

A web-enabled, school-based intervention for bullying prevention (LINKlusive): a cluster randomised trial



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Summary

Background There is a need for more sustainable interventions and for assessing the effectiveness of school-based universal anti-bullying programmes in vulnerable populations. We assessed the efficacy of a multicomponent, web-enabled, school-based intervention that aims to improve school climate and reduce bullying (LINKlusive) relative to conventional practices (control condition).

Methods We conducted a cluster randomised controlled trial in primary and secondary schools in Madrid, Spain. The primary outcome measure was peer-reported bullying victimisation after the 12-week intervention (study endpoint). We analysed data using longitudinal mixed-effects models. The trial was registered with the ISRCTN registry (15719015).

Findings We included 20 schools (10 in each group); 6542 students participated at baseline; 6403 were assessed at study endpoint. After the intervention, there was a statistically significant reduction in bullying victimisation in both the intervention (OR 0.61, 95% CI [0.41, 0.90]) and control groups (OR 0.69, 95% CI [0.51, 0.92]), with no evidence of differences in the whole sample (OR 0.89, 95% CI [0.58, 1.36]; aOR 0.89, 95% CI [0.58, 1.37]). Subgroup analyses showed a statistically significant effect of LINKlusive on bullying victimisation in primary education (aOR 0.68, 95% CI [0.47, 0.98]). In students with peer-reported bullying victimisation at baseline, LINKlusive showed a statistically significant effect on depression (−1.43, 95% CI [−2.46, −0.40], adjusted standardised mean difference (SMD) −0.41) and quality of life (2.18, 95% CI [0.80, 3.56], adjusted SMD 0.45).

Interpretation LINKlusive could be effective in reducing bullying victimisation in primary school students. Sustainable whole-school interventions to promote mental health and reduce risk factors are warranted to improve outcomes in young people, especially in the early years of education.

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Introduction

Bullying can be defined as deliberate, repetitive aggressive behaviour inflicted upon a person by one or more of their peers where there is an imbalance of power favouring the perpetrator(s).¹ Bullying is a global

phenomenon that has received increasing attention in recent years as a major public health concern due to high prevalence rates and negative lifetime health, economic, and societal consequences.^{2–7} At least one-third of the worldwide population experience bullying

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Research in context

Evidence before this study

Compelling evidence supports the pervasive negative effects of bullying on health, educational, and social outcomes across the lifespan. Numerous trials have assessed the efficacy of school-based antibullying programmes. However, there is a need for more sustainable web-based programs that include students, parents, and teachers. In addition, there is insufficient information on the effectiveness of universal programmes in vulnerable populations such as youth with special educational needs. We searched PubMed, PsycINFO, and ERIC from database inception to April 30, 2023, without restrictions by language and using the search terms (effectiveness OR efficiency OR efficacy) AND (“bullying” OR “perpetrator*” OR “victim*” OR “peer violence” OR “cyberbullying” OR “anti-bullying”) AND (peer OR school) AND (“intervention” OR “curriculum” OR “prevention” OR “program” OR “school climate” OR “school-based” OR “trial”). Eligible publications were meta-analyses of original studies. Meta-analyses reported overall effectiveness of anti-bullying programmes on bullying prevention and mental health measures, with small individual effect sizes. After manual search, we found a single meta-analysis reporting on anti-

bullying interventions in young people with disabilities, which included only one randomised study.

Added value of this study

We present evidence that a multicomponent web-enabled whole-school intervention had positive effects on peer-reported bullying victimisation in primary school, with comparable, non-significant, effects in students with special educational needs. The intervention was also effective in improving mental health in students showing peer-reported victimisation at baseline. Our findings support the feasibility and potential utility of easy-to-apply anti-bullying interventions as universal and targeted preventive strategies in primary school students. This supports the idea that these interventions may have a therapeutic window in primary school ages.

Implications of all the available evidence

Antibullying programmes may be an effective strategy for primary prevention in mental health, especially in the early years of education. There is a need for sustainable interventions targeting vulnerable subgroups to improve outcomes in young people.

victimisation in their lifetime.^{8,9} These rates are even higher in some vulnerable populations, such as young people with special educational needs (SEN) or disabilities and other minorities.⁹ Schools are essential environments for development of socio-emotional skills and peer relationships and offer a unique opportunity to deliver preventive strategies during childhood and adolescence.^{10,11} Addressing bullying through school-based programmes may be an effective preventive intervention for mental health.¹²

The results of a recent meta-analysis by our group support the effectiveness of school anti-bullying programmes in reducing bullying and improving mental health in children and adolescents.¹³ In fact, the population impact of anti-bullying programmes is greater than that of taking aspirin to prevent death during the six months after a first non-haemorrhagic stroke or of vaccinating girls against human papillomavirus to prevent cervical cancer.¹³ Cost-effectiveness analyses have also shown that anti-bullying interventions result in significant savings to society.¹⁴ Previous studies also suggest that the effects of anti-bullying interventions may be maintained over follow-ups ranging from 1 to 144 weeks and that they could be effective for both primary and secondary school students.¹³

Addressing the complexity of the phenomenon of bullying may require comprehensive and systemic approaches that promote the participation of teachers, students, and families.¹⁵ Despite compelling evidence supporting the effectiveness and cost-effectiveness of

multicomponent programmes addressing bullying, there is still a need for more sustainable interventions.¹⁶ This is because many of these programmes incur high short-term costs and require a significant time investment, which limits their applicability in some contexts. In this concern, digitally-assisted interventions could help to overcome some of these limitations.¹⁷ Increasing evidence supports the effectiveness of some digital health interventions in reducing bullying and cyberbullying, with results comparable to those reported for face-to-face interventions.¹⁸ However, less is known about the effectiveness of fully digitally-enabled comprehensive anti-bullying programmes.^{13,18}

The transition towards a more inclusive education system that mainstreams children with special educational/healthcare needs or disabilities is not without risks, as these populations experience increased likelihoods of bullying and mental disorders.^{9,19} Therefore, there is a need to assess whether universal school-based anti-bullying programmes are also effective in vulnerable populations such as SEN students or if they require specific interventions. However, evidence based on randomised trials is still lacking.²⁰

LINKlusive is a multicomponent, web-enabled, school-based anti-bullying programme that builds upon Sociescuela, an online bullying assessment tool that has been widely used in the Madrid region (by more than 100,000 students per year) in recent years.²¹ LINKlusive's innovations are in its use of a fully web-enabled intervention package that integrates all the

required components for training, assessment, and guidance for intervention delivery. It also innovates by applying sociometric assessment to guide targeted interventions and by including specific universal contents promoting respect for diversity.²¹ We aimed to develop an intervention that could be universally implemented across the educational stages where SEN are more frequently mainstreamed in our context. To account for potential differences in developmental stages, we adapted our educational contents for primary and secondary school students, as in previous comprehensive programmes addressing bullying such as KiVa.²²

We hypothesised that LINKlusive would be effective in reducing bullying victimisation after the 12-week intervention. As secondary objectives, we aimed to assess the effectiveness of the intervention i) on other bullying and mental health outcome measures, ii) in SEN students and students experiencing bullying victimisation at baseline, and iii) in subgroups based on sex and educational stage (primary vs secondary school). These subgroups were selected considering differences in bullying prevalence^{23,24} and previous evidence suggesting potential differences in effectiveness for some interventions in these subgroups.^{22,25,26} Additionally, we aimed to further explore whether intervention effects were sustained after a 1-year follow-up.

Methods

Study design and participants

During the 2018–2019 school year, we conducted a school-based, parallel, pragmatic, cluster randomised controlled trial in 20 publicly-funded primary and secondary schools in the Madrid region comparing LINKlusive with conventional practices. We used a cluster design because the intervention was delivered at the school level. All children and adolescents who were enrolled in compulsory education from year 3 onwards (ages 8–18 years at baseline) could participate in the study. To increase sample representativeness, we did not apply any exclusion criteria for students.

Fig. 1 shows the selection procedure for schools. Schools were selected from among publicly-funded primary and secondary schools enrolling youth with SEN in mainstream classrooms in the Madrid region ($n = 1882$). Inclusion criteria were as follows: i) one previous assessment of bullying with Sociescuola in the past three years, ii) peer-reported bullying victimisation rates of at least 5% in the latest available assessment with Sociescuola, and iii) for primary schools, presence of specific classrooms for children with neurodevelopmental disorders (NDD). We applied the latter criterion to enrich the sample for children with NDD, since students with SEN due to autism and other neurodevelopmental conditions mainstreamed in regular schools are preferentially assigned to schools that have such classrooms. This selection process yielded a

sample size of $n = 29$ schools ($n = 12$ primary and $n = 17$ secondary schools; see Fig. 1 for further details).

The Deontology Commission of the School of Psychology, Universidad Complutense in Madrid, Spain reviewed and approved the study. Head teacher consent was required for school participation. Written parental consent was required for use of individual data collected for the study. Information sheets and consent forms were identical in intervention and control schools. The trial was registered retrospectively after enrolment (May 2020) with the ISRCTN registry (15719015).

We followed CONSORT guidelines²⁷ for cluster-randomised trials to report our trial design, analyses, and interpretation and TIDieR reporting guidelines²⁸ to describe the intervention (see Checklists in the Supplement).

Randomisation and masking

In a first stage, we selected all schools meeting the abovementioned inclusion criteria ($n = 29$). In a second stage, we stratified the sample by educational stage (primary vs secondary school) and randomly selected five schools for each arm of the trial in each stratum using SPSS 25.0. These twenty schools (ten primary schools and ten secondary schools) were offered participation; none of them refused to participate. Due to the study design, allocation was not concealed, and the study was not blinded to participating schools or researchers. Psychological and bullying assessments were based on student reports (peer-report or self-report) on an online platform. Students were unaware of the study hypotheses and there were no direct assessments of the outcome measures by members of the research group.

Study procedures

Of the 6909 eligible participants in the twenty participating schools, 6542 (94.68%) consented and were assessed at baseline. Pupils in both groups completed bullying (i.e. peer- and self-reported measures) and self-reported mental health and quality of life assessments on the web-based platform (www.sociescuola.es) at baseline (January 2019), study endpoint (May–June 2019), and two years after the endpoint. A one-year follow-up was planned in the initial protocol, but it had to be postponed until the end of the 2020–2021 school year due to the COVID-19 pandemic, with schools still closed at the time of the planned assessment. The 12-week intervention in the experimental group took place between February and May 2019. Experimental schools did not continue the intervention between the endpoint and follow-up assessments.

Assessments were completed using computers or tablets during regular school hours in computer classrooms or in the students' regular classrooms and took approximately 30 min to complete. Sociescuola was used to identify bullying victims and perpetrators through

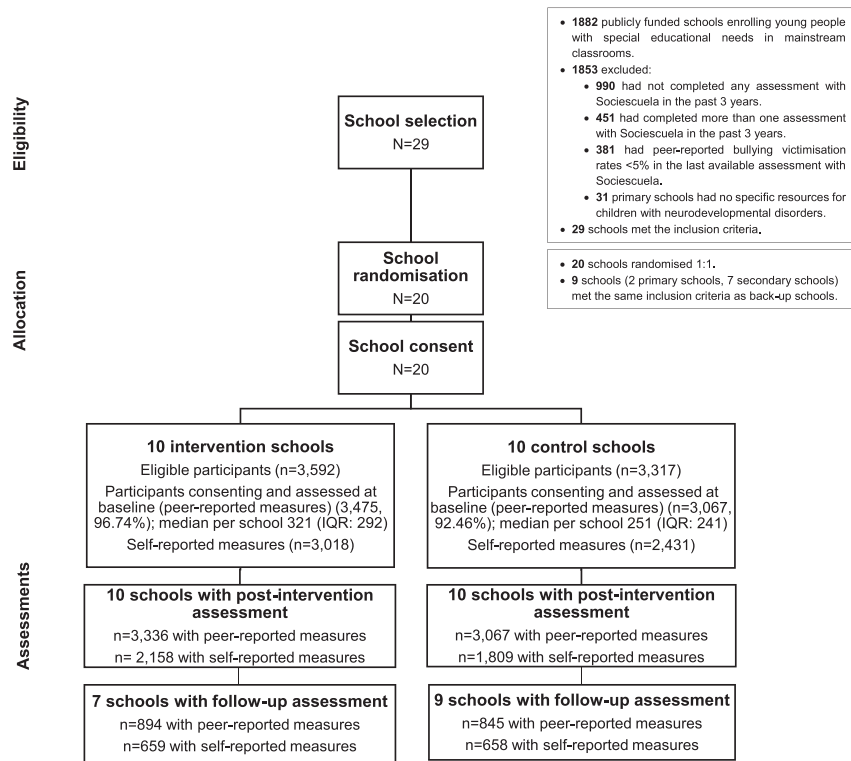


Fig. 1: Trial profile. Abbreviations: IQR, interquartile range. Sample size varied across the different self-reported bullying and psychological measures; we report sample sizes based on the number of participants with data for at least one of the self-reported measures at each visit.

analysis of social networks (social maps or sociograms) within each classroom in both experimental and control schools. Students without consent to participate in the study either did not go to the computer room or carried out an alternative activity on the computer or tablet. Teachers participating in the assessment process received instruction through the assessment platform including technical instructions on how to administer the questionnaire and what information they should convey to the students. Teachers were available in the classroom during assessments for technical questions or clarification and provided support for children with SEN and comprehension difficulties.

Experimental intervention

Experimental schools received the web-enabled LINKlusive intervention programme. The LINKlusive programme combines i) universal educational components for teachers, families, and students, and ii) a targeted component for dealing with identified bullying situations (see Supplement). We designed the multicomponent intervention considering available evidence supporting comprehensive and systemic approaches to bullying prevention.¹⁵ Furthermore, we selected specific components based on their association with intervention effectiveness in a previous meta-analysis²⁹ and their

inclusion in other comprehensive anti-bullying programmes.³⁰

The universal educational components of LINKlusive include online training for families (4 sessions) and teachers (6 sessions) and a web-enabled, teacher-delivered educational programme for students (10 sessions lasting about 40 min each during regular school hours). This educational content uses two methods to create a preventive school culture and improve school climate: 1) increasing knowledge of bullying and fostering attitudes and strategies for addressing it effectively and 2) promoting socio-emotional learning and respect for diversity to facilitate integration of those perceived as different, who are frequently bullying targets. The educational contents can be accessed at www.linklusive.org.

The web-guided targeted intervention programme for identified bullying situations is based on a combination of teacher-delivered classroom organisation and peer-support strategies, and school counsellor-delivered activities and exercises for bullying victims and perpetrators based on their individual profiles. The targeted programme aims to identify and intervene early in bullying situations to prevent their chronification and the incidence of new cases. It aims to address some of the mechanisms underlying bullying initiation and

perpetuation, including conditions of the peer group (e.g. social hierarchy, aggressive group norms, presence of attitudes favouring bullying) and social status of the victim within the classroom (e.g. lacking social support, high peer rejection). This is accomplished by modifying the group's social architecture and dynamics and providing targeted support to victims and perpetrators. A demo version of the assessment tool and intervention plans can be found at www.linklusive.org.

A voluntary feasibility study was conducted during the 2018–2019 school year in six publicly-funded primary and secondary schools in the Madrid region to test a preliminary version of the LINKlusive web-enabled intervention programme. There was no overlap between schools participating in the feasibility study and schools participating in the trial. The intervention was feasible and well accepted by participants. Teachers provided feedback on the materials and the online assessment and intervention platform and collected opinions from students. This feedback was later incorporated into the final version of the [Study Protocol](#).³⁰

Control condition

All participating schools received standard anti-bullying strategies available in the Madrid region, including established school- and region-specific anti-bullying protocols for identified cases. Control schools did not receive any interventions or information from the online assessment platform other than the social maps or sociograms and did not have access to LINKlusive's educational programme.

Further details of the intervention and the [Study Protocol](#) can be found in the Supplement and elsewhere.³⁰

Primary outcome measure

The primary outcome measure of the trial was peer-reported bullying victimisation at study endpoint. Peer reported bullying victimisation was assessed by analysing the group structure and social networks within the classroom with Sociescucla.³⁰ In brief, students provide peer nominations and ratings of their social preferences. We defined peer-reported victimisation and perpetration as receiving at least two peer nominations as either victims or perpetrators in any of the items of the Sociescucla victimisation subscale.²¹ Sociescucla was previously validated in a large sample of Spanish children and adolescents and found to have appropriate psychometric properties, with Cronbach's alpha for the victimisation subscale of 0.73.²¹

While self-reported measures have long been the conventional method for assessing bullying, there is growing acknowledgment of their limitations. These limitations include the lack of anonymity in self-reports³¹ and some students' reluctance to identify themselves as victims of bullying.^{32,33} These factors may

contribute, at least in part, to the relatively weak correlations observed between self-reported and peer-reported measures of bullying.¹⁹ We chose peer-reported bullying victimisation as our main outcome measure. This decision was made to leverage all the information provided by Sociescucla, while also considering limitations to recognising and providing an accurate self-report of bullying situations in young people with SEN, especially in those with difficulties interpreting social situations.²⁰

Secondary outcome measures

Secondary outcome measures were peer-reported bullying victimisation at follow-up and peer-reported bullying perpetration, self-reported bullying victimisation and perpetration, and psychological measures at study endpoint and follow-up.

We collected self-reported bullying victimisation and perpetration experiences using a specifically designed 16-item questionnaire, previously used and validated in Spanish students.³⁴ It assesses the intensity and frequency of social, verbal, and physical bullying and cyberbullying plus one global item. For purposes of this study, we identified bullying victims and perpetrators as those who responded that they engaged in at least one of the behaviours specified in the questionnaire at least once or twice a month.

The study also assessed psychological measures including general psychopathology, depressive symptoms, psychotic-like experiences, self-esteem, and quality of life. General psychopathology was assessed using the Internalising and Externalising subscales of the self-report version of the Spanish Strengths and Difficulties Questionnaire (SDQ). Cronbach's alphas for the self-report version of the Internalising and Externalising scales in previous studies were 0.66 and 0.76, respectively.³⁵ Both subscales show good convergent and discriminant validity across informants and clinical disorders and may be preferable to individual scales for low-risk samples such as ours.³⁶

Depressive symptoms were assessed using nine selected items from the Major Depression Disorder subscale of the Revised Child Anxiety and Depression Scale, which measures child-reported depression and anxiety symptoms with good validity and reliability.³⁷ This version was used in previous bullying studies, with good internal consistency (Cronbach's alpha 0.81).³⁸ Psychotic-like experiences were assessed with a selection of 15 items from the Spanish version of the CAPE (Community Assessment of Psychic Experiences) that assess the positive symptom dimension.^{39,40} Self-esteem was assessed with a 10-item adapted version of the Rosenberg Self-Esteem Scale, a self-report questionnaire that assesses self-esteem with good internal consistency (Cronbach's alpha ranging from 0.77 to 0.88) and test-retest reliability (correlations in the range of 0.82 and 0.88).⁴¹ This adapted version was validated in

Spanish children and adolescents and found to have good internal consistency in a previous study (Cronbach's alpha 0.81).⁴² Health-related quality of life was assessed with the Spanish self-report version of the KIDscreen-10.⁴³ The KIDscreen assesses quality of life from the perspective of the young person's mental, physical, and social wellbeing. It was developed and validated for children and adolescents 8–18 years of age in 13 EU countries.⁴⁴ The KIDscreen-10 is based on a Rasch analysis of the KIDscreen-27 version and shows adequate validity, internal consistency (Cronbach's alpha 0.82), and test-retest reliability ($r = 0.73$; ICC = 0.72).^{43,45}

Other measures

Demographic information (self-reported age and sex) was collected through Sociescuola. The socio-economic level of the participating school was estimated using statistical data from the district or town published by the Spanish National Statistics Institute. Form teachers identified students with SEN and recorded their educational diagnoses, as provided by psychoeducational guidance teams (see [Supplementary Table S1](#)), and specific resources for children with NDD available at each school through Sociescuola. For purposes of this study, the SEN group included students receiving educational support due to neurodevelopmental or psychiatric conditions. Following the Madrid Department of Education policies, students with SEN were integrated either full- or part-time into regular classrooms. SEN students with full-time integration receive pedagogic support within their regular classroom. SEN students with part-time integration spend between one- and two-thirds of the time with their peer group in their regular classrooms and receive complementary pedagogic and social support through specific activities in a specialised classroom during the remaining school hours. SEN students assigned to these classrooms also receive support to facilitate integration into the regular classroom as well as during unstructured activities such as recess.³⁰

With the support of a non-profit organisation working with this population, we developed two adapted versions of the peer- and self-reported bullying questionnaires for young people with mild intellectual disability and autism (using pictograms). These were feasibility-tested by young people with NDD.

We collected information using ad-hoc questionnaires or data from the online platform on additional anti-bullying activities available at all the participating schools. We also collected programme completion information (e.g. percentage of teachers and parents completing the training online, number of classrooms participating in the intervention at each school, mean number of educational programme sessions completed at each school) in the intervention group schools.

Statistical analyses

We used the following data to determine the necessary sample size: i) an estimated bullying point-prevalence rate of 3.8% in the largest study conducted in a representative sample of the Spanish adolescent population,³⁴ ii) data suggesting 20–50% reductions in bullying rates with previous effective interventions,²⁹ and iii) an estimated population sample size of 100,000 students (based on previous Sociescuola usage data in the Madrid region). On that basis, a sample size of [388 to 2148] students was needed to detect absolute reductions in prevalence rates of [0.8% to 1.9%] with a power of 80% and a significance level of 5%. We used a standard mean estimation of the intraclass correlation coefficient (ICC) of 0.05 and estimated a cluster size for each classroom of 21.⁴⁶ This yielded a design effect or variance inflation ratio of 2 and a target sample size of [776 to 4296] pupils. To reach an approximate sample size of 4200 pupils, twenty schools comprising a total of approximately 200 classrooms were needed.

We conducted an intention-to-treat (ITT) analysis as our main analysis. A secondary per-protocol analysis included classrooms that i) had participated in both the baseline and post-intervention assessments and ii) in the case of experimental schools, had completed at least 6 sessions of the student educational programme.

We performed separate multi-level generalised mixed (logistic or linear) regression models to assess the effect of treatment group on the primary outcome measure (i.e. peer-reported bullying victimisation) and each secondary outcome measure. We included fixed effects of treatment group (experimental vs control), time as a categorical variable with either two (baseline and endpoint) or three (baseline, endpoint, and follow-up) levels, as applicable, and the interaction between treatment group and time. We examined the estimates of the fixed coefficients for the intervention (relative to the control group) at endpoint or follow-up (relative to baseline) to compare differences in change from baseline to each of these timepoints between the two treatment arms. The school and classroom were included as random-effect variables, while the individual was included as a repeated-effect variable, to account for correlations within schools and classrooms and repeated measures within participants, respectively.

In a second set of adjusted analyses, we adjusted the models for i) school variables: socio-economic status – i.e. low mean per capita yearly income (<14,000 euros) of the neighbourhood or town where the school was located vs medium-high–, percentage of migrants, school size –large (i.e. >400 pupils) vs medium-small–, and educational stage –primary vs secondary school–, ii) classroom variables: number of pupils per classroom, and iii) individual variables: age and sex.

We performed planned secondary subgroup analyses by sex and educational level at study endpoint. We assessed the effect of the interaction between either

subgroup, treatment group, and time in the fully adjusted models and conducted stratified analyses by sex and educational level for each outcome.

To assess the targeted effect of the intervention in the vulnerable groups of SEN and bullying victims, we conducted sensitivity analyses at study endpoint. This was carried out i) in the subgroup of SEN students in primary school (considering the significant effect in the primary school subgroup), ii) including only classrooms with at least one student with SEN, and iii) in the subgroup of students with peer-reported bullying victimisation at baseline.

To test the effects of concomitant interventions and adherence to the intervention on our main outcome measure, we performed three sets of sensitivity analyses for peer-reported bullying victimisation in i) the whole sample, ii) primary school, and iii) SEN in primary school at study endpoint after excluding a) schools participating in complementary activities ($n = 4$), b) experimental schools not completing a mean of at least 7 sessions of the student educational programme ($n = 3$), and c) experimental schools where families had not completed a mean of at least 2 sessions of the educational programme ($n = 4$).

For continuous outcome measures, we report unadjusted and adjusted mean differences with 95% confidence intervals (CI) and adjusted effect sizes (standardised mean difference; SMD). For binary outcome measures, we report unadjusted and adjusted odds ratios (OR) with 95% CI, based on the mixed regression model estimates. All the analyses were done in SPSS 25.0. Statistical tests were two-tailed, and statistical significance was set at 5%. We applied a false discovery rate (FDR) Bonferroni-Hochberg correction for multiple comparisons to secondary outcome variables in the main analyses. This function computes the FDR threshold for a vector of p-values. The percentage of tolerated false positives was set at 5% ($q < 0.05$).

Role of the funding source

The funder of the study played no role in study design, data collection, data analysis, data interpretation, or writing of the report.

Results

Between November 2018 and February 2019, 20 schools (10 in each group) including 6542 students (48.2% female, mean age: 12.49 ± 2.32 , [8, 18] years) in 267 classrooms were identified and recruited and completed the baseline assessment. Of those, 6403 students were assessed at study endpoint (see Fig. 1). The sample not assessed at study endpoint ($n = 139$) belonged to six classrooms in intervention schools and was overall comparable to the sample assessed at study endpoint

except for a marginal difference in age (see Supplementary Table S2).

Table 1 shows the demographic characteristics of the intervention and control groups in the ITT sample ($n = 6542$). There were 318 SEN students (4.9% of the whole sample), with 58.4% of the classrooms having at least one SEN student. Peer-reported bullying victimisation rates at baseline were 4.6% and 5.1% in the intervention and control groups, respectively. In the whole sample, there were statistically significant differences in bullying prevalence rates between primary and secondary school (8.8% vs 2.9%, OR 3.38, 95% CI [2.26, 5.05], $p < 0.001$), between boys and girls (6.1% vs 3.4%, OR 1.87, 95% CI [1.45, 2.41], $p < 0.001$), and between students with and without SEN (16.7% vs 4.2%, OR 4.49, 95% CI [3.00, 6.73], $p < 0.001$).

Out of the sample with available peer-reported data, 1093 (16.71%) and 2436 (37.24%) participants did not complete any self-reported assessments at baseline or study endpoint, respectively. Overall, males, students in primary and control schools, and students with SEN showed a higher proportion of missing self-reported data (see Supplementary Table S3). At baseline, intraclass correlation coefficients for school and classroom ranged from 0.01 to 0.12 and from 0.02 to 0.21, respectively (see Supplementary Table S4). Cronbach's alphas were >0.7 for all the self-reported psychological measures except for the externalising subscale of the SDQ ($\alpha = 0.583$; see Supplementary Table S5).

We did not find any statistically significant difference in peer-reported bullying victimisation in the baseline (OR 0.90, 95% CI [0.43, 1.90]) or endpoint assessments (OR 0.80, 95% CI [0.38, 1.67]) between the intervention and control groups. Peer-reported bullying victimisation decreased statistically significantly in both the intervention (OR 0.61, 95% CI [0.41, 0.90]) and the control (OR 0.69, 95% CI [0.51, 0.92]) groups, with no statistically significant differences over time between the two treatment groups (OR 0.89, 95% CI [0.58, 1.36]; adjusted OR (aOR) 0.89, 95% CI [0.57, 1.38]). We found a greater decrease in depression scores in the intervention relative to the control group in the unadjusted (-0.39 , 95% CI $[-0.77, -0.01]$) and adjusted (-0.40 , 95% CI $[-0.78, -0.02]$) analyses—with a small effect size (adjusted SMD -0.07). However, these results did not survive an FDR correction for multiple comparisons. There were no statistically significant change differences in any other bullying or psychological outcome measures between the intervention and control groups at study endpoint (see Table 2).

Supplementary Table S6 shows the results of the secondary subgroup analyses by educational stage and sex at study endpoint. There was a trend-level interaction effect of educational stage ($p = 0.079$) on our primary outcome measure. Stratified analyses by

	Control group	Intervention group
School characteristics		
Number of schools	10	10
Educational stage (primary school)	5 (50%)	5 (50%)
School sex mix (mixed)	10 (100%)	10 (100%)
Environment (urban)	6 (60%)	7 (70%)
School size (large)	3 (30%)	3 (30%)
Socio-economic status (medium-high mean per capita income)	5 (50%)	6 (60%)
Migrants (mean percentage)	18.47 (11.02)	21.47 (12.85)
SEN students per school (mean percentage)	5.12 (3.43)	5.71 (3.21)
Classroom characteristics		
Number of classrooms	126	141
Students per classroom, mean [range]	24.01 [9, 36]	24.64 [9, 33]
At least 1 SEN student in the classroom	72 (57.1%)	85 (60.3%)
Student characteristics		
Number of students	3067	3475
Age (years)	12.69 (2.33)	12.49 (2.32)
Sex		
Girl	1480 (48.3%)	1675 (48.2%)
Boy	1587 (51.7%)	1800 (51.8%)
Educational stage		
Primary school	908 (29.6%)	1218 (35.1%)
Secondary school	2159 (70.4%)	2257 (64.9%)
SEN (yes)	155 (5.1%)	163 (4.7%)
Peer-reported bullying victimisation (yes)	155 (5.1%)	160 (4.6%)

Abbreviations: SEN: special educational needs. Data are n (%) or mean (SD) unless otherwise specified.

Table 1: Baseline characteristics.

educational stage showed opposite effects in primary and secondary school, with a statistically significant effect of the intervention on peer-reported bullying victimisation in primary school (aOR = 0.67, 95% CI [0.47, 0.98]) and no significant effects in secondary school (Supplementary Figure S1).

For the secondary outcome measures, we found a statistically significant interaction effect of sex on internalising symptoms, with opposite effects in boys and girls and a statistically significant effect only found in girls (-0.21, 95% CI [-0.42, -0.00]). We also found a similar trend-level interaction effect (p = 0.080) of sex on quality of life, with no statistically significant effects in either boys or girls. We did not find any statistically significant interaction effects of educational stage or sex for any further bullying or psychological variables.

Considering a potential effect of the intervention on our primary outcome measure in primary school, we performed a sensitivity analysis in the primary school sample. We found no statistically significant effects on any other bullying or psychological outcome measures at study endpoint, except for a smaller decrease in externalising symptoms in the intervention relative to the control group (adjusted mean difference 0.27, 95% CI [0.10, 0.45], SMD 0.16) (see Supplementary Table S7).

A per-protocol analysis showed comparable results for all variables for the whole sample and for the primary school subgroup at study endpoint (Supplementary Tables S8 and S9).

A sensitivity analysis in the subsample of SEN students in primary school showed a comparable effect size, in terms of direction and magnitude, to that found for the primary school subgroup for the primary outcome measure. However, it was not statistically significant (OR 0.56, 95% CI [0.22, 1.39]), p = .209; aOR 0.54, 95% CI [0.19, 1.50], p = 0.235; Supplementary Figure S1). Sensitivity analyses of classrooms including at least one SEN student showed larger effects on peer-reported bullying victimisation and depression at study endpoint relative to those found in the main analyses both in the whole sample and in primary school. Effects were comparable for other variables (Supplementary Tables S10 and S11).

Supplementary Figure S2 and Supplementary Table S12 show exploratory analyses assessing changes in psychological measures at study endpoint in the subsample with peer-reported bullying victimisation at baseline (n = 315). In this subsample, peer-reported bullying victimisation decreased more in the intervention than in the control group (76.8% vs 63.2%, p = 0.002). The fully adjusted models showed greater

Intervention group	Control group			Differences in change from baseline to the study endpoint in the intervention group compared to the change in the control group			Differences in change from baseline to follow-up in the intervention group compared to the change in the control group					
	Baseline n = 3475	Endpoint n = 3336	Follow-up n = 894	Baseline n = 3067	Endpoint n = 3067	Follow-up n = 845	Unadjusted OR, (95% CI), p	Adjusted OR, (95% CI), p	Unadjusted OR, (95% CI), p	Adjusted OR, (95% CI), p		
Bullying measures												
Peer-reported victimisation	160 (4.6%)	99 (3.0%)	25 (2.8%)	155 (5.1%)	110 (3.6%)	15 (1.8%)	0.89, [0.58, 1.36], p = 0.590	0.89, [0.58, 1.37], p = 0.342	1.57, [0.58, 4.29], p = 0.378	1.61, [0.60, 4.33], p = 0.342		
Peer-reported perpetration	144 (4.1%)	86 (2.6%)	12 (1.3%)	121 (3.9%)	63 (2.1%)	19 (2.2%)	1.18, [0.50, 2.75], p = 0.707	1.18, [0.49, 2.83], p = 0.710	0.49, [0.20, 1.20], p = 0.120	0.47, [0.19, 1.13], p = 0.092		
Self-reported victimisation	76 (2.5%)	49 (2.3%)	23 (3.6%)	68 (2.8%)	54 (3.0%)	20 (3.1%)	0.81, [0.51, 1.28], p = 0.359	0.81, [0.51, 1.28], p = 0.369	1.12, [0.56, 2.27], p = 0.758	1.13, [0.54, 2.35], p = 0.743		
Self-reported perpetration	208 (6.9%)	161 (7.5%)	48 (7.4%)	213 (8.8%)	146 (8.1%)	61 (9.4%)	1.25, [0.88, 1.78], p = 0.206	1.24, [0.88, 1.76], p = 0.212	1.44, [0.71, 2.93], p = 0.312	1.46, [0.74, 2.89], p = 0.278		
Psychological measures	Baseline n = 2998	Endpoint n = 2139	Follow-up n = 659	Baseline n = 2414	Endpoint n = 1803	Follow-up n = 658	Unadjusted mean difference, (95% CI), p	Adjusted mean difference, (95% CI), p	Adjusted ES	Unadjusted mean difference, (95% CI), p	Adjusted mean difference, (95% CI), p	Adjusted ES
SDQ	4.95 (3.10)	4.56 (3.12)	6.64 (3.51)	5.19 (3.21)	4.83 (3.31)	6.69 (3.46)	-0.02, [-0.29, 0.25], p = 0.881	-0.04, [-0.30, 0.23], p = 0.786	-0.01	0.24, [-0.38, 0.87], p = 0.441	0.31, [-0.35, 0.98], p = 0.358	0.05
SDQ	5.98 (2.85)	5.74 (2.86)	7.45 (2.94)	6.21 (2.97)	5.84 (2.98)	7.23 (2.77)	0.13, [-0.10, 0.37], p = 0.366	0.13, [-0.11, 0.37], p = 0.297	0.03	0.51, [-0.00, 1.03], p = 0.051	0.56, [-0.01, 1.13], p = 0.053	0.11
Depression	5.92 (4.53)	5.54 (4.62)	6.39 (5.08)	6.11 (4.85)	6.08 (5.12)	6.21 (4.94)	-0.39, [-0.77, -0.01], p = 0.045	-0.40, [-0.78, -0.02], p = 0.039	-0.07	0.37, [-0.58, 1.32], p = 0.447	0.42, [-0.54, 1.37], p = 0.395	0.05
Self-esteem	18.21 (5.06)	17.89 (5.36)	17.38 (5.01)	18.32 (5.36)	18.13 (5.81)	17.25 (4.97)	-0.15, [-0.56, 0.26], p = 0.463	-0.17, [-0.58, 0.23], p = 0.402	-0.03	0.31, [-0.61, 1.22], p = 0.509	0.37, [-0.59, 1.33], p = 0.452	0.04
CAPE	10.78 (7.66)	9.89 (7.70)	10.41 (8.17)	11.20 (7.49)	10.43 (7.91)	10.70 (8.25)	-0.17, [-0.77, 0.43], p = 0.577	-0.18, [-0.78, 0.42], p = 0.547	-0.02	0.43, [-1.84, 2.70], p = 0.712	0.52, [-1.83, 2.86], p = 0.665	0.02
KIDSCREEN-10	39.71 (5.73)	39.81 (6.01)	39.76 (5.70)	39.42 (5.76)	39.49 (6.35)	39.74 (5.43)	0.03, [-0.61, 0.68], p = 0.920	0.03, [-0.61, 0.67], p = 0.931	0.00	-0.36, [-1.06, 0.33], p = 0.306	-0.37, [-1.00, 0.26], p = 0.250	-0.06

Effects are odds ratios for bullying measures and mean differences for psychological measures. Effects are based on the fixed coefficients for the intervention group (relative to the control group) at either study endpoint or follow-up (relative to baseline) and reflect differences between treatment arms in changes in each variable from baseline to each of those timepoints. Unadjusted effects are based on the model including time as categorical variable with three levels (baseline, endpoint, and follow-up), intervention, and the interaction between time and intervention. Adjusted effects are based on the model additionally including all the covariates. Effect sizes (ES) are standardised mean differences based on the estimates from the fully adjusted model. Significant results at the uncorrected p-value threshold are shown in bold. Significant results for depression at study endpoint did not survive false discovery rate correction. Sample size varied across the different self-reported measures; we report sample sizes based on the number of participants with data for peer-reported bullying victimisation and with complete data for at least one of the self-reported psychological measures at each visit. Abbreviations: SDQ, Strengths and Difficulties Questionnaire; CAPE: Community Assessment of Psychic Experiences; KIDSCREEN-10, Health-Related Quality of Life Questionnaire for Children and Young People.

Table 2: Changes in bullying and psychological measures in the whole sample (intention-to-treat analysis).

decreases in depression scores (-1.43, 95% CI [-2.46, -0.40], adjusted SMD -0.41), and greater increases in quality of life (2.18, 95% CI [0.80, 3.56], adjusted SMD 0.45) in the intervention relative to the control group. These effects remained statistically significant after adjusting for victimisation (Supplementary Table S13). We did not find any significant interaction effects for sex or educational stage in the follow-up exploratory analyses. Effects were comparable overall in primary and secondary school and in both sexes. In the SEN subsample with peer-reported victimisation at baseline, we found larger effects for depression and smaller effects for quality of life. Due to the small sample size, we did not conduct a sensitivity analysis in the SEN subsample in primary school with peer-reported victimisation at baseline (Supplementary Table S13).

Seven experimental and nine control schools completed the follow-up visit approximately two years after the post-intervention assessment. About 26.6% of the original sample (n = 1739) completed the follow-up visit. There were no statistically significant differences in the proportion of students in the intervention

(n = 895, 25.76%) and control groups (n = 844, 27.52%) completing the follow-up. The sample completing the follow-up included more students in primary school, was younger, and had higher peer-reported victimisation rates, both at baseline and at study endpoint (see Supplementary Table S14). We did not find a statistically significant effect of the intervention on peer-reported bullying victimisation at the follow-up visit in either the whole sample (OR 1.57, 95% CI [0.58, 4.29]; aOR 1.61, 95% CI [0.60, 4.33]) or in the primary school subgroup (OR 0.88, 95% CI [0.35, 2.22]; aOR 0.90, 95% CI [0.35, 2.32]). The fully adjusted models showed a non-significant trend toward a greater decrease in peer-reported bullying perpetration in the whole sample (aOR 0.47, [0.19, 1.13]), with a statistically significant effect in the same direction and of slightly larger magnitude in the sensitivity analysis in primary school (aOR 0.31, 95% CI [0.11, 0.88]). See Table 2 and Supplementary Table S7.

See Supplement for details on concomitant anti-bullying activities and adherence to the intervention in the participating schools.

Discussion

We found that a multicomponent, web-enabled, school-based intervention targeting pupils, teachers, and parents reduced bullying victimisation in primary but not in secondary schools enrolling young people with special educational needs. Effects in primary education were comparable to those previously reported for school-based programmes overall (ES -0.150 , 95% CI $[-0.191$ to $-0.109]$, as opposed to -0.205 , 95% CI $[-0.405, -0.001]$ in our sample).¹³ We also found that, in students exposed to bullying at baseline, the intervention was associated with a significant decrease in depressive symptoms and improvement in quality of life. Although these findings should be interpreted with caution and warrant replication, they suggest the potential effectiveness of LINKlusive in younger students and bullying victims.

Even though contents were adapted for primary and secondary schools and despite comparable effectiveness of school-based anti-bullying programmes in children and adolescents in a previous meta-analysis,¹³ our results would suggest potential efficacy of the intervention at the universal level only in the younger group. This could be interpreted in different ways. First, the higher baseline prevalence in primary students gives the intervention more leeway for improvement. Second, previous evidence suggests that school-based interventions targeting social networks within the classroom such as LINKlusive may be more effective in children, for whom the classroom constitutes the main peer group, than in adolescents.^{22,47–49} Finally, as we have extensively discussed, there is the concept of therapeutic windows for primary and secondary prevention in mental health.^{12,50} Moral values (e.g. standards of right and wrong), social skills, and empathy (e.g. non-discrimination, respect for diversity) are gained throughout childhood, and a social-emotional approach may be less effective if implemented at later stages.^{51,52}

In students exposed to bullying at baseline, the intervention was associated with statistically significant improvements in wellbeing, as reflected in psychological and quality of life measures, that were not fully explained by changes in victimisation status. This supports the notion that some of the beneficial effects of school-based anti-bullying programmes targeting school climate and socio-emotional learning may go beyond the direct effects on bullying. Effect sizes in victims were overall larger than those previously reported for universal interventions,¹³ thus supporting that vulnerable populations may benefit the most in terms of mental health. The positive effects found in students exposed to bullying at baseline were comparable in primary and secondary schools. This suggests that despite a lack of effectiveness of the intervention at the universal level in secondary school students, the intervention could be effective at the targeted level across both age groups. Improvement in wellbeing, depression, and other

psychological measures in those exposed to bullying is important, considering the widespread and enduring negative effects of bullying on lifetime health and socioeconomic outcomes.⁵³ Evidence also suggests that shortening the duration of mental health disorders in youth could reduce the risk of adverse psychiatric outcomes in adulthood.⁵⁴

Few studies have focussed on bullying behaviour in the vulnerable population of children and adolescents with SEN and even fewer have directly assessed the efficacy of anti-bullying interventions in this population.²⁰ In our sample, bullying victimisation was 4.5 times more likely in SEN students. Although our study was not sufficiently powered to assess efficacy in this subpopulation, exploratory sensitivity analyses showed larger effects for peer-reported bullying victimisation and depression when assessing classrooms including SEN only. They also showed an effect size for the subgroup of SEN students in primary school comparable to that found for the overall primary school sample. We also found a statistically significant effect of the intervention on depressive symptoms in SEN students exposed to bullying at baseline, with larger effects than those found in the whole sample. Although these results warrant replication in a larger sample, this seems an important finding given the current tendency to integrate SEN students into mainstream schools and the lack of interventions to reduce bullying and improve wellbeing in this vulnerable population.

Overall, the intervention was well accepted and adherence rates were high, with roughly 98% of the included classrooms completing at least six sessions of the educational programme and the endpoint assessment. Integration of the content into a platform that is already available and widely used facilitated programme implementation. The web-enabled, teacher-delivered nature of the programme further supports its feasibility and potential sustainability, even in contexts with relatively low resources. Contrary to our expectations, families completed a mean of only two of the four educational programme sessions. Considering that excluding schools in which families completed a mean of fewer than two sessions led to larger overall effects, future studies should try to increase family participation in the educational programme.

This study has several limitations. First, the bullying assessment method used in both treatment groups may also identify victims and guide interventions in the control group. Since *Sociescuela* is widely used in the Madrid region, it would seem ethically inappropriate not to provide this information to the control group. Second, bullying prevalence rates were relatively low in our sample, and several centres received concomitant interventions. This potentially limited our capability to detect significant effectiveness of the intervention. Sensitivity analyses showed higher bullying prevalence rates at baseline and greater effectiveness of the

intervention in centres not receiving concomitant interventions, thus suggesting a potential floor effect in our main analyses. Furthermore, we used an estimated ICC of 0.05 for classrooms to calculate sample size, but post-hoc analyses revealed higher ICC for schools and classrooms in our sample, thus supporting that our analyses may have been underpowered for our main outcome measure. Larger studies are warranted. Third, due to COVID-19, students were in lockdown at the intended follow-up one year after the intervention, which therefore had to be done two years after the intervention. This caused a higher attrition rate, as data were missing for students who left school during these two years, and the effect of the intervention may have had a greater chance of fading away over that time. Furthermore, the sample completing the follow-up had greater bullying prevalence rates both at baseline and study endpoint, which may also have influenced our results. Fourth, the presence of teachers and peers in the room during assessments and student awareness of being assessed in the school environment may influence their replies. Nevertheless, teachers do not have access to individual student victimisation or perpetration status, the names of those providing the peer nominations, or individual test results for self-reported psychological measures, and efforts are made to maximise confidentiality during assessments. Fifth, the sample size for students and schools in the stratified analyses by educational stage was small, and we did not use additional stratification variables for randomisation, which may increase the risk of unbalanced samples in each stratum. Sixth, schools were offered to participate and completed the baseline assessment after randomisation and allocation to the intervention arms. However, no school refused to participate in either intervention group, and all measures were collected from students who were not aware of study hypotheses or intervention allocation before the baseline assessment. Seventh, considering the number of missing data for self-reported variables, especially in the control group, the secondary results on self-reported bullying and psychological outcomes need to be interpreted with caution. Eighth, we did not collect information on relevant variables such as individual socio-economic status, ethnicity, or educational outcomes. Ninth, although schools participating in the trial were representative of schools in the Madrid region in terms of urbanicity, migration rates, and mean yearly income,⁵⁵ generalisability of the study results to other contexts may be limited. Finally, our design does not allow us to identify which components may be more efficacious and what may work better for whom.

Preventive interventions in schools aimed at improving school climate and reducing bullying are of the utmost importance. A recently released WHO report recommends that mental health interventions be more ecological and take place at the community

level, including in schools.⁵⁶ At the same time, the concept of primary prevention in psychiatry and mental health has gained momentum in the last decade.^{12,57,58} In different systematic “meta-umbrella” syntheses of umbrella reviews, we have previously shown that childhood adversities such as bullying are among the most robust modifiable risk factors for developing severe mental disorders, including psychotic disorders.^{59,60} In fact, evidence from the UK suggests that young people who are frequently bullied are 2.5 times more likely to use mental health services, both in childhood and adolescence, than non-bullied young people. Furthermore, this association carries over into midlife where they still have a 30% higher likelihood of using such services than their non-bullied peers.⁶¹

In summary, there may be windows of opportunity for school anti-bullying programmes, with more likelihood of a positive impact in primary than in secondary school. Vulnerable students, including students exposed to bullying and those with special educational needs, may benefit the most from these interventions.

Contributors

CA and CDC contributed to conceptualisation, funding acquisition, and methodology of the study. JMB and MHD designed the assessment platform, elaborated the educational materials, and developed the personalised intervention plans. JMB, MAP, and RAC supported assessments at schools. ISM provided support for implementation of the trial at publicly funded schools in the Madrid region. JMB and CDC directly accessed and verified the data. CDC conducted the statistical analyses. All authors had full access to all the data in the study, have reviewed and approved the manuscript, and accept responsibility for the decision to submit for publication.

Data sharing statement

Deidentified individual data that underlie the results reported in this article and the data dictionary will be available after publication to researchers who provide a sound methodological proposal. Proposals should be directed to carango@hggm.es. To gain access, data requestors will need to sign a data access agreement.

Declaration of interests

CA has been a consultant to or has received honoraria or grants from Acadia, AMGEN, Angelini, AstraZeneca, Bristol-Myers-Squibb, Caja Navarra, Comunidad de Madrid, Exeltis, Fundación Alicia Koplowitz, Fundación Familia Alonso, Fundación Mutua Madrileña, Gedeon Richter, Instituto de Salud Carlos III (Spanish Ministry of Science and Innovation), Janssen Cilag, Lundbeck, Minerva, Ministerio de Educación, NARSAD, Otsuka, Roche, Sage, Sanofi, Schering Plough, Servier, Shire, Stanley Foundation, Sumitomo Dainippon Pharma, Sunovion, Takeda, and Teva. JMB developed the Sociescuela software, which is managed by a non-profit company. CDC has received grant support from Instituto de Salud Carlos III (Spanish Ministry of Science and Innovation), honoraria from Exeltis and Angelini, and travel support from Janssen and Angelini. The remaining authors declare no conflict of interest related to this work.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.eclinm.2024.102427>.

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