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

Submission date
09/09/2022

Recruitment status
No longer recruiting

Registration date
12/09/2022

Overall study status
Completed

Last Edited
04/10/2024

Condition category
Mental and Behavioural Disorders

[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 for schools is an interactive digital programme aiming to teach primary school children about emotional well-being and resilience. The researchers want to know if children will learn to eat well, sleep well, and balance being active with relaxing, as well as understanding and managing their thoughts, feelings and behaviours. They have tried to make the programme fun, using friendly and appealing characters. The programme follows the National Curriculum and has been developed by the CUES-Ed team. The researchers are a team of health professionals and researchers from the South London and Maudsley National Health Service Foundation Trust and King's College London. The CUES-Ed team want to find out if CUES for schools is helpful for children, compared to the usual school curriculum. This needs a large study, with lots of schools.

Who can participate?
Primary schools in England with a Year 4 (8-9 years) and Year 5 (9-10 years) intake

What does the study involve?
Schools will agree for teachers to teach the CUES for schools 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) twice, before and after CUES. They will rate the class as a whole, not any individual child. They will complete a form to let the research team know which sessions they delivered and how many children have attended. Some schools will do CUES straight away, some schools will just do the class ratings now and do CUES 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 now and schools not doing CUES yet to see if there is a difference. Which schools do CUES 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 workbook, about their learning from CUES, their thoughts, feelings, behaviour and coping, and questionnaires about emotional and behavioural problems and how they are doing at school and home. The questions are designed for children of this age and lots of children have filled them in. 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 twice, and the main outcome questionnaire, about emotional and behavioural problems, three times (0, 8 and 16 weeks after randomisation).

What are the possible benefits and risks of participating?
The researchers do not think CUES for schools 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 of 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 July 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

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Additional identifiers

Protocol serial number
HR/DP-21/22-28344

Study information

Scientific Title
A cluster randomised, 16-week, parallel-group multicentre trial to compare the effectiveness of a digital school-based cognitive behavioural resilience/wellbeing-building intervention (CUES for schools) targeting emotional and behavioural problems in vulnerable year 4 primary school children in whole classes, compared to the usual school curriculum

Study objectives
Primary objective:
The primary objective of this trial is to evaluate the effectiveness of CUES for schools compared to the usual school curriculum in improving emotional/behavioural problems for vulnerable year 4 children at 16 weeks post-randomisation, as measured using the Me & My Feelings questionnaire total score. This objective relates to the primary sub-population of children meeting the threshold for vulnerability (M&MF-E >9 and/or M&MF-B >5) at baseline assessment. A between-group effect size of d = 0.2 will be considered a minimum clinically significant effect, with this translating to a difference of approximately 1 point on the M&MF total scale.

Secondary objective(s):
Secondary aims will be to investigate the impact of the CUES for schools intervention on secondary wellbeing outcomes and on teacher-rated classroom behaviour, as well as exploring the effectiveness of CUES for schools across the wider school population (both vulnerable and non-vulnerable), as measured using the M&MF. More specifically, the researchers will explore change in the CUES for schools group compared to the usual curriculum on the variables below for the vulnerable sub-population and the whole school population.

Vulnerable sub-population:
1. M&MF behavioural sub-scores at 16 weeks
2. M&MF emotional sub-scales at 16 weeks
3. The Children's Outcome Rating Scale (CORS) at 16 weeks
4. Child workbook well-being scores at 16 weeks
5. Child workbook cognitive scores at 16 weeks

Whole school population:
1. M&MF total scores at 16 weeks
2. CORS at 16 weeks
3. Child workbook well-being scores at 16 weeks
4. Child workbook cognitive scores at 16 weeks
5. Teacher ratings of whole class behaviour at 16 weeks
6. Teacher ratings – self-rated coping scale at 16 weeks

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/08/2022, King's College London College Research Ethics Committee (KCL CREC, The Chair, Health Faculties Research Ethics Sub-Committee, Research Ethics Office, Room 4.16/ 4.16A Waterloo Bridge Wing, Franklin Wilkins Building, Waterloo Road, London, SE1 9NH, UK; +44 (0)2078484020; rec@kcl.ac.uk), ref: HR/DP-21/22-28344

Primary study design
Interventional

Study design
16-week multicentre parallel-group cluster randomized controlled trial

Study type(s)
Other

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

Interventions
The study comprises a cluster randomised controlled trial comparing the CUES for schools digital programme to a waitlist control group. The design is a parallel-group cluster randomised controlled trial with random allocation of schools to one of two arms in a 1:1 ratio by covariate constrained cluster randomisation balancing on school deprivation and school size.

CUES for schools 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 in inner and outer London and the surrounding area. All schools will be contacted to express interest in participation, those expressing interest will be followed up for participation. The feasibility study (ISRCTN12486546) allowed the researchers to estimate a sample size of 2,200 vulnerable children across 74 schools. Schools are approached at the headteacher/senior leadership team (SLT) level. 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 20-30 children per class. Child participants will be the Year 4 cohort of the consenting school (aged 8-9 years).

Children will complete measures of emotional/behavioural problems, wellbeing, and the child workbook, and teachers will complete whole class ratings of behaviour at 0 and 16 weeks post-randomisation. Children will complete the main measure of emotional and behavioural difficulties a third time at 8 weeks post-randomisation. The researchers will also identify any adverse events, defined as a report from any school, class, parent, 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
Behavioural

Primary outcome(s)
Children's emotional/behavioural problems are measured using the Me & My Feelings questionnaire (M&MF) total scale at 0, 8, and 16 weeks. The between-group difference of vulnerable children at 16 weeks is the primary outcome. This measure comprises 16 items, each rated 0 (best) to 2 (worst), with total scores ranging from 0 – 32. The total score is made up from two subscales – emotional difficulties (M&MF-E, 10 items) and behavioral difficulties (M&MF-B, 6 items) – with children meeting the criterion for being vulnerable based on M&MF-E >9 and/or M&MF-B >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.

Key secondary outcome(s)
Vulnerable sub-population:
1. Children's emotional problems are measured using the M&MF-E 10 item subscale (M&MF items 1-10) at 0, 8, and 16 weeks. Scores range from 0-20, with lower scores indicating more positive outcomes (clinical cut-off >9)
2. Children's behavioural problems are measured using the M&MF-B 6 item subscale (M&MF items 11-16) at 0, 8, and16 weeks. Scores range from 0-12, with lower scores indicating more positive outcomes (clinical cut-off >5)
3. Children's overall wellbeing is measured using the Children's Outcome Rating Scale (CORS) four-item total scale at 0 and 16 weeks. This scale is designed to measure wellbeing and distress, with each item rated 0 (worst) to 10 (best) with scores below 32 considered to represent clinical levels of distress/poor wellbeing.
4. Children's day-to-day wellbeing is measured using a seven-item wellbeing rating scale completed as part of a Child Workbook, at 0 and 16 weeks. Each item is rated from 0 (worst) to 10 (best), with total scores ranging from 0-70. Items have been designed as a means to assess the learning from the CUES programme. The items have been completed by large numbers of children during in-service delivery of CUES, and the feasibility pilot.
5. Children's cognitive vulnerability is measured using an eight-item cognitive rating scale completed as part of a Child Workbook at 0 and 16 weeks. Each item is rated from 0-1, with one item rated from 0-2. Total scores range from 0-9. As with child workbook wellbeing rating scores, this outcome is designed to assess learning from the CUES programme.

Whole school population:
In addition to the measures above, outcomes for the whole school population will be assessed using the following:
1. Class behaviour is measured using two teacher-completed ratings at 0 and 16 weeks. Teachers estimate the proportion of the class displaying positive behaviours, rated as the total number of students within the class who ‘often’ or ‘sometimes’ display these behaviours.
2. Teacher coping is measured by a four-item coping scale at 0 and 16 weeks. Each item is rated from 0 (worst) to 4 (best), with total scores ranging from 0-16. This scale is designed to indicate how well the teacher feels they are able to manage emotional upset experienced by children within the classroom
3. Adverse events are measured by a teacher report of safeguarding concerns, completed weekly from 0 to 16 weeks, as well as any child, parent, other teacher, school, or research team reports of adverse events, at 8 and 16 weeks

In addition, the following measures will be collected by the research team but will not be formally analysed by the trial statisticians:

1. Teacher adherence is measured using a self-report checklist completed weekly from 0 to 16 weeks
2. Child attendance is measured by a teacher report of the number of children missing CUES sessions completed weekly from 0 to 16 weeks
3. The usual emotional and social learning curriculum is measured by the school senior leadership team self-report at 0 weeks

Completion date
31/07/2023

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

Sex
All

Key exclusion criteria
Does not meet the inclusion criteria

Date of first enrolment
19/09/2022

Date of final enrolment
31/03/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
South London & Maudsley NHS Foundation Trust
CUES-Ed
Mapother House

De Crespigny Park
Denmark Hill
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SE5 8AF

Sponsor information

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?
Protocol article		03/04/2023	04/10/2024	Yes	No
Participant information sheet	Children version 3	29/07/2022	12/09/2022	No	Yes
Participant information sheet	Headteachers version 3	29/07/2022	12/09/2022	No	Yes
Participant information sheet	Parents version 3	29/07/2022	12/09/2022	No	Yes
Participant information sheet	Teachers version 3	29/07/2022	12/09/2022	No	Yes
Protocol file	version 1.0	12/09/2022	14/09/2022	No	No