement without it being clinically significant, and vice versa.

The fidelity checklist will be scored in various ways. Traditionally, clinical researchers calculate an index of the proportion of practitioners demonstrating a prespecified level of treatment fidelity. For each KIT intervention with a young person, we will calculate the proportions of completeness for each KIT phase across sessions and a total completeness score. That is, we will score the presence of each item on the checklist as a '1' and calculate the proportion of items scored within each phase. Items will be counted if they occur at last once during the intervention, not for the number of times they occur. We will also create a total score by summing the subscale scores together. We will then determine a threshold for a 'complete' KIT intervention (e.g. scoring at least 75% of items within each subscale, across all subscales), and determine the proportion of KIT interventions meeting this threshold. This will allow us to conduct sensitivity analyses with 'complete' KIT interventions vs. 'incomplete' KIT interventions. Since fidelity data will be assessed over time, we can also control for session-by-session fidelity scores in the multilevel growth models of YP-CORE trajectories and analyse patterns/profiles of scores on the fidelity checklists that predict better outcomes.

As for the Implementation Survey, we will use measures of central tendency and dispersion to get an overall sense of how practitioners experienced implementing KIT. We will also examine the distribution of responses for each item to determine what practitioners favoured most/least about KIT. Some questions, e.g. confidence around delivering KIT, can be used as moderators in the multilevel growth curve models. Depending on the number and richness of responses, we will analyse free-text responses with thematic analysis to draw out practitioners' views of the advantages and barriers to delivering KIT.

Interim analyses {21b}

In a previous version of this protocol, we planned to estimate the sample's conditional power after recruiting 50% of the target ($n = 30$) or if we have not met our recruitment target by the first deadline (February 2024),

whichever comes first. We re-estimated the sample size towards the end of the first recruitment wave (June 2024) by estimating the number of participants needed to reach 90% power using the difference in standard deviations between the baseline and intervention phases (1.07), autocorrelation (0.4), missingness (66%), and number of start weeks (3–6), informed by data from complete cases collected to date. Since the conditional power estimate indicates that we need more participants to reach the initial target ($n=60$) and updated target ($n=72$), we will extend recruitment to a second wave, starting in August/September 2024.

We will also conduct safety checks by examining trends in the YP-CORE data, particularly if we encounter multiple adverse events. Safety checks will involve visual analysis of YP-CORE scores for each participant during the baseline and intervention phases to assess for any consistent negative trends. Reliable and clinically significant deterioration in YP-CORE scores that might be associated with the trial will be raised with the Adverse Events Oversight Group, who will decide on whether to discontinue the trial (see {5d}).

Methods for additional analyses (e.g. subgroup analyses) {20b}

As described in {20a}, we will examine (and control for) group differences in demographics and baseline wait period assignment by including these variables as covariates in our multilevel growth models.

We will also conduct sensitivity analyses that compare the results from piecewise multilevel growth models before and after excluding the following groups to examine their impact on the main findings:

- Young people whose KIT interventions did not meet fidelity requirements (see {20a})
- Young people who did not start the intervention on their allocated start week, either because they/their practitioner did not attend the intervention session or the first intervention session fell on a school closure and was moved to another date.

If the proportion of missing data is high (e.g. > 30% of observations), we also compare intention-to-treat findings from our main piecewise multilevel growth model with a growth model where missing data is handled with multiple imputation (assuming our data do not violate the necessary assumptions).

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

We will analyse all available outcomes on an intention-to-treat basis, including young people who did not start the intervention after the baseline wait period on the allocated start week (e.g. due to school closures or pupil/practitioner absences) or complete the intervention. We will treat school closures as missing entries, as it is not feasible to coordinate young people and practitioners to complete the YP-CORE during school holidays. Missing data patterns will also be caused by different baseline and intervention lengths; however, multilevel models can handle missing data due to varying treatment lengths [65]. We will assess whether clinical variables (e.g. baseline symptom scores), the baseline wait period, and demographic variables, predict different types of missing data, the reasons for which will be logged by school-based staff (e.g. missing due to school closures, young person/practitioner absence, young person withdrawal from trial, other). Depending on the proportion of missingness (e.g. > 30% of observations) and its implied mechanisms, we will run a sensitivity analysis whilst handling missing data with methods such as multiple imputation.

Plans to give access to the full protocol, participant level-data and statistical code {31c}

The full protocol and statistical code will be available upon request.

Oversight and monitoring

Composition of the coordinating centre and trial steering committee {5d}

Coordinating centre

The EBPU at UCL acts as the coordinating centre for the trial. EBPU investigators are involved in the design, evaluation, and dissemination of the trial. They also provide ethical oversight and research governance during the trial.

Trial management group

The trial management group will oversee the day-to-day running of the trial and is composed of researchers at Place2Be's Research and Evaluation team and UCL's Evidence-Based Practice Unit (EBPU). Place2Be researchers will be the main contact for Place2Be practitioners during the trial (note that practitioners fall under Place2Be's clinical services not the Research and Evaluation team). Place2Be researchers will explain the purpose and procedures of the trial to practitioners and will also be the first point of contact if practitioners have questions or difficulties related to recruitment, baseline wait periods, intervention delivery, recording data electronically, and logging adverse events. EBPU researchers will support with issues with protocol adherence (e.g. what to do if young people and/or practitioners miss the first baseline/intervention session). The trial management group

will correspond weekly and will meet monthly. Neither Place2Be researchers nor EBPU researchers will be involved in any clinical input and will not have any contact with the young people, parents/carers, or schools recruited into the trial.

Adverse Events Oversight Group (AEOG)

The AEOG is made up of three senior researchers and clinicians who are not directly involved in the trial. The group will oversee decisions about the trial's conduct and (dis)continuation in relation to adverse events. The AEOG will meet quarterly to review the adverse events log and any interim analyses. The AEOG will also be required to meet within three working days of being contacted about a serious adverse event and/or an adverse event likely related to the trial.

Composition of the data monitoring committee, its role and reporting structure {21a}

Data monitoring will be carried out centrally every 3 months by a member of the Place2Be research team and supported by EBPU researchers who are not involved in the main analysis. Any concerns around safety based on data monitoring checks will be raised with the AEOG.

Adverse event reporting and harms {22}

Place2Be practitioners will serve as the first contact for collecting and reporting information about adverse events. If an adverse event is reported by a young person in the weekly baseline or intervention session check-ins, or if a family member or school staff report an adverse event on behalf of a young person, then practitioners are required to complete a pseudonymised adverse events form and send this to Place2Be researchers. The form lists different types of standard and severe adverse events and asks practitioners to judge how likely they think the event was related to trial participation. The list of adverse events includes:

1. Violent behaviour resulting in physical harm to another person.
2. Self-harm.
3. Suicidal ideation*: a preoccupation with suicide/thoughts about suicide, with no clear plans to take own life.
4. Suicidal intent*: concrete and deliberate plans to end own life, with a conscious desire to escape from the world and a resolve to act purposively in this regard, e.g. a suicide attempt. This may be a deliberate action or disclosure of a deliberate action.
5. Hospitalisation due to drugs or alcohol, self-harm, or for psychiatric reasons* (including in-patient hospitalisation or significant disability/incapacity)
6. Death, including suicide*.
7. Risk score of 3 or above* on the YP-CORE.
8. Adverse events that occur and are not pre-defined above are labelled 'other' with details provided and recorded in the form.

*Serious adverse events

Place2Be researchers will check that the adverse events form is completed and all identifiable information is removed before sending it to EBPU researchers within 2 days of a serious adverse event or adverse event likely related to the trial, or within 5 days of an adverse event that was unlikely related to the trial.

For serious adverse events and adverse events likely related to trial participation, the trial steering committee, who serve as the Adverse Events Oversight Group, will be notified immediately and no later than a week after the adverse event form was reported to EBPU. The steering committee will meet to discuss the adverse event, decide whether the trial is safe to continue, and communicate their recommendation within three working days to the trial evaluators (EBPU) and the sponsors (Anna Freud and Place2Be). These parties then need to decide within one working day of whether to continue the trial and will communicate this with the steering committee and trial management group.

If the study is terminated, young people who were awaiting KIT during the baseline period will be offered support from Place2Be or signposted to relevant services within and outside school (e.g. pastoral support, CAMHS). If the adverse event raises safeguarding concerns, then Place2Be will refer the young person to their in-house safeguarding team, who will conduct or update a risk assessment and create/review a safety plan if necessary.

Regarding complaints procedures, young people and families will be provided with contact details in the study information forms and upon request so they can make a complaint against the conduct of the research or their experience of a practitioner or researcher. Place2Be and EBPU will follow their standard complaints investigation procedures.

Frequency and plans for auditing trial conduct {23}

See {5d}.

Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees) {25}

EBPU investigators will be responsible for communicating any protocol amendments to UCL's research ethics committee, whilst Place2Be will be responsible for communicating amendments to Place2Be practitioners and young people.

Dissemination plans {31a}

We will disseminate the trial results via standard academic outlets, including scientific journals, conference posters and presentations, and lectures. Findings will also be disseminated in UCL/Anna Freud and Place2Be newsletters and webpages and shared with young people who participated as well as the participating schools.

Discussion

Implications

The KIT trial aims to broaden the evidence base for school-based CBT interventions by testing an individually delivered, semi-structured, and flexible psychological therapy for young people in UK secondary schools. KIT offers an alternative to humanistic school-based counselling—the most widely offered form of counselling in the UK [18]—which is open-ended, problem non-specific, and non-directive. School-based counselling will benefit some pupils, but there will be others who benefit from a more goal-focused, problem-specific, and directive intervention like KIT. Ultimately, our goal is to build an evidence base of school-based psychological interventions that work [17], so that young people have a selection of interventions to choose from that best fit their needs.

Practical and operational issues

A practical limitation of the KIT trial is that the two-step allocation process only allows for partial blindness of allocators to the baseline wait periods assigned to young people. Specifically, EBPU investigators who generate the random list of wait periods will be blind to details about the young people they are allocated to. However, Place2Be researchers will not be blind to either the wait period or the young person it is assigned to. However, Place2Be researchers will not be sent clinical information about young people, minimising the risk of unconscious bias in assignments. Furthermore, Place2Be researchers will be required to assign wait periods based solely on when they receive consent from young people and will keep dated records of communication that can be audited.

Another practical concern is that there might be higher dropout rates in young people who are randomly allocated to a longer baseline phase. This will produce missing data patterns that are not missing at random and could impact our statistical power and bias our findings. We chose not to oversample for longer baseline wait periods due to ethical concerns around extending waiting times for support. We will check whether the assigned baseline wait period predicts dropout rates and conduct a sensitivity analysis with young people assigned to longer baseline phases to check for any differences in the results which might indicate bias. Furthermore, we will control for the assigned baseline wait period in all multilevel growth curve models.

Methodological issues

This is a pragmatic, randomised multiple baseline trial in which we are attempting to establish a causal relationship in time between KIT and young people's mental health, whilst preserving the natural conditions that KIT are delivered in. Our inferences about KIT's efficacy will therefore be more applicable to everyday practice within UK secondary schools. However, there are limits to the degree to which we can generalise our findings to school-based counselling services across the UK, as we did not randomly sample schools, nor did we evaluate a range of school-based counselling providers. Other providers might require adjustments when delivering KIT in secondary schools depending on their resources and ways of operating.

We are using a non-concurrent design, where participants start the baseline phases at different times rather than simultaneously like in a concurrent design. Non-concurrent designs control for various threats to internal validity, including change due to maturation and test–retest effects, but are not immune to history effects (e.g. changes occurring outside of the intervention, such as increased conflict at home for a single young person, or the outbreak of a virus that affects the whole school; but see [66]). Furthermore, whilst randomising on a rolling basis means that we can evaluate KIT as each new young person is referred (albeit with a variable wait period), this means we were also unable to stratify our sample by demographics, or block randomise based on region, school, or therapist.

Another point to consider about our pragmatic trial is that KIT is semi-structured rather than fully manualised. Again, this will allow us to evaluate KIT as it would arise in an everyday context, including the unique ways in which practitioners employ their varied skills in other modalities to engage young people and communicate the ideas behind CBT. However, we will also be introducing uncontrolled variability in what is being offered between practitioners (and even amongst young people seeing the same practitioner), making comparisons more

challenging. Nonetheless, there are still fixed components of KIT that will guide clinicians and create continuity between interventions, and we will have some record of what is occurring within sessions based on the fidelity checklists.

Trial status

The protocol described is version 3 (13/06/24). Version 2 of the protocol was initially completed on 18/01/2024 and submitted on 02/02/24. The first of two recruitment waves began on 01/08/2022 and finished at the end of February 2024. We will begin recruiting for additional participants from August/September 2024 until February 2025 as we did not reach our sample size/power target for 2023/2024.

Abbreviations

AOEG	Adverse Events Oversight Group
CBT	Cognitive behavioural therapy
CYPMHS	Children and Young People's Mental Health Services
EBPU	Evidence Based Practice Unit
KIT	Knowledge Insight Tools
RCADS	Revised Child Anxiety and Depression Scales
YP-CORE	Young Person's Clinical Outcomes in Routine Evaluation Scale

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13063-024-08299-z.

Supplementary Material 1.

Supplementary Material 2.

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We would like to thank Rebecca Wilkinson-Quinn for driving the recruitment of school-based staff, Marie Adams for her support with measure development, Niki Cooper for her clinical oversight, and Professor James Wason for his suggestions with the randomisation procedure.

Authors' contributions {31b}

JD is the Principal Investigator: she was involved in conceiving and designing the study, overseeing the running of the project, providing leadership and supervision, drafting the proposal and study protocol, and will be involved in interpreting the data and disseminating the results. MC, TL, and JS were involved in the study design, running the project, drafting the study protocol, and will be involved in the statistical analysis, interpreting the data and disseminating the results. HW and SG were involved in running the project and reviewing the study protocol. All authors have read and approved the final manuscript.

Authors' information

JD is Professor of Child Mental Health and Wellbeing and director of the Evidence-Based Practice Unit, which is a collaboration between UCL and the Anna Freud.
MC, STL, and JS are post-doctoral research fellows based at the Evidence-Based Practice Unit.
SG is Head of Evaluation at Place2Be, and HW is the Research Partnerships Manager at Place2Be.

Funding {4}

The study was jointly funded by Place2Be and Anna Freud. The EBPU, which is a collaboration between UCL and Anna Freud, are involved in the trial's design, evaluation, and dissemination. Place2Be are involved in delivering the intervention and data collection.

Availability of data and materials {29}

EBPU investigators will have access to the final, pseudonymised dataset. Dating sharing agreements limit the EBPU access to the de-identified data held by Place2Be.

Declarations

Ethics approval and consent to participate {24}

University College London, Research Ethics Committee (5420/004). Opt-in informed consent will be obtained from all young people over the age of 15, as well as opt-out informed consent from parents/guardians for young people younger than 16.

Consent for publication {32}

Consent forms and information sheets given to young people (+16 years and −16 years), parents/guardians, and head teachers can be found in the ethics form.

Competing interests {28}

JD, MC, STL, and JS hold paid positions at Anna Freud. HW and SG hold paid positions at Place2Be. None of the authors were involved in the development of Knowledge Insight Tools or benefit financially from Knowledge Insight Tools.

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