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Efficacy of a web-enabled, school-based, preventative intervention on bullying prevalence and mental health in children and adolescents

Submission date
14/05/2020

Recruitment status
No longer recruiting

Registration date
20/05/2020

Overall study status
Completed

Last Edited
06/02/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Background and study aims
Approximately 10-15% of children and adolescents have experienced bullying victimization in their lifetime. Exposure to bullying is associated with an increased risk of mental and physical health problems. Children with disabilities are at greater risk of suffering from bullying and mental disorders. Making anti-bullying interventions web-enabled may increase their applicability to different settings and incur significantly lower costs than traditional interventions.

This project aims to evaluate the efficacy of a specific, web-enabled, school-based bullying prevention intervention in reducing bullying behavior as well as to analyze the effects of such intervention on psychological measures and quality of life in children and adolescents.

Who can participate?
Students attending publicly funded primary and secondary schools in the region of Madrid.

What does the study involve?
Twenty public schools enrolling children with special educational needs in regular classrooms are randomly allocated to one of two groups. Ten schools will receive a web-enabled, school-based preventive intervention targeting bullying behavior and promoting respect to diversity for 12 weeks. This intervention consists of an online training programme for teachers and parents, an educational programme for pupils, and a targeted intervention for victims and bullies. Materials and sessions have been adapted for children with special educational needs.

The other ten schools will not receive any specific intervention besides anti-bullying policies already available in the region of Madrid.

Before the study begins pupils will be invite to complete a web-enabled assessment about bullying behavior that they have experienced or witnessed, their mental health and wellbeing,

and quality of life. This assessment will be repeated after the intervention and then again after 1 year.

What are the possible benefits and risks of participating?
It is expected that the schools and participants may benefit from identifying bullying situations through the online platform in both treatment arms and from the intervention in the intervention arm. The participants may also contribute to improving knowledge of school bullying and development of anti-bullying preventive strategies. This is a minimal risk research study testing a preventive educational programme. There are no expected risks directly derived from the intervention. Adverse events are not assessed at the individual level. If there are negative outcomes at the school level, researchers may decide to terminate the trial.

Where is the study run from?
The study is coordinated by
1. The Department of Research and Psychology in Education, Universidad Complutense (Spain)
2. The Department of Child and Adolescent Psychiatry, Hospital General Universitario Gregorio Marañón (Spain)
The trial will be conducted at publicly funded schools in the Madrid region.

When is the study starting and how long is it expected to run for?
From January 2017 to June 2020

Who is funding the study?
1. Instituto de Salud Carlos III, Spanish Ministry of Science, and Innovation (Spain)
2. The European Regional Development Fund, "A way of making Europe" (EU)

Who is the main contact?
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Type(s)
Public

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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
Efficacy of a school-based preventative intervention on bullying prevalence and mental health in children and adolescents: a cluster-randomized trial

Acronym
LINKlusive

Study objectives
A web-enabled, school-based preventive intervention targeting bullying and promoting respect for diversity will be associated with a reduction in bullying prevalence, improved mental health and quality of life in children and adolescents receiving the intervention relative to the control group.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 21/01/2019, The Deontology Commission at the School of Psychology of Universidad Complutense (Campus de Somosaguas, 28223, Pozuelo de Alarcón, Madrid, Spain; lelopezb@psi.ucm.es; +34 91 394 3095), ref: 2018/19-005

Study design
Controlled parallel school-based cluster-randomized trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
School

Study type(s)
Prevention

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
Bullying, bullying victimization, mental health

Interventions
Twenty public schools are randomised 1:1 to either a preventive intervention or the control condition.

The intervention group receives a school-based web-enabled bullying prevention programme (LINKlusive) over approximately 12 weeks. The intervention consists of three main components: i) an online training programme for teachers and parents, ii) a web-guided educational programme for students, focusing on promoting respect for diversity, empathy, and social skill development, and iii) a web-guided, teacher-delivered, targeted intervention programme for those involved in bullying situations based on peer-support strategies.

The control group receives usual practice (including anti-bullying strategies already in place in publicly funded schools in the Madrid region) for the same period.

Participants are assessed at baseline, after the intervention (12 weeks), and one year after the intervention.

Multi-stage cluster sampling is done among publicly funded schools in Madrid. In a first stage, all schools fulfilling inclusion criteria are selected. In a second stage, these centres are randomised 1:1 to the intervention and control groups. Ten schools (5 primary schools and 5 secondary schools) are offered participation in each cluster, with a list of back-up schools in case of refusal to participate.

Intervention Type
Mixed

Primary outcome measure
Peer-reported bullying victimization measured using student-provided peer nominations and ratings of their social preferences collected through a web-based platform (www.sociescuela.es) to develop social maps at baseline, 12 weeks, and one year after the intervention ends. Sociescuela is a web-based bullying assessment instrument and is composed of three subscales: i) a victimisation subscale, ii) an acceptance subscale, and iii) a subscale of perceived attributes, which helps identify different victim profiles (e.g. active vs. passive).

Secondary outcome measures
1. Self-reported bullying and victimization measured using a self-report questionnaire collected through a web-based platform (www.sociescuela.es) at baseline, 12 weeks, and one year after the intervention ends. This specifically designed questionnaire, assesses different bullying behaviours and their intensity and frequency, and is based on customary bullying definitions and previous questionnaires used in other bullying prevention programmes such as KiVA.

2. Psychological measures of general psychopathology, psychotic-like experiences, depressive symptoms, and self-esteem are measured using questionnaires collected through a web-based platform (www.sociescuela.es) at baseline, 12 weeks, and one year after the intervention ends. General psychopathology is assessed using the self-report Spanish version of the Strengths and Difficulties Questionnaire (SDQ). Internalising and externalising psychopathology are measured with the internalising and externalising subscales of the SDQ. Positive psychotic-like experiences are assessed with the Spanish version of the Community Assessment of Psychic Experiences (CAPE-P15). Depressive symptoms are assessed using nine selected items on the Major Depression Disorder subscale of the Revised Child Anxiety and Depression Scale. Self-esteem is assessed with an adapted version of the Rosenberg self-esteem scale.
3. Quality of life measured using the Spanish version of the KIDscreen-10 via a web-based platform (www.sociescuela.es) at baseline, 12 weeks, and one year after the intervention ends

Overall study start date
01/01/2017

Completion date
30/06/2020

Eligibility

Key inclusion criteria
1. Primary and secondary publicly funded schools in the Madrid region where
1.1. Headteacher consent is provided
1.2. Pupils with special educational needs are enrolled in regular classrooms and/or specialized educational services for children with neurodevelopmental disorders are provided
2. Pupils enrolled in participating schools
2.1. Parental consent is given for participation
2.2. Aged 8 to 16 years (primary school grades 3 to 6 and secondary school grades 1 to 4)
3. Teachers at participating schools primary schools, teaching primary school grades 3 to 6 or secondary school grades 1 to 4 who agree to participate in the study

Participant type(s)
Learner/student

Age group
Child

Lower age limit
8 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
20 schools (10 intervention, 10 control)

Total final enrolment
20

Key exclusion criteria
Private or concerted schools will not be included

Date of first enrolment
01/11/2018

Date of final enrolment
31/01/2019

Locations

Countries of recruitment
Spain

Study participating centre
Universidad Complutense de Madrid
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School of Psychology
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Sponsor type
Not defined

Funder(s)

Funder type
Government

Funder Name
Ministerio de Ciencia e Innovación, Instituto de Salud Carlos III

Funder Name
European Regional Development Fund

Alternative Name(s)
Europski Fond za Regionalni Razvoj, Den Europæiske Fond for Regionaludvikling, Europees Fonds voor Regionale Ontwikkeling, Euroopa Regionaalarengu Fond, Fonds Européen de Développement Régional, Europäischer Fonds für regionale Entwicklung, Európai Regionális Fejlesztési Alap, Fondo Europeo di Sviluppo Regionale, Eiropas Reģionālās attīstības fonds, Europos Regionines Pletros Fondas, Europejski Fundusz Rozwoju Regionalnego, Fundo Europeu de Desenvolvimento Regional, Fondul European de Dezvoltare Regională, Európsky Fond Regionálneho Rozvoja, Fondo Europeo de Desarrollo Regional, Европейски фонд за регионално развитие, Evropský fond pro regionální rozvoj, Ευρωπαϊκό Ταμείο Περιφερειακής Ανάπτυξης, Il-Fond Ewropew għall-Iżvilupp Reġjonali, Evropski sklad za regionalni razvoj, Euroopan aluekehitysrahasto, Europeiska regionala utvecklingsfonden, ERDF, FEDER, EFRE, ΕΦΠΑ, EFRR, EFRU, ERFi, ETPA, FEDER, FESR, ERAF, ERPF, ERFA, L-FEŻR, EFRO, EFRR, FEDR, ESRR, EAKR, Eruf

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Results and Publications

Publication and dissemination plan
Planned publication in high-impact peer-reviewed journal

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The datasets generated during the current study will be available upon request from the principal investigator after de-identification. Individual de-identified data will be available for researchers who provide a methodologically sound research proposal, to conduct the analyses required to achieve the aims included in the approved proposal. These proposals should fulfill all the applicable ethical and legal requirements. To gain access, data requestors will need to sign a data access agreement. Proposals should be directed to carango@hggm.es. This data will become will available immediately after the main paper has been published, with no end date.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		26/04/2021	17/05/2021	Yes	No
Results article		26/01/2024	06/02/2024	Yes	No