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# Building Resilience in Children. The CUES-Ed research project: a feasibility study for a comparison of the CUES-Ed resilience-building digital programme for primary school children compared to the usual school curriculum

**Submission date**
26/10/2021

**Recruitment status**
No longer recruiting

**Registration date**
28/10/2021

**Overall study status**
Completed

**Last Edited**
14/09/2022

**Condition category**
Other

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

**Plain English summary of protocol**
Background and study aims
CUES-Ed is a fun and interactive programme of learning to teach primary school children about emotional well-being and resilience. Children learn through friendly and appealing characters to eat well, sleep well, and balance being active with relaxing, as well as understanding and managing their thoughts, feelings and behaviours. The programme has been developed by the CUES-Ed team, a team of health professionals and researchers from the South London and Maudsley National Health Service (NHS) Foundation Trust and King's College London. The CUES-Ed programme supports the National Curriculum. The CUES-Ed team want to find out if CUES-Ed is helpful. This needs a large study, with lots of schools. Before they do this they need to find out, in a smaller study, how schools, parents, and children find the project. The aim of this study is to find out how many schools, parents, and children agree to take part, how many children and teachers fill in measures of how helpful CUES-Ed is, whether teachers can deliver CUES-Ed lessons, and how we best measure these outcomes.

Who can participate?
Primary schools in England (ten for this study)

What does the study involve?
Schools will agree for teachers to teach the CUES-Ed programme for around an hour each week in 20-minute sessions over 12 weeks. As well as the classroom sessions, there is a website children can visit from home. Teachers will rate the behaviour of their class (e.g. paying attention, getting on together) three times, before, during, and after CUES-Ed. They will rate the class as a whole, not any individual child. A researcher from the team will visit the class, in person or by a remote link, to make the same rating, so they can compare their rating to the teacher's rating to see if they are the same. The researcher will also rate how the teacher is teaching CUES-Ed.

Some schools will do CUES-Ed straight away, some schools will just do the three class ratings now and do CUES-Ed later in the school year or in the following school year. The researchers will compare children's ratings and class ratings for schools doing CUES-Ed now and schools not doing CUES-Ed yet to see if there is a difference. Which schools do CUES-Ed now and which schools do it later will be decided randomly, a bit like tossing a coin. This means the study is a randomised controlled trial. As well as the teacher ratings, children will fill in a quiz booklet, about their learning from CUES-Ed, their thoughts, feelings, behaviour and coping, and how they are doing at school and home on a ten-point scale. The puzzles are designed by the CUES-Ed team to be fun. Lots of children have filled them in and have enjoyed doing them. They include scenarios about understanding and coping with emotions and common perceptual experiences (like hearing your name called when nobody is there). The researchers are trying to measure common day-to-day emotional and behavioural difficulties for children that might affect them in the classroom. They do not ask about any specific mental health problems or risks. The questions take around 15 minutes to answer. Like the teacher ratings, the researchers will ask children to fill in the booklets three times. The booklets will be seen by teachers and school staff to see how the class is doing.

What are the possible benefits and risks of participating?
The researchers do not think CUES-Ed is harmful in any way. They want it to be helpful and it has been designed to be fun. The programme and the booklets are designed for children by researchers with many years' experience working with children. They ask about day-to-day experiences that may impact classroom behaviour. The researchers do not expect them to be distressing. It is hoped that the children will enjoy taking part in the study and will learn some useful ways of coping with day to day stresses.

Where is the study run from?
South London & Maudsley NHS Foundation Trust and King's College London (UK)

When is the study starting and how long is it expected to run for?
April 2021 to January 2023

Who is funding the study?
1. Monday Charitable Trust (UK)
2. South London and Maudsley NHS Foundation Trust (UK)

Who is the main contact?
1. Dr Deborah Plant
2. Dr Suzanne Jolley, suzanne.jolley@kcl.ac.uk

# Contact information

### Type(s)
Public

### Contact name
Dr Suzanne Jolley

### ORCID ID
https://orcid.org/0000-0003-1622-0051

### Contact details

Department of Psychology
Institute of Psychiatry, Psychology and Neuroscience
King's College London
London
United Kingdom
SE5 8AF
+44 (0)20 7848 5028
suzanne.jolley@kcl.ac.uk

### Type(s)
Scientific

### Contact name
Dr Suzanne Jolley

### Contact details
Department of Psychology
Institute of Psychiatry, Psychology and Neuroscience
King's College London
London
United Kingdom
SE5 8AF
+44 (0)2078485028
suzanne.jolley@kcl.ac.uk

## Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### ClinicalTrials.gov (NCT)
Nil known

### Protocol serial number
Nil known

## Study information

### Scientific 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

### Study objectives
Primary objective:
Evaluate trial procedures

Secondary objective(s):
1. Estimate parameters to determine the sample size for a full trial
2. Validate classroom-based outcome measure
3. Standardise teacher adherence rating
4. Validate child quiz outcome measure

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Approved 21/10/2021, King's College London College Research Ethics Committee (KCL CREC, The Chair, Health Faculties Research Ethics Sub-Committee; +44 (0)2078484020; rec@kcl.ac.uk), ref: LRS/DP-21/22-25994

## Study design
Single-centre feasibility pilot of a parallel-group cluster randomized controlled trial

## Primary study design
Interventional

## Study type(s)
Other

## Health condition(s) or problem(s) studied
Wellbeing/resilience in primary school children

## Interventions
The study comprises a randomised controlled feasibility pilot study of procedures for a trial comparing the CUES-Ed digital programme to a waitlist control group. The researchers also wish to estimate variability in outcome parameters to inform sample size calculation and refine three non-standardised trial measures: a measure of teacher adherence in delivering the programme; a teacher-rated measure of class behaviour; and a child-rated quiz about the learning covered by CUES-Ed.

The design is a parallel-group feasibility cluster randomised controlled trial with random allocation of schools to one of two arms in a 1:1 ratio by ovariate constrained cluster randomisation balancing on school deprivation and school size.

CUES-Ed is a digital programme designed for whole classes of Year 4 primary school children (ages 8-9), aiming to improve wellbeing and resilience, particularly in vulnerable children (i.e. those scoring above cut-offs for emotional and/or behavioural problems on the Me and My Feelings measure, Deighton et al., 2013). The programme comprises 12 hours of teaching, delivered as three 20-minute lessons each week.

There are three levels of participation. Schools will be recruited from amongst those familiar with the CUES-Ed programme, as the researchers are piloting trial procedures. They will recruit to allow them to randomise ten schools, including both inner city and contrasting settings to estimate the variability between schools. They anticipate recruiting ten schools, with all schools agreeing to participate, and can recruit more if this is required. Schools are approached at the headteacher level, with the agreement of the Local Authority for the research team to make the

approach. Schools must be Local Authority governed, with a Year 4 and Year 5 intake, located in England. Within each school between one and three Year 4 classes are expected, with approximately 30 children per class. Child participants will be the Year 4 cohort of the consenting school (aged 8-9 years). The aim is to recruit 600 children.

Children will complete measures of emotional/behavioural problems, wellbeing, and the child quiz, and teachers will complete whole class ratings of behaviour at 0, 8 and 16 weeks. The researchers will also identify any adverse events, defined as a report from any school, class, parent, or child, or the research team, of any difficulty during the study. Events will then be reviewed for severity and attributability to the study by the study steering group.

## Intervention Type
Other

## Primary outcome(s)
Trial feasibility determined using:
1. Randomisation rate recorded as the number of schools randomised of those approached, recorded during the trial
2. Consent/assent and baseline data completion rate recorded as the number of children completing baseline with parental consent and child assent of those sent information sheets, recorded during the trial
3. Child assent rates recorded as the number of children assenting in each target class, recorded at their first assessment point
4. Follow-up rates recorded as the number of children completing outcomes at baseline and follow-up at 8 or 16 weeks
5. Adherence of teachers recorded as teacher delivery of the intervention, assessed by an observer at a single timepoint for each teacher using a bespoke measure to be developed during the pilot
6. Fidelity of intervention recorded as the number of schools randomised to receive intervention or control receiving the allocated condition, recorded throughout the trial

## Key secondary outcome(s))
1. Parameter estimation to determine the sample size for a full trial calculated using outcome data for the proposed primary clinical outcome measure (see below)
2. Validation of the classroom-based outcome measure (see below) by psychometric testing of collected data and comparison of teacher ratings to an observer rating conducted at a single timepoint for each teacher
3. Design and testing of teacher adherence ratings, conducted at a single timepoint for each teacher
4. Validation of the child quiz outcome measure (see below) by comparing collected data to standardised components and other study measures
5. Questionnaires/participant-completed measures are as follows:
5.1. Child emotional/behavioural problems will be measured by the proposed primary questionnaire outcome for the future RCT, the Me and My Feelings instrument comprising 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. The measure is completed at 0, 8 and 16 weeks.
5.2. Child wellbeing will be assessed by the proposed secondary questionnaire outcome for the future RCT, The Children’s Outcome Rating Scale (CORS). This 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. The measure is completed at 0, 8 and 16 weeks.
5.3. Child resilience will be measured by a quiz assessing learning from CUES-Ed, which has been completed by large numbers of children during in-service delivery of CUES-Ed, so is acceptable for completion, with face validity. The researchers are in the process of establishing norms and will validate the measure as part of this pilot study. The measure is completed at 0, 8 and 16 weeks.
5.4. Classroom impact will be measured by a teacher-completed 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'. The researchers will validate this measure as part of this pilot study. The measure is completed at 0, 8 and 16 weeks.

### Completion date
31/01/2023

## Eligibility

### Key inclusion criteria
1. Schools: Local Authority run primary schools with Year 4 and Year 5 cohorts in England
2. Children: attending the school in Year 4 (aged 8-9 years)

### Participant type(s)
Other

### Healthy volunteers allowed
No

### Age group
Child

### Lower age limit
8 years

### Upper age limit
9 years

### Sex
All

### Total final enrolment
718

### Key exclusion criteria
Does not meet inclusion criteria

### Date of first enrolment
14/11/2021

### Date of final enrolment

31/01/2022

# Locations

**Countries of recruitment**
United Kingdom

England

**Study participating centre**
**South London & Maudsley NHS Foundation Trust**
CUES-Ed
Mapother House
De Crespigniy Park
Denmark Hill
London
United Kingdom
SE5 8AF

# Sponsor information

**Organisation**
South London and Maudsley NHS Foundation Trust

**ROR**
https://ror.org/015803449

**Organisation**
King's College London

**ROR**
https://ror.org/0220mzb33

# Funder(s)

**Funder type**
Hospital/treatment centre

**Funder Name**
South London and Maudsley NHS Foundation Trust

### Alternative Name(s)

### Funding Body Type
Government organisation

### Funding Body Subtype
Local government

### Location
United Kingdom

### Funder Name
Monday Charitable Trust

## Results and Publications

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository at King's College London, once the study has been completed, and will be accessible by request to Dr Suzanne Jolley (suzanne.jolley@kcl.ac.uk) for any purpose compatible with the original ethical approval for the study, under which consent to collect the data was obtained.

### IPD sharing plan summary
Stored in non-publicly available repository, Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet version 1 | 11/11/2025 | 11/11/2025 | No | Yes |
| Protocol file | | 25/10/2021 | 14/09/2022 | No | No |