1. Title

1.1 Protocol Full Title:

A feasibility, cluster randomised, 16-week, parallel-group pilot study to investigate the feasibility of trial procedures for a larger multicentre comparison of a digital school-based cognitive behavioural resilience/wellbeing-building intervention ('CUES-Ed') targeting emotional and behavioural problems in vulnerable primary school children in whole classes, compared to the usual school curriculum.

1.2 Protocol Short Title/Acronym:

Building Resilience in Children. The CUES-Ed research project: feasibility study.

2. Trial registration

Identifiers:

ISRCTN – ISRCTN12486546

REC Number – LRS/DP-21/22-25994

3. Protocol version: V1 25/10/21

4. Funding

Funding to conduct the trial is provided by the Monday Charity Trust charitable grant.

5. Roles and responsibilities

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Appendix 1: Study Synopsis

Title of clinical trial	A feasibility, cluster randomised, 16-week, parallel-group pilot study to investigate the feasibility of trial procedures for a larger multicentre comparison of a digital school-based cognitive behavioural resilience/wellbeing-building intervention ('CUES-Ed') targeting emotional and behavioural problems in vulnerable primary school children in whole classes, compared to the usual school curriculum.
Protocol Short Title/Acronym	Building Resilience in Children. The CUES-Ed research project: feasibility study.
Study Phase if not mentioned in title	Feasibility study
Sponsor name	SLaM/KCL
Chief Investigator	Dr. Debbie Plant
REC number	LRS/DP-21/22-25994
Medical condition or disease under investigation	Emotional and behavioural problems in vulnerable children (scoring at or below borderline/clinical cut-off) receiving the intervention in whole classes
Purpose of clinical trial	To investigate the feasibility of trial procedures
Primary objective	Evaluate trial procedures
Secondary objective (s)	Estimate parameters to determine sample size for a full trial Validate classroom-based outcome measure Standardise teacher adherence rating Validate child quiz
Trial Design	Parallel group cluster RCT
Endpoints	Primary endpoint: post intervention at 16 weeks
Sample Size	We plan to consent 360 children from 10 schools (each with 2 classes)
Summary of eligibility criteria	*Inclusion criteria:* In Year 4 of a participating school Parental consent/child assent *Exclusion criteria:* None
Intervention	A cognitive behavioural resilience/wellbeing building intervention, comprising seven modules with 25 learning objectives, delivered weekly to whole classes, on a digital platform, facilitated by teachers

	(Digital CUES-Ed CBT programme, teacher led). The intervention lasts 12 weeks. The delivery window will be 16 weeks to fit school terms. Assessments will be completed at 0, 8 and 16 weeks, within a 1-month window.
Maximum duration of treatment of a Subject	16-weeks
Version and date of protocol amendments	V1 251021

CONTENTS

ITEMS 1-5: ADMINISTRATIVE INFORMATION……..……..……1-2
1. Title
2. Trial registration
3. Protocol version
4. Funding
5. Roles & responsibilities

Appendix 1: Protocol Synopsis……..……..3-4

ITEMS 6-8: INTRODUCTION……..……...7-13
6. Background & rationale
6.1 Background & rationale
6.2 Choice of comparators
7. Objectives
7.1. Trial objective
7.1.1 Primary objectives
7.1.2 Secondary objectives
8. Trial design
8.1 Trial design
8.2 Trial flowchart

ITEMS 9-15: METHODS: PARTICIPANTS, INTERVENTIONS, OUTCOMES…..13-22
9. Study setting
10. Eligibility criteria
10.1 Inclusion criteria
10.2 Exclusion criteria
11. Interventions
11.1 Interventions
11.2 Modifications: withdrawal
11.3 Adherence
11.4 Concomitant care
12. Outcomes
12.1 Primary outcome measures
12.2 Secondary outcome measures
13. Participant timeline
13.1 Assessment battery
13.2 Additional information
13.3 Table of contacts
13.4 Study flow diagram
14. Sample size
15. Recruitment
15.1 Schools
15.2 Parents and children

ITEMS 16-17: METHODS: ASSIGNMENT OF INTERVENTIONS……22-23
16. Allocation
16.1 Sequence generation
16.2 Concealment mechanism
16.3 Implementation
17. Blinding
17.1 Blinding
17.2 Emergency unblinding

ITEMS 18-20: METHODS: DATA COLLECTION, MANAGEMENT, ANALYSIS……..…..23-24
18. Data collection methods
18.1 Collection of primary and secondary outcomes
18.2 Retention strategies
19. Data management
19.1 Data forms and entry
19.2 Data editing
19.3 Data discrepancies
19.4 Data security and back-up
20. Statistical methods
20.1 Outcomes
20.2 Additional analyses
20.3 Analysis population and missing data

ITEMS 21-23: METHODS: MONITORING……..24-27
21. Data monitoring
22. Harms
22.1 Assessment of Safety
22.2 Specification, Timing and Recording of Safety Parameters
22.3 Procedures for Recording and Reporting Adverse Events
22.4 Adverse events that do not require reporting
22.5 Treatment Stopping Rules
23. Auditing data and quality assurance

ITEMS 24-31: ETHICS AND DISSEMINATION……..27-28
24. Research ethics approval
25. Protocol amendments
26. Consent or assent
27. Confidentiality
28. Declaration of interests
29. Access to data
30. Ancillary and post-trial care
31. Dissemination policy
31.1 Trial results
31.2 Authorship
31.3 Reproducible research and sharing

ITEMS 32-33 APPENDICES, FIGURES, REFERENCES

6. Background & Rationale

6.1 Study Background

6.1.1 Context and need for the CUES-Ed intervention

As many as 1 in 8 school aged children will experience a mental health problem, such as anxiety and depression, with many more experiencing significant emotional difficulties which impact on learning, behaviour, social relationships, motivation and increase vulnerability to mental health difficulties in later adolescence and adult life. 75% of adult mental illness is present by the age of 21, and 50% by the age of 15. Worldwide, mental health conditions account for 16% of the global burden of disease and injury in young people (WHO, 2018).

However, according to the Association of School and College Leaders, 65% of head teachers say they struggle to get mental health services for pupils. Additionally, the NSPCC reports that up to 20% of referrals to CAMHS are rejected. Across King's Health Partners, our services are seeing significant rises in demand and these are forecast to grow by 41% between 2018 and 2028.

CUES-Ed was born out of recognition that children need access to effective early intervention to manage these difficulties, build emotional resilience and prevent mental health difficulties escalating. Teaching children independent skills and effective strategies is fundamental to building this resilience and the capacity they need to move into healthy adolescence and adult life.

This is supported by specific feedback from young adolescents taking part in a CBT research trial (Jolley et al., 2018) highlighting that, whilst they valued the CBT intervention, they had been struggling with their difficulties for a long time and would have liked to learn mental health knowledge and coping skills from a much earlier age. We want to reduce stigma and raise awareness of mental health issues for children and young people by starting developmentally appropriate interventions early - normalising emotional experience and expression and providing accessible, cost-effective, evidence-based treatment. Tackling children's wellbeing and mental health within their school setting enables us to have a far greater, non-stigmatising reach and build strong links between health and education.

6.1.2 CUES-Ed intervention

CUES-Ed is an innovative prevention and early intervention programme rooted in evidence-based Cognitive Behaviour Therapy (CBT) and designed by Clinical Psychologists as a result of direct feedback gathered over many years from children we have worked with in Child and Adolescent Mental Health

CUES-Ed is designed for delivery to whole classes of primary-aged children (7-10 years) to ensure they learn useful ways of looking after themselves and their mental health. They are taught by clinical psychologists or CBT therapists to understand when things are not going well and develop life-long skills to help manage any difficulties now and those that might emerge later in adolescence or adulthood. While all children are expected to gain some benefit, vulnerable children within the class are the key target group for change.

Learning about mental health needs to start from an early age for it to be most effective – and we have found a way of engaging children in a creative and interactive way – with exciting, visually strong and recognisable branding and characters that promote mental health in a positive way.

Across eight whole-class sessions, children learn cognitive strategies and simple but effective behavioural techniques through fun hands-on activities that make abstract concepts more concrete and memorable.

Feedback on CUES-Ed from teachers:

"This program has been meaningful and with a clear purpose. The impact on the children cannot be underestimated – this program has not been an 'add on', but has really started to change the attitudes of the children."

"All the children have been able to access the course. They have learned strategies and vocabulary to help them. They have become more confident in recognising and talking about their feelings and are applying their strategies in class, the playground and at home."

"[The best thing about CUES-Ed is] knowledge and skills help children in many areas e.g. friendships, learning, attitude, dealing with problems at home and school. Skills will stay with them as they progress helping them to be reflective and emotionally resilient."

We promote flexible and adaptive responses to difficulties, including self-regulation (the ability to monitor and manage thoughts, behaviours and emotions; especially important when things are difficult or when strong emotions take over) and support-seeking - recognising when extra help is needed. These approaches encourage children to learn the skills that can help build their resilience from an early age. The CUES-Ed workbook for children, parent newsletters, weekly home-tasks and digital development reinforce the key concepts at school and home and promote long-term retention of learning.

6.1.3 Why Cognitive Behaviour Therapy?

CBT is based on the theory that thoughts, feelings, what we do and how our body feels are all connected. If we change one of these then we can alter the others. When we feel worried or distressed we often fall into patterns of thinking and responding which can worsen how we feel.

CBT helps us notice and change these so that we can feel better - with a range of practical strategies that can help us in the here and now. CBT has a good evidence base which has been carefully reviewed by the National Institute for Health and Clinical Excellence (NICE), who provide independent, evidence-based guidance for the NHS on the most effective ways to treat disease and ill health. It is recommended for a wide range of mental health problems in adults, older adults, children and young people.

CBT also provides a comprehensive range of practical strategies that are applicable to a broad and non-clinical population. As such, it is relevant to the whole class setting where 'one size doesn't fit all'. Rather than targeting a specific problem, CUES-Ed utilises core CBT techniques and aims to teach children how to manage their current and future wellbeing - by recognising, understanding and problem solving the transdiagnostic cognitive, social, physiological, perceptual, emotional and behavioural vulnerabilities implicated in a range of mental health problems.

6.1.4 Feasibility of the intervention: safety, acceptability and potential helpfulness

CUES-Ed has been delivered in person to over 6000 primary school children in 78 schools to date, primarily across South London – see Appendix 2 for a full list of the schools we have worked with.

Feedback on CUES-Ed from children:

"I think my mind is a whole lot calmer and I'm much more aware of my thoughts, my feelings and my behaviours. You have inspired me to tell my family and friends about what we have been doing…"

"I never thought there were so many ways to calm down!"

"CUES-Ed has made me understand more about my feelings and also how to handle my emotions when times are tough. I am very grateful for the CUES-Ed team because they have helped me very much."

Service evaluation (Redfern et al 2019) shows high ratings of acceptability by children and teachers and improvements on whole class mental health knowledge and well-being. Children's written feedback suggested benefits in emotional literacy, understanding how to look after their mental health, normalising emotional responses to confusing/difficult experiences, and emotion-regulation strategies.

Importantly, children identified as more vulnerable consistently show significant improvement following the CUES-Ed programme. Vulnerability was defined as those scoring within a clinical range on self-report measures of wellbeing/distress. The Children's Outcome Rating Scale (CORS, Duncan, Miller & Sparks, 2003) measures wellbeing/distress across four items, each rated 0 (worst) to 10 (best); clinical cut-off <32. Me and My Feelings (Deighton et al., 2013) comprises 16 items, each rated 0 (best) to 2 (worst), measuring emotional (M&MF-E) and behavioural (M&MF-B) difficulties (M&MF-E, ten items; borderline/clinical cut-off >9; M&MF-B, six items; borderline/clinical cut-off >5).

See table below:

Measure	n	% of cohort	Pre-Mean (SD)	Post-Mean (SD)	p
Wellbeing / distress	227	45%	22.98 (6.68)	26.56 (8.64)	<0.01
Emotional difficulties	144	28%	11.9 (2.45)	9.99 (3.33)	<0.01
Behavioural difficulties	100	20%	7.43 (1.46)	6.04 (2.44)	<0.01

Key: SD=standard deviation

In-service clinic data for over 3,000 children receiving CUES-Ed showed whole class benefits of children being better able to look after themselves, improved emotional literacy and an increased repertoire of coping strategies. Improved general well-being, emotional well-being and behaviour was found for vulnerable children.

We have also collected teacher-rated outcomes using a bespoke questionnaire since 2016. To date 77 teachers have completed this about their whole class before and after the CUES-Ed programme. Teachers were asked to rate the number of children who never, always or sometimes demonstrate certain classroom attitudes and

behaviours. Following CUES-Ed delivery, teachers reported a significant increase in the number of children who:

- Could self-regulate emotion – i.e. could cheer themselves up when they were feeling sad, worried or angry.
- Were able to use a range of problem-solving strategies.
- Were able to explain why they had behaved in a certain way.
- Would keep going and persevere when they are finding work difficult.

They also reported a significant decrease in the number of children whose feelings got in the way of their learning. In addition, after CUES-Ed delivery teachers reported a significant improvement in their own knowledge of strategies to calm children and help them with worries. Teachers reported that difficult behaviours had significantly less impact within the classroom after CUES-Ed delivery.

6.1.5 Digital teacher-led delivery

Expert delivery is not a suitable model for widescale implementation. Most recently, we have designed a digital version of the programme, for teachers to deliver. Piloting has shown acceptability and feasibility of this format.

6.1.6 The proposed study

To inform a future large scale trial, we wish to first ascertain feasibility of trial procedures, refine our measures, and estimate parameters for sample size calculation in a feasibility pilot study.

6.2 Choice of comparators

We will compare CUES-Ed to a waitlist control intervention. The current state of evidence leaves open the question of whether whole class wellbeing interventions can be helpfully delivered at scale in schools. We are not yet at the stage of choosing between interventions, or identifying the helpful or active components, which would indicate an active control. Asking if delivering is better than not delivering will provide helpful information. A waitlist control intervention is therefore an appropriate choice for a large scale trial. This study is a feasibility pilot to inform such a trial, so we will use the same waitlist control condition as we intend to use in the larger study.

7. Trial Objectives

7.1 Trial Objectives

Aims: We plan to test the feasibility of our trial procedures for a subsequent study evaluating the effectiveness of the CUES-Ed intervention, as an adjunct to the usual school curriculum, compared to the usual school curriculum alone, in reducing emotional and behavioural problems in vulnerable Year 4 schoolchildren in England, receiving the intervention as part of a whole class.

Feasibility will be judged as being able to: randomise schools; obtain parental consent for the use of data for research purposes; deliver the intervention adherently; ensure child attendance; complete child and teacher outcomes at scheduled times (0, 8 and 16 weeks), within a one month window for completion at each timepoint (i.e. between 6 and 10 weeks for the 8 week assessment and between 14 and 18 weeks for the 16 week assessment), with retention from baseline to follow-up. Secondary aims will be to estimate parameters for a sample size calculation for the subsequent larger trial, standardise our measures of adherence of teacher delivery, and validate our teacher-rated measure of classroom behaviour and child quiz.

The sample for the study will comprise consenting (n=360) children in ten schools. Criteria for judging feasibility are as follows:

7.1.1 Randomising schools:

- Randomisation according to allocation without contamination for all ten schools

7.1.2 Parental and child consent:

- ≥ 60% of targeted parents (i.e. parents of children in participating classes) giving informed consent for data use (n=360, from 600)

7.1.3 Adherent delivery:

- Of the ten teachers delivering the intervention, at least eight achieving acceptable adherence ratings for an observed session

7.1.4 Outcome completion:

- ≥80% of children completing outcome measures and giving assent for these to be used for research (n=288, from 360).

7.2 Primary objectives

- To determine the that the future RCT is feasible, we will conduct a feasibility study to test the ability to consent parents and children and follow up the children in 10 schools, rating child emotional and behavioural problems using the Me and My Feelings questionnaire (M&MF, Deighton et al 2013), as well as wellbeing (using The Children's Outcome Rating Scale, CORS, Duncan, Miller & Sparks, 2003)

7.3 Secondary objectives

- Teacher measures: To validate a teacher rating of whole class behaviour
- Estimate parameters to determine sample size for a full trial
- Validate classroom-based outcome measure
- Standardise teacher adherence rating
- Validate child quiz

8. Trial Design

8.1 Design

The design will be a parallel group feasibility cluster RCT with random allocation of schools to one of two arms, in a 1:1 ratio.

The usual school curriculum will be delivered without interference in both conditions, with assessments at baseline (0-weeks), 8-weeks and 16-weeks (post intervention, primary endpoint) and a proposed primary outcome of emotional and behavioural problems for vulnerable children at 16-weeks. Waitlist control participants will be offered the intervention later in the term or the following school year. The intervention will be delivered to whole classes; each school will be two or three form entry, and thus comprise two or three classes. Each class will comprise around thirty children

Schools will be randomised to classes receiving CUES-Ed, in addition to the usual school curriculum, either now (CUES-Ed) or later (waitlist control, WL). The usual school curriculum is nationally set, with limited scope for variation by school. We will record what is delivered in the usual curriculum, but will not interfere with usual delivery. In particular, as CUES-Ed will not comprise additional hours of teaching, we will record any difference arising in the routine curriculum delivered in intervention and control schools.

Trained research workers will complete assessments with children and teachers at baseline (T0), 8-weeks (T1) and 16-weeks (T2, post therapy), see Figure 1.

We will not be able to blind participants or teachers to treatment group. The RAs completing outcome assessments will also not be blinded to treatment allocation, as there are usually indicators in the classroom when children have received the intervention, and the children talk about the intervention. Once collected, data will be processed by a RA fully blind to allocation. These RAs will be shielded from discussions where the possibility of unblinding might arise. Information on allocation will be restricted to the trial co-ordinator and maintained in a separate database from outcome measures. Breaks of blind procedure will be monitored, and an alternative data processor identified for the subsequent assessments. We will ask RAs to guess allocation group for each school as a test of the success of our efforts to maintain blindness. We will report any instances of unblinding in subsequent publications.

8.2 Trial Flowchart

	Engagement with school	Baseline 0-weeks	Pre-intervention	0-16 weeks	8-weeks	16-weeks
Headteacher consent	X					
Parent letter, opt-out/consent option	X					
Teacher liaison/consent	X					
Child assent		X				
Randomisation			X			
Intervention				X		
Assessment measures						
Primary outcome (proposed): Child-rated emotional and behavioural problems (Me and My Feelings)		X				X
Secondary outcome: Child-rated emotional and behavioural problems (Me and My Feelings)					X	
Secondary outcome: Child-rated wellbeing (Child outcome rating scale)		X			X	X
Secondary outcome: Teacher-rated classroom behaviour		X			X	X
Secondary outcome: Child-rated quiz		X			X	X

9-15: METHODS: PARTICIPANTS, INTERVENTIONS, OUTCOMES

9. Study setting

We will approach primary schools in London and the home counties, run by Local Education Authorities, who are known to the CUES-Ed service. We will aim to recruit differing schools, to estimate variability in outcome between schools for the larger trial which will recruit nationwide.

Once Local Education Authorities have agreed for us to contact schools in their area, we will contact headteachers. For the feasibility pilot, we are contacting schools who know of the CUES-Ed service, as they will be well-placed to feedback on the impact of trial procedures. We expect to be approaching local authorities *at least six weeks*

before the anticipated randomisation date for a school and headteachers and teachers at least a month before.

Headteachers will be asked for their agreement to participate on behalf of their school. Headteachers will consult with teachers of Year 4 children before agreeing to participate, to ensure willingness to deliver the intervention. Once headteachers have consented on behalf of the school, teachers will be asked formally for their consent separately.

Once headteachers and teachers have consented, the school will be considered to be participating in the study.

At least two weeks before randomisation, participating schools will send information sheets and consent forms to parents by their usual method for sending school-based permissions (paper letter and/or email).

- Information sheets will inform parents of the school's decision to deliver the intervention as part of a randomised controlled study, and to complete evaluation measures. Parents will be offered the option to remove their child from the CUES-Ed teaching and assessments if they wish, but will not be asked to consent to this.

- Parents will be asked for consent to use their child's self-report measures for a research purpose.

- Consents will be returned to the school by the school's usual method of return of other school-based permissions. In addition, the research team will be present at the school gates during drop-off and pick-up times to take consent forms directly.

At the same time as parent information sheets are sent out, children will be told about the study by their teacher, using a video from the study team to ensure key information is covered.

Baseline assessments will commence *two weeks after* parental consents are sent out, to ensure parents have time to opt out of CUES-Ed teaching and assessments should they wish to.

- Children will be asked for assent for data use, and also given the opportunity to withdraw from the CUES-Ed intervention and assessment at the first baseline assessment.

- If any child is considered by the class teacher to be expressing a wish not to participate, in either the intervention or assessment, this will be dealt with at the teacher's discretion, as the teacher is responsible for the children's wellbeing and safety during the school day. As part of the school consent, withdrawn children will be found an alternative classroom activity. The teacher information sheet will make clear to teachers that participation in the study should not change their usual treatment of children, outside delivery of the intervention. We expect requests to remove children to be rare: in service delivery of CUES-Ed to 6,000 children has generated only two parental withdrawals, and no child withdrawals. Unless withdrawn, children will otherwise complete

the intervention and assessments. In this way, children will not feel stigmatised by being excluded from the class-based intervention and evaluation by not consenting to the use of data for research. Data for children without parental consent or not assenting will be kept separately and confidentially by the school and securely destroyed without sight by the research team.

- Teacher ratings are based on a whole class and the collection and use of these for a research purpose will be covered by the headteacher consent. The research team will liaise with the school administration to access returned consent forms. School consents will include agreement for the school office to follow-up non-returned consents and to ask permission for the research team to be in touch to support completion.

10. Eligibility

10.1 Inclusion Criteria

The school and child inclusion criteria are shown as follows:

School (cluster) inclusion criteria:

- Run by the Local Education Authority/borough, providing mainstream education.
- In London or the home counties
- With an intake at Year 4 (children aged 8-9 years) and Year 5 (children aged 9-10 years)

Student inclusion criteria:

- All children in Year 4 (aged 8-9 years)

10.2 Exclusion Criteria

School (Cluster) exclusion criteria:

- Private or specialist schools.

Student exclusion criteria:

- None

11. Trial Intervention

11.1 Interventions

11.1.1 Waitlist control Schools

The usual school curriculum will be delivered to all children, irrespective of receipt of CUES-Ed. The usual school curriculum is nationally set, with limited scope for variation by school. We will record what is delivered in the usual curriculum, but will not interfere with usual delivery. In particular, as CUES-Ed will not comprise

additional hours of teaching, we will record any difference arising in the routine curriculum delivered in intervention and waitlist control schools.

11.1.2 Intervention Schools

CUES-Ed comprises 7 modules, delivered over 16 weeks, in sessions of 20 minutes, three times/week. The programme consists of digital interactive sessions. Teachers need only to run the session: content and interactivities are part of the package. The package relies on appealing branding, and engaging characters. This is crucial when working with children, and has been a key feature noted positively in feedback to date. Children in the intervention arm will receive CUES-Ed straight away. Children in the waitlist control arm will receive CUES-Ed later in the term or in the following academic year.

11.2 Teachers

The intervention is designed to be delivered by teachers with minimal training. Instructions for the use of the package will be delivered during a thirty minute video compiled by the research team. This will be given to teachers after randomisation.

11.3 Adherence

Teacher adherence to the programme will be assessed by a classroom observation, using a checklist, which will be standardised as part of the pilot study. The intervention material itself is pre-prepared. Teachers will be rated on their presentation and discussion of the material. Sessions will be pseudorandomly selected in advance and blind to school and teacher, to ensure beginning, middle and end sessions are all sampled.

Child attendance will be measured according to the register for the school session; the teacher will routinely record any children sitting out that session, and teachers and heads agree as part of the school/teacher consent process to collect that information for the research team.

12. Outcomes

12.1 Primary outcome measures

For the feasibility outcomes the parameters are based upon the following progression criteria:

Criteria	Green (Go)	Amber (Proceed with changes)	Red Not feasible to proceed)
Randomise schools	10	8	<8
Consent/Baseline data for children from parents	360/600=60%	240/600=40%	<240/600
Child assent	360/600=60%	240/600=40%	<240/600
Children providing baseline data	360/600=60%	240/600=40%	<240/600
Followed up	%80	70%	<70%
Adherence of teachers	%80	70%	<70%
Fidelity of intervention*	%80	70%	<70%

* Fidelity is determined by whether CUES-Ed schools get CUES-Ed and waitlist control schools do not get CUES-Ed between 0-16 weeks

12.2 Secondary outcome measures

Parameter estimation to determine sample size for a full trial will be based on outcomes on the proposed primary clinical outcome measure, M&MF (see 12.3).

Validation of the classroom based outcome measure (see 12.3) will be done through psychometric testing of collected data and comparison of teacher ratings to an observer rating.

Teacher adherence ratings will be designed and tested during the pilot.

Child quiz data will be collected during the pilot. Stigma and appraisal components have been standardised (Underwood et al., in press): we will check current data follows the same pattern, and validate the remaining components of the quiz again the other study measures (M&MF, CORS, see 12.3).

12.3 Proposed primary and secondary questionnaire outcome measures

- We plan to use the following instrument as the potential primary outcome for the future RCT, Me and My Feelings (Deighton et al., 2013). This comprises 16 items, each rated 0 (best) to 2 (worst), measuring emotional (M&MF-E) and behavioral (M&MF-B) difficulties (M&MF-E, ten items; borderline/clinical cut-off >9; M&MF-B, six items; borderline/clinical cut-off >5). The measure is designed specifically for use in schools to evaluate public health initiatives, and has been widely used with children of this age group.

Proposed secondary outcomes for the future RCT are:

- The Children's Outcome Rating Scale (CORS, Duncan, Miller & Sparks, 2003) measures wellbeing/distress across four items, each rated 0 (worst) to 10 (best); clinical cut-off <32. The measure is widely used with children of this age.

- Children complete a quiz assessing learning from CUES-Ed (see Appendix 1). The quiz has been completed by large numbers of children during in-service delivery of CUES-Ed, so is acceptable for completion, with face validity. We are in the process of establishing norms, and will validate the measure as part of this pilot study.

- Teachers complete a rating of whole class behaviour involving estimates of the proportion of the class displaying particular behaviours 'always' or 'never', with the remainder displaying the behaviour 'sometimes'. We will validate this measure as part of this pilot study (see Appendix 2).

In addition:

- *Teacher adherence* data will be collected from a checklist to be standardised during the study.

- *Child attendance* data will be collected from the class register

13. Participant timeline

The delivery timeline needs to fit school terms, so has been designed to accommodate breaks.

Week	Study phase	Activity
-6+	Pre-engagement	• Approach local authority
-4+	Engagement	• Approach headteachers. • As part of consent, heads check teacher availability. • Headteacher consent • Teacher consent
-3 to -2	Participation, pre-randomisation	• Letter, information sheet and consent sent to parents • Classes informed of study by teacher using video from research team
-1 to 0	Baseline	• Child assent • Child measures • Teacher measures
0	Randomisation	• Research team informs school of allocation
<2	Intervention start (intervention arm only)	• Intervention arm teachers watch training video and commence CUES-Ed delivery
8	8-weeks assessment	• Child measures • Teacher measures
16	16-weeks assessment	• Child measures • Teacher measures • Final point for return of parent consent • Final sort of data into that with consent/assent for research use and that to be securely destroyed
16+	Waitlist control arm offered CUES-Ed at convenient point for school	

The table above summarises the study timeline from first contact.

Following randomisation:

For schools in the intervention arm (CUES-Ed), teachers will watch the instructional video, and start the training. CUES-Ed delivery should start within two weeks of randomisation, and proceed at an hour each week. There are 12 hours of teaching to deliver within the 16-week window. Measures will be completed at 8-weeks post-randomisation and 16-weeks post-randomisation.

For schools in the waitlist control arm (WL), the outcome measures at 8-weeks and 16-weeks will be completed without the class receiving the CUES-Ed programme.

The end of the trial will be defined as the last follow-up assessment at 16 weeks. Waitlist control participants will then receive CUES-Ed, at a time suitable in the context of the usual curriculum. This will not be part of the outcomes of the study.

13.3 Table of contacts

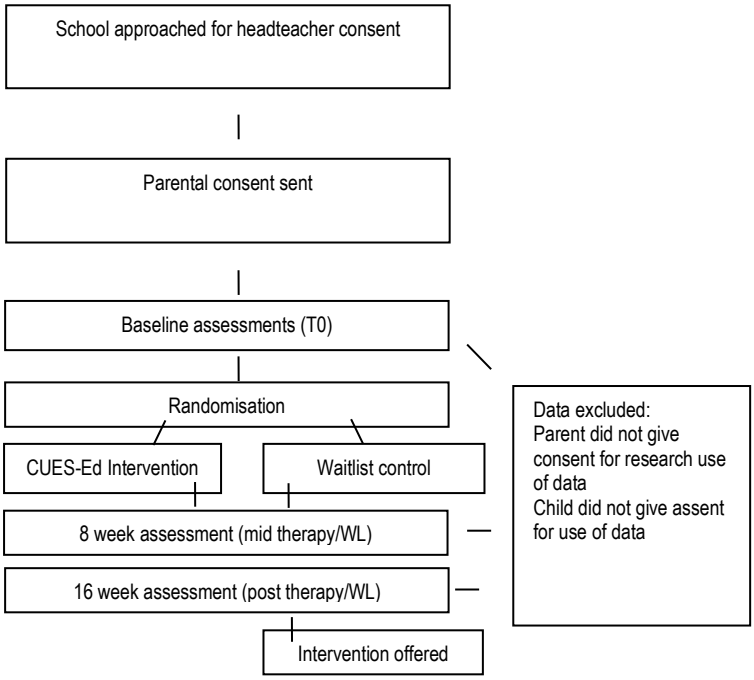
	Engagement with school	Baseline assessment 0-weeks	Pre-intervention	0-16 weeks	8-weeks	16-weeks
Headteacher consent	X (Research lead/ Headteacher 30 minutes*)					
Parent letter, consent	X (School/parent 30 minutes*)					
Teacher liaison and consent	X (Research team/ Headteacher/ Teacher 30 minutes*)					
Assessment		X (Children 15 minutes)			X (Children 15 minutes)	X (Children 15 minutes)
Randomisation			X (Researcher 24 hours)			
Intervention				X (Teacher/ children 12 x 1 hour**)		
Adherence				X (Researcher/ teacher 1 hour)		

**30 minutes includes 15 minutes to read the information and 15 to discuss/decide*

***Teaching takes places during three 20 minute sessions/week for 12 weeks; with school holidays, the delivery window is expected to be up to 16 weeks*

13.4 Study flow diagram

Figure 1: Design



14. Sample size

We estimate from two classes within 10 schools there will be approximately 600 children and we anticipate that 60% of parents of the children will consent (n=360). We anticipate the key challenge to the success of running the future confirmatory RCT will be to understand the follow up rate. By consenting and collecting baseline data from 360 children we will be able to estimate the follow up rate (assumed to be 80%) with ± 4.1%.

15: Recruitment

15.1 Schools:

For the feasibility pilot study, we will recruit schools known to the CUES-Ed service, by liaising directly with local authorities and headteachers. Each school will be approached for headteacher consent. Teachers will be approached by their head to discuss participation. However, as the headteacher is also their manager, they will each have a separate meeting with the research team to ensure they have the opportunity to decline participation should they wish to. Heads will agree, as part of their consent on behalf of the school, to teachers being free to decide to participate or otherwise without this compromising their relationship with their school in any way.

15.2 Parents:

Once headteacher and teacher consent is secured, letters will be sent to all parents in the target year group explaining the study and seeking consent to use outcome measures for a research purpose. Parents will receive one telephone follow-up from the school office – they will be asked if they would be willing for the research team to contact them. Parents agreeing to this contact will also be followed up by the

research team. We will also place research team members in playgrounds during drop-off and pick-up times with additional forms for parents to sign.

15.3 Children:

All children will be invited to attend CUES-Ed sessions and complete outcomes, unless parents, or the children themselves request not to participate. This is because it is important that the parental consent process does not result in children feeling excluded or stigmatised. Children will give assent for the use of the measures for research. This will be given as privately as possible, again to avoid any stigma. We will only use data when both parents and children consent.

METHODS: ASSIGNMENT OF INTERVENTIONS

16. Randomisation

16.1 Sequence generation

Randomisation will be carried out following consent and when teachers and children have completed baseline assessment and prior to the start of the intervention. For the pilot study, cluster randomisation will be managed by the study statistician. We will randomise using covariate constrained cluster randomisation balancing on school deprivation and school size (Carter and Hood, 2008).

16.2 Concealment mechanism

Randomisation will be managed by the study statistician. Cluster characteristics needed by the statistician in order to perform the randomisation will be sent through by the trial manager once the school is confirmed as taking part in the study. Allocations will then be sent to the trial manager once all baseline data has been collected from the participants.

16.3 Implementation

Schools will be randomised once baseline assessments are completed. The member of the study team collecting baseline (0-week) measures will alert the study statistician who will send the allocation to the study PI or an allocated deputy from within the research team. This person will communicate with the school and ensure that appropriate steps are initiated (teacher training for intervention schools).

17. Blinding, emergency unblinding

We will not be able to blind participants to treatment group. Similarly, the teachers cannot be blind to allocation as they will deliver the intervention. The RAs completing outcome assessments will be exposed to school interiors decorated with CUES-Ed materials and children's chatter about the intervention (or the absence of these indicators) and thus will not be blind to allocation. However, once collected, data will be processed by RAs blind to allocation.

Baseline assessments will be carried out blind to treatment allocation. Follow-up assessments cannot be blinded. Once data is collected, it will be processed by

researchers blind to treatment allocation. Emergency unblinding will not be necessary.

18. Data collection

18.1 Data collection methods

Outcome measures (child emotional/behavioural problems, child wellbeing, teacher rated class behaviour) will be completed by children and teachers at 0, 8 and 16-weeks, on paper, with support from the research worker as required. Measures will be completed as a group in the classroom. Assessments should occur within a 1-month window of their calendar date, counted from the day of randomisation. Assessments will be collected by teachers, checking child assent and cross-referencing with parental consent. Assessment packs for children with both parental consent and child assent will be stored in the classroom, securely, separately from those without consent/assent. Once the final assessments are completed, the research team will collect the secured data and confidentially destroy, without access, data for children without consent/assent for research use. Data for children with both parental consent and child assent will be returned to the research team's trust base for entry.

18.2 Retention

Children will be assessed in the classroom. Absent children and teachers will be followed up on their return to school, providing this falls within the 1-month window.

19. Data management

19.1 Data forms and entry

Data will be collected in paper format and will be entered onto a secure web application REDCap, with integrated participant and range checks. Paper forms will be stored securely by the research team until the end of the study (January 2023).

19.2 Data transmission and editing

Separate databases will be created for school level data, child level data, teacher adherence data, and allocation. The database will be designed to only accept within range responses. Range and value checks and spot checks against paper copies will be employed to check data.

19.3 Discrepancy checks

Data discrepancies that cannot be resolved by simple checking and reference to paper copies will be referred to the steering committee, blind to allocation, for discussion of a resolution.

19.4 Security and back-up of data

Once all data is entered, the database will be locked. Data will be stored on password protected systems in SLaM and KCL. The allocation database will be accessible only to the lead research worker (who will not conduct post-baseline assessments) and the CI (DP) until the study is completed. Outcome data processing

will be carried out by researchers who do not have access to allocation, intervention or feedback data. After data is checked, blind to allocation, a final database will be returned to the statistician, who will combine with allocation data for analysis.

The Chief Investigator will act as custodian for the trial data. The following guidelines will be strictly adhered to:

Child/teacher data will be pseudonymised for the duration of the study and fully anonymised at the end of the study. The fully anonymised data will be kept indefinitely. Fully identifiable personal details will be kept on paper in a locked filing cabinet in a locked or occupied office; on secure Trust computers; and, encrypted, on password protected computers in the university until the end of the study (January 2023).

Pseudonymised data will be stored on personal laptop computers, using MHRN recommended encryption (Trucrypt).

All trial data will be stored in line with the Data Protection Act and archived in line with the relevant institutional policies.

20. Statistical methods

Prior to the database lock a statistical analysis plan will be developed and approved by the Trial Team.

20.1 Primary outcome analysis

The primary feasibility outcomes will be assessed by proportions, with their associated 95% confidence interval. No hypothesis tests will be carried out on these.

20.2 Secondary outcome analysis

The potential primary outcome the M&MF will be summarised using a mixed effects linear regression, fitting a random effect to explain the heterogeneity across school and class. Fixed effects will include baseline score, child sex and age. The between-group summary effect will be reported with the 95% confidence interval and intra-cluster correlation.
All other secondary outcome measures will be summarised descriptively and to show levels of completeness.

20.3 Missing data and population under investigation

Data will be explored for structural missingness and reported accordingly. The primary population under investigation will be the modified intention to treat (ITT). The ITT population will be defined as all children with at least one post baseline timepoint.

20.4 Additional analyses

Psychometric analyses will be employed to validate the child quiz, teacher classroom ratings and teacher adherence rating. Vulnerable children will be identified as those scoring in the borderline or clinical range on either subscale of the M&MF.

21. Data monitoring

Data monitoring will be the responsibility of the study research lead (SJ), overseen by the trial management group and the steering committee. As data will be collected over a relatively short period of time, there will be no interim analyses. As we do not

anticipate risks to participant safety as a direct result of the study and will not be conducting any interim data analysis, we will not convene a separate Data Monitoring Committee, and will devolve these functions to the trial steering committee (TSC) which will be detailed in the TSC charter. The study will be subject to the standard local and national governance frameworks of SLaM R&D, CAMHS clinical services and research co-ordination, and our ethics committee.

The pilot study will be overseen by a steering committee comprising the research team, an education representative and a senior academic not directly involved in the study.

An independent steering committee will be established for the future, full trial.

22. Harms

We will ask teachers to report to the study team any concerns about CUES-Ed or the assessment protocol or any other aspect of the study, expressed by teachers themselves, parents, or children. These will be reviewed by the steering committee for severity, and attributability to the study in liaison with the school, and parents if relevant. Adverse events judged serious and attributed to participation in the study will be reported as below. We do not envisage, given the extensive delivery to date, without any adverse events, that these will be a frequent occurrence, or that an event will trigger cessation of the study.

22.1 Procedures for Recording and Reporting Adverse Events

In other research other than CTIMPs, a *serious adverse event* (SAE) is defined as an untoward occurrence that:
(a) results in death;
(b) is life-threatening;
(c) requires hospitalisation or prolongation of existing hospitalisation;
(d) results in persistent or significant disability or incapacity;
(e) consists of a congenital anomaly or birth defect; or
(f) is otherwise considered medically significant by the investigator.

An SAE occurring to a research participant should be reported to the main REC where in the opinion of the Chief Investigator the event was:
• *Related* – that is, it resulted from administration of any of the research procedures, and
• *Unexpected* – that is, the type of event is not listed in the protocol as an expected occurrence.

	Who	When	How	To Whom
SAE	Chief Investigator (CI) or sponsor.	Within 15 days of the CI becoming aware of the event.	SAE report form for non-CTIMPs, available from NRES website.	Main REC for the trial.
Urgent safety measures	Chief Investigator or sponsor. *Or exceptionally by local Principal Investigator (PI).*	(i) Immediately. (ii) Within 3 days.	(i) By telephone. (ii) Notice in writing setting out the reasons for the urgent safety measures and the plan for further action.	Main REC for the trial. REC Co-ordinator will acknowledge within 30 days. *If notified by PI, relevant local REC should also be informed.*

Type	Who	When	How	To Whom
Progress reports	To be submitted by sponsor, sponsor's legal representative or Chief Investigator (CI). Must always be signed by CI.	Annually (starting 12 months after the date of the favourable opinion) *Main REC may exceptionally request more frequent reports.*	Annual progress report form (non-CTIMPs), available from NRES website.	Main REC for the study.
Declaration of the conclusion or early termination of the research	Sponsor or CI.	Within 90 days (conclusion). Within 15 days (early termination). *The end of the study should be defined in the protocol.*	End of study declaration form, available from the NRES website.	Main REC for the study.
Summary of final report	Sponsor or CI.	Within one year of the conclusion of the research.	No standard format. The summary should include information on whether the study achieved its objectives, the main findings and arrangements for publication or dissemination including feedback to participants.	Main REC for the study.

We do not anticipate safety concerns arising as a direct result of CUEs-Ed, which is usually perceived as helpful by children, schools and families. However, we will monitor adverse events carefully~~,~~ and ensure they are appropriately documented and addressed. Any that arise as a result of the intervention, however unlikely this may be, will be escalated to represented governing bodies for review, and opinion as to necessary adjustments to protocol. Adverse events and progress will be reported by the study team to the main REC and the local Trust R&D, following the schedule above.

22.2 Adverse events that do not require reporting

We will review all adverse events with the reporting school, and report these in study publications, and to the main REC, the TSC, and the local authority as required, following the schedule above.

22.3 Treatment Stopping Rules

The trial may be prematurely discontinued by the Sponsor, Chief Investigator or REC on the basis of new safety information or for other reasons given by the Ethics Committee or the steering/oversight group.

If the trial is prematurely discontinued, active participants will be informed and no further participant data will be collected. Arrangements will be made directly with participating schools and the local authority to ensure that the education and wellbeing of children is not compromised by this process. The Research Ethics Committee will be informed following the schedule above.

22.4 Withdrawal of participants

Schools will have the right to withdraw from the study at any time up until the start of delivery for any reason. Once delivery has begun, both children and parents will also be involved and a school opt out will need to take their wellbeing and expectations into account. Teachers can choose to opt out at any time: schools undertake to find a

replacement at the point of consent. Parents may choose to opt their child out of the use of data for research purposes at any point prior to full anonymisation of the data. Children can also withdraw their assent at any time up until full anonymisation. If children are absent on the day of assessment, we will make every effort to follow up within the one month assessment window, being led by the school or parents as to any restrictions on this (e.g. the child being severely unwell).

It is understood by all concerned that an excessive rate of withdrawals can render the study uninterpretable; therefore, unnecessary withdrawal of participants should be avoided. Should a participant of any kind decide to withdraw from the study, all efforts will be made to report the reason for withdrawal as thoroughly as possible. Should a participant withdraw from the study intervention only, efforts will be made to continue to obtain follow-up data, providing consent and assent for data use remain in place.

Parents who wish to withdraw their child from the study intervention will be asked to confirm whether they are still willing for their child to attend assessments and contribute data to the study.

23. Auditing

As we do not anticipate risks to participant safety as a direct result of the study and will not be conducting any interim data analysis, we will not convene a Data Monitoring Committee. The study will be subject to the standard local and national governance frameworks of SLaM R&D, CAMHS clinical services and research co-ordination, and our ethics committee.

Auditing will take place as required by funder/governing bodies, overseen by the study team and independent advisors. The data collection period is expected to be short, so we do not expect any auditing meetings to be required.

ETHICS AND DISSEMINATION

24. Ethical approval

We will apply for university ethics before the start of the study.

25. Protocol amendments

These will be submitted for regulatory body approval and documented in the protocol log of amendments.

26. Consent or assent

26.1 Consent or assent– we will seek school and teacher consent to participate, and parental consent to use their child's information for a research purpose, with child assent. Should any child prefer not to participate in the CUES-Ed teaching or data collection this will be addressed at the teacher's discretion, as they are responsible for the child's safety and wellbeing during the school day. Information

sheets will make clear that usual practice in this regard should not be compromised by participation in the research.

26.2 Ancillary studies: These will require a separate consent.

27. Confidentiality

Children may provide new personal information to the research team on their written questionnaires. Where this concerns there care and safety, it will be passed on to school, parental (or other, as appropriate) authorities.

28. Declaration of interests

The PI runs the CUES-Ed service. However, this is primarily funded by SLaM, so there is no direct financial conflict of interest. Otherwise, no member of the research team has a conflict of interest.

29. Access to Data

Data will be stored in a King's College repository, and made available upon request. The Investigator(s) will permit trial-related monitoring, audits, REC review, and regulatory inspections by providing the Sponsor(s) and REC direct access to source data and other documents providing this is within the bounds of data protection and the protection of participants' confidentiality.

30. Ancillary and post-trial care

This is unlikely to be required, but schools will be able to contact the research team with concerns if they wish, following the end of the trial.

31. Dissemination policy

Findings will be communicated to participating school heads, who will be free to choose the best method for their school for dissemination. We will present the findings of the research at conferences and will publish in peer-reviewed journals. Locally, we will present to services within our Academic Health Sciences Network, where we have close practice and training links.

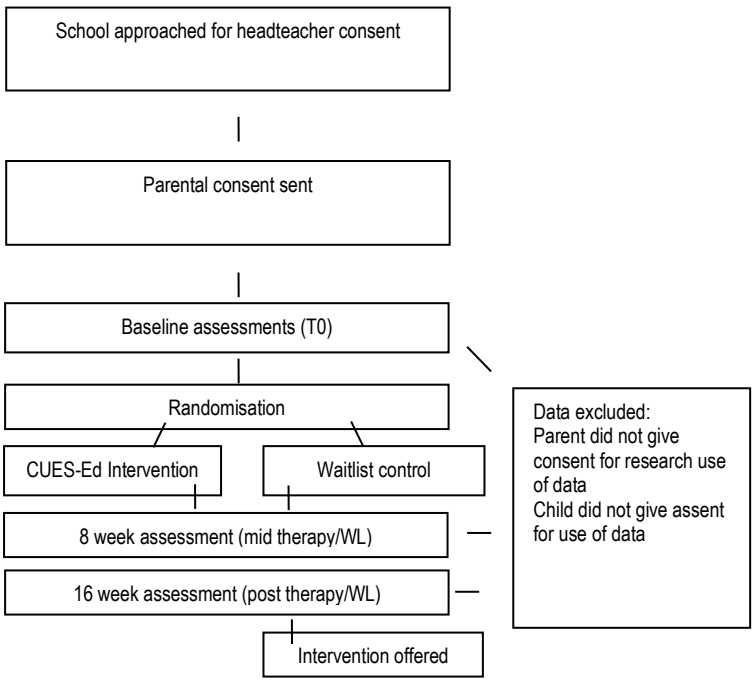
31.1 Trial results – these will be reported at the end of the study for all schools.

31.2 Authorship – will be determined by contribution to the paper in question

31.3 Reproducible research – data will be placed in the KCL repository once anonymised.

32-33. Appendices & figures

Figure 1: Design



Signatures

To be signed by Chief Investigator minimum and statistician if applicable.

_____

Chief Investigator Date
Print name

_____

Statistician (if applicable) Date
Print name

REFERENCE LIST

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