Trial of anti-bullying programme KiVa-SEND

| Submission date 31/03/2025 | Recruitment status No longer recruiting | Prospectively registeredProtocol |
|-------------------------------------|---------------------------------------------------|------------------------------------------------------------------------------------------|
| Registration date 31/03/2025 | Overall study status Ongoing | Statistical analysis plan Results |
| Last Edited 31/03/2025 | Condition category Other | Individual participant data [X] Record updated in last year |

Plain English Summary

Background and study aims

Bullying is a public health risk with rates amongst children with special educational needs and disabilities (SEND) between 25-69%, with the higher rates found for pupils separated from mainstream schools. One of the greatest victimisation risk factors is being 'different', which includes physical appearance and physical or learning disability. Yet to date, there are no antibullying programmes designed specifically for pupils with SEND. This study aims to work with eight UK special schools to trial the feasibility of a new anti-bullying programme, KiVa-SEND.

Who can participate?

Pupils aged between 7 and 14 years old were included during baseline data collection from eligible classes, and their teachers.

What does the study involve?

Questionnaire data will be collected from pupils and teachers at baseline and at a 12-month follow-up with an embedded process evaluation. Four schools will deliver KiVa-SEND over one academic year, and four schools will continue as usual. Results will inform a later definitive randomised controlled trial of KiVa-SEND.

What are the possible benefits and risks of participating?

There are potentially no immediate benefits of the trial. Bullying perpetration and/or bullying victimisation may reduce for those delivering KiVa-SEND (but this study is not measuring that impact). The trial will lead to a better understanding of the feasibility of running KiVa-SEND in special schools, and the potential to begin a definitive randomised controlled trial. There are minimal risks of the trial.

Where is the study run from? University of Oxford, UK

When is the study starting and how long is it expected to run for? September 2024 to September 2026

Who is funding the study? Baily Thomas Charitable Fund Who is the main contact? Dr Julia Badger (Principal Investigator), julia.badger@education.ox.ac.uk

Study website

https://www.education.ox.ac.uk/project/feasibility-trial-of-an-adapted-anti-bullying-programme-for-children-in-special-schools/

Contact information

Type(s) Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number Nil known

IRAS number

ClinicalTrials.gov number Nil known

Secondary identifying numbers Nil known

Study information

Scientific Title

Feasibility randomised controlled trial of adapted anti-bullying programme for special education schools: KiVa-SEND

Acronym KiVa-SEND

Study hypothesis

As a feasibility trial, no hypotheses will be generated. However, the following feasibility outcome data will be collected: Primary outcomes – 1) recruitment and retention, 2) adherence to the programme, 3) staff survey completion, 4) pupil survey completion. Secondary outcomes – 1) pupil self-report data on bullying involvement, 2) staff data on pupil mental health and pupil involvement in bullying, 3) differences between the usual practice of anti-bullying programmes, and KiVa-SEND.

Ethics approval required

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Ethics approval(s)

Approved 05/09/2024, University of Oxford's Central University Research Ethics Committee (Wellington Square, Oxford, OX1 2JD, United Kingdom; +44 (0)1865 616578; ethics@socsci.ox.ac. uk), ref: R95368/RE001

Study design

Single-centre two-arm intervention feasibility cluster randomized controlled trial with a 1:1 blocked randomisation allocation ratio of schools and an embedded process evaluation

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

Condition

Feasibility of implementing an anti-bullying programme in UK special schools

Interventions

Eight UK special schools will participate; randomly allocated, using blocked randomisation, on a 1:1 basis to either implement the anti-bullying programme KiVa-SEND (intervention group) or continue as usual (comparison group). Those allocated to the intervention arm will deliver KiVa-SEND over one academic year (September 2025 – July 2026) as part of their Personal, Social, Health and Economic (PHSE) education classes (KiVa-SEND: a total of 20, 45-minute lessons covering topics such as 'being part of a group', 'school environment', 'friendships', 'emotions', 'inclusion and difference', as well as traditional and cyber bullying).

Schools vary in their students' primary educational need and will include a large proportion of students with learning disability, either identified from their Education, Health and Care Plan (EHCP) or the school's database. Recruited schools fall within 50 miles of Oxford. Participants from select classes from year 3 to year 8 (ages 7 – 13) will provide baseline data between April –

July 2025, and follow-up data between April – July 2026 (when in year 4 – 9, aged 8 – 14). Pupil data (an adapted version of the Olweus Bully/Victim Questionnaire) will be collected from between 2 and 6 classes per school (all eight schools), selected by the school based on the eligibility of the students in each class to access the KiVa-SEND materials. Staff data (Teacher Strengths and Difficulties Questionnaire, and Adapted Teachers' Perception on Bullying) will also be collected from the pupils' teachers at each time point. Schools opt into the trial, parents can opt their child out of the data collection (although in these cases the pupil will still be able to attend the KiVa-SEND (intervention) lessons if their school is allocated to the intervention), and pupils must assent to take part in the data collection on the day.

For the process evaluation, a sub-set of staff and pupils will be invited to take part in interviews (staff and pupils) or a Talking Mats session (pupils); separate consent will be required from staff and assent must be given by the pupils. Teaching staff – Three to six semi-structured interviews will be conducted with teaching staff: 1-2 from a comparison school and 2-4 from two intervention schools. Interviews will explore school sign-up to the study, retention, acceptability of research design and adherence to materials. Pupils – Up to 10 semi-structured interviews or Talking Mats sessions will be conducted with pupils from intervention schools. Sessions will explore enjoyment and engagement of the lessons, materials, activities and questionnaires. The project will follow MRC guidelines on process evaluations for complex interventions (Skevington et al., 2021) to explore a) recruitment and retention, b) implementation and adherence of the adapted KiVa programme, c) engagement and acceptability of/to pupils and staff and d) suitability of the outcome measures. This will help us to shape the research design and methods for a definitive trial. Interviews will be audio-recorded, transcribed, and thematically analysed

Intervention Type

Other

Primary outcome measure

Primary outcomes are feasibility outcomes using data collected during the process evaluation, semi-structured interviews with staff:

1. Recruitment and retention:

- 1.1. What proportion of approached schools decided to take part in the trial?
- 1.2. What proportion of recruited schools remained in the trial?
- 1.3. What proportion of eligible children are opting out of the trial by parents/guardians?
- 1.4 Are schools willing to be randomly assigned (Yes/No)?
- 2. Adherence:

2.1. Are teachers able to implement and adhere to the KiVa-SEND programme with a good level of fidelity? (data on percentage adherence to lesson plans)

2.2. Are the manualised lesson plans and activities acceptable to the teaching staff? (Yes/No - with suggested changes)

3. Are staff willing and able to complete the outcomes measures (perceived bullying of each pupil; mental health of each pupil)? (Yes/No) measured using data collected from staff surveys 4. Are pupils able to understand and complete the outcome measures (experience of bullying involvement)? (Yes/No) measured using data collected from the pupil survey

Secondary outcome measures

The proposed primary outcome to be explored for a future definitive trial is self-reported bullying victimisation measured using the following tools:

1. Pupils' self-reported victimisation and perpetration measured using the Olweus Bully/Victim Questionnaire (OBVQ)

2. Staff-reported pupil mental health measured using The Strengths and Difficulties Questionnaire (TSDQ),

3. Staff-reported pupil involvement in bullying situations measured using the Teachers' Perceptions on Bullying - adapted

Anti-bullying programmes – 1) How is the usual practice of anti-bullying programmes and procedures different from KiVa-SEND? Measured via school policies and data gathered from the school.

Overall study start date

05/09/2024

Overall study end date 30/09/2026

Eligibility

Participant inclusion criteria Schools:

1. Special education schools

2. Within a 50-mile radius of Oxford

Pupils:

Attending a special education school
 Aged between 7 and 14 during baseline data collection

Participant type(s) Learner/student

Age group

Child

Lower age limit

7 Years

Upper age limit

15 Years

Sex

Both

Target number of participants

8 schools, 2-6 classes per school, between 128 and 384 learners and between 16 and 96 teachers (depending on whether each class retains the same teacher at both time points).

Participant exclusion criteria

Schools:

1. Mainstream schools

2. Opened within the past year

Pupils:

1. Pupils who are unable to access the KiVa-SEND materials, for example, those who cannot integrate into a classroom setting or those who cannot access curriculum-style learning

2. Pupils whose parents have withdrawn consent

3. Eligible pupils who joined the school after the baseline data collection

4. Children who are not aged between 7 and 14 at baseline data collection.

Recruitment start date

01/10/2024

Recruitment end date

31/03/2025

Locations

Countries of recruitment England

United Kingdom

Study participating centre University of Oxford 15 Norham Gardens, Department of Education Oxford United Kingdom OX2 6PY

Sponsor information

Organisation

University of Oxford

Sponsor details

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Sponsor type

University/education

Website

https://www.education.ox.ac.uk

ROR https://ror.org/052gg0110

Funder(s)

Funder type Charity

Funder Name Baily Thomas Charitable Fund

Alternative Name(s) The Baily Thomas Charitable Fund

Funding Body Type Private sector organisation

Funding Body Subtype Trusts, charities, foundations (both public and private)

Location United Kingdom

Results and Publications

Publication and dissemination plan

A protocol paper will be published in 2025. The full feasibility trial results will be published in 2027 once the trial is complete.

Intention to publish date 01/10/2027

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to the small sample size, personal and sensitive data from children and schools.

IPD sharing plan summary

Not expected to be made available