

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	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 28/10/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 14/09/2022	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

<http://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

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Cluster randomised trial

Study setting(s)

School

Study type(s)

Other

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 overariate 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 measure

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

Secondary outcome measures

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.

Overall study start date

01/04/2021

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

Age group

Child

Lower age limit

8 Years

Upper age limit

9 Years

Sex

Both

Target number of participants

600 children across ten schools

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

England

United Kingdom

Study participating centre

South London & Maudsley NHS Foundation Trust

CUES-Ed

Mapother House

De Crespigny Park

Denmark Hill

London

United Kingdom

SE5 8AF

Sponsor information

Organisation

South London and Maudsley NHS Foundation Trust

Sponsor details

R&D Department

Room W1.11

Institute of Psychiatry, Psychology & Neuroscience

De Crespigny Park

London

England

United Kingdom

SE5 8AF
+44 (0)20 7848 0251
slam-ioppn.research@kcl.ac.uk

Sponsor type

Hospital/treatment centre

Website

<http://www.slam.nhs.uk/>

ROR

<https://ror.org/015803449>

Organisation

King's College London

Sponsor details

Room 1.8 Hodgkin Building
Guy's Campus
London
England
United Kingdom
SE1 4UL
+44 (0)20 7848 6960
rgei-team@kcl.ac.uk

Sponsor type

University/education

Website

<http://www.kcl.ac.uk/index.aspx>

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

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal. The trial protocol including the statistical analysis plan is not published or available online and will be made available with the study record once fully signed off by the study statistician.

Intention to publish date

31/01/2024

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?
Protocol file	version 1	25/10/2021	14/09/2022	No	No