

# Three gold-standard evaluations in Portugal, Czechia and the UK of an augmented social play intervention (Lina) to test its effects on belonging and costs for schools

<b>Submission date</b> 15/09/2025	<b>Recruitment status</b> Not yet recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 15/09/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 15/09/2025	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Mental ill-health and social isolation have rapidly increased among young people, particularly after the COVID-19 pandemic. A sense of belongingness has been shown to play a significant role in alleviating loneliness and improving mental health and wellbeing for young people. Positive school experiences are strongly associated with students' sense of belonging, especially in secondary schools. Further, evidence suggests that a strong sense of belonging at school is linked to increased pro-social behaviour, reduced school violence, bullying, and mental illness. The ASPbelong programme has developed Augmented Social Play (ASP), which is a novel approach that uses smartphones to deliver real-world group experiences in a classroom. It combines immersive storytelling, augmented reality, collaborative face-to-face gameplay and evidence-based psychotherapeutic principles to boost pupils' mental health while fostering a greater sense of belonging. Building on this work, ASP#1 (Lina) is a full-scale, multi-session intervention that is delivered within the context of routine school lessons.

This study aims to establish whether Lina increases students' sense of belonging and has a positive impact on students' mental health and wellbeing. It also aims to examine the real-term cost of Lina to schools, compared to standard lessons.. The study will also examine the mechanisms through which Lina has an impact on these outcomes, the most robust way of implementing Lina in schools, and students' and teachers' experiences of playing Lina across very diverse contexts. The study will take place in parallel in Portugal, Czechia and the UK and will examine results from each country separately before examining them across the three countries.

### Who can participate?

Secondary school students aged 12-13 years (year 7 or 8, depending on the country) in Portugal, Czechia, and the United Kingdom. All students can participate irrespective of gender and whether or not they are experiencing mental health challenges.

What does the study involve?

Classes taking part in the study will receive 6 weekly sessions of Lina during regular school lessons. Control classes will continue to do standard school activities, and will be placed on a waitlist - these classes will experience Lina in the following academic year.

Students will complete questionnaires/surveys at three time points:

1. Before the sessions start (baseline)
2. Immediately after the sessions (6–10 weeks after baseline)
3. Six months after baseline

The surveys will ask about:

1. Sense of belonging in the classroom
2. Mental health and wellbeing (including feelings of depression and social anxiety)
3. Social awareness and emotional skills
4. Loneliness
5. Stigmatisation

Some students and teachers will also be invited to interviews and/or focus group discussions to share their experiences of participating and facilitating Lina.

What are the possible benefits and risks of participating?

Benefits:

1. Improved sense of belonging in the classroom
2. Potential improvements in mental health and wellbeing
3. Opportunity to participate in engaging, collaborative, and fun classroom activities
4. Contributing to research that may help other students in the future
5. Inclusion of schools in a large, international trial

Risks:

1. The measures cover topics such as mental health and wellbeing, experiences of belongingness, and relationships with peers - this could potentially trigger upsetting emotions, and be reminders of personal issues. In order to mitigate this risk, we have refined and reviewed all measures/topic guides with young people to ensure that questions are not distressing. We are also planning on working in close collaboration with schools (and particularly teachers) to ensure that there is adequate support for all young people.
2. Since focus groups are not confidential, all participants will be able to hear each other's views, and therefore information could be shared more widely. In order to mitigate this, we will be reinforcing "rules of the room" at the start and end to reiterate the importance of confidentiality and safeguarding.
3. We will be collecting some sensitive/personal information from participants, for example, salary information from teachers for estimating resources/costs. Some participants might be uncomfortable with sharing this information.

Where is the study run from?

The trial is sponsored by the University of Birmingham, coordinated by the ASPbelong Consortium, and will involve schools and research teams in Portugal, Czechia, and the United Kingdom.

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

The study will take place during the 2025/26 school year, with follow-up surveys six months after baseline data collection. Additional evaluation will continue into the 2026/27 school year.

Who is funding the study?

1. HORIZON EUROPE Framework Programme, European Union
2. UK Research and Innovation (UKRI)

Who is the main contact?

UK - Prof. Kate Anne Woodcock, k.a.woodcock.bham.ac.uk

CZ - Mgr. Alžběta Šašinková, strnadova@phil.muni.cz

PT - Dr. Vítor Alexandre Coelho, vitorpcoelho@gmail.com

### **Study website**

<https://www.augmentedsocialplay.com/>

## **Contact information**

### **Type(s)**

Public, Scientific, Principal Investigator

### **Contact name**

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### **Contact details**

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## **Additional identifiers**

### **EudraCT/CTIS number**

Nil known

### **IRAS number**

### **ClinicalTrials.gov number**

Nil known

### **Secondary identifying numbers**

HORIZON EUROPE grant agreement ID 101080665

## **Study information**

### **Scientific Title**

Three cluster randomised controlled trials in Portugal, Czechia, and the United Kingdom testing the effectiveness and cost-effectiveness of an Augmented Social Play intervention (Lina) versus usual school provision in supporting sense of belonging among young people

### **Acronym**

## **Study objectives**

### **BACKGROUND AND RATIONALE**

Social isolation and consequent mental ill-health are rising among young people. Positive secondary school experiences have been linked to increased school belonging, which has further links with improved psychological wellbeing and pro-social behaviour.

The ASPbelong programme of research has previously developed a novel intervention that makes use of Augmented Social Play (ASP). ASP uses smartphones to deliver real-world group experiences in a classroom that combines immersive storytelling, augmented reality, collaborative face-to-face gameplay and evidence-based psychotherapeutic principles to boost individuals' mental health by fostering a greater sense of belonging within a classroom context. Drawing on this developmental work, the ASPbelong Consortium have co-produced Lina, a full-scale, multi-session intervention that is delivered within the context of routine school lessons.

Whilst feasibility has been established through previous work, the effectiveness of the intervention is yet to be established. The current trial is therefore the next step in developing Lina and demonstrating its effectiveness on a variety of wellbeing and mental health outcomes, but primarily on sense of belonging. The trial and embedded implementation evaluation will give definitive answers as to how effective this novel intervention is across three national contexts. As well as producing understanding about the best ways to implement the intervention into routine school activities across a number of different contexts.

### **PRIMARY OBJECTIVE**

The primary aim of the trials is to assess the effectiveness of Lina in improving children's sense of belonging within a classroom environment in Portugal, Czechia and the United Kingdom.

### **SECONDARY OBJECTIVES**

1. To test the impact of Lina on improving young people's mental health and wellbeing (more broadly and, specifically, in terms of depression and social anxiety)
2. To test the impact of Lina on other secondary outcomes, including social awareness, loneliness and young people's stigmatising beliefs.
3. To collect the costs of delivering the intervention in comparison to routine school costs, and conduct a comprehensive economic evaluation to establish whether Lina presents good value for money.

### **FURTHER OBJECTIVES**

1. To conduct an embedded implementation evaluation to investigate how Lina is delivered in schools both within and outside of a trial setting.
2. Understand adolescents' and teachers' experiences of participating in Lina through interviews and focus groups, and evaluate how the intervention can be adapted to meet the mental health needs of vulnerable adolescents.

## **Ethics approval required**

Ethics approval required

## **Ethics approval(s)**

1. Approved 06/05/2025, Science, Technology, Engineering and Mathematics Committee (University of Birmingham, Edgbaston, Birmingham, B15 2TT, United Kingdom; +44 (0)121 414 3344; [ethics-queries@contacts.bham.ac.uk](mailto:ethics-queries@contacts.bham.ac.uk)), ref: ERN\_3004-May2025

2. Approved 08/09/2025, Comissão de Ética e Deontologia da Faculdade de Psicologia (Faculdade de Psicologia, Alameda da Universidade, Lisboa, 1649-013, Portugal; +351 217 943 655; deontologia@fp.ul.pt), ref: -

3. Submitted 15/09/2025, Etická Komise pro výzkum Masarykovy Univerzity (Research Ethics Committee at Masaryk University) (Masarykova Univerzita, Žerotínovo nám. 617/9, Brno 602 00, Česká republika, Brno, 602 00, Czech Republic; +420 549 49 6290; ekv@muni.cz), ref: EKV-2022-090

## **Study design**

Cluster randomized parallel-group controlled school-based trial in three countries

## **Primary study design**

Interventional

## **Secondary study design**

Cluster randomised trial

## **Study setting(s)**

School

## **Study type(s)**

Efficacy

## **Participant information sheet**

## **Health condition(s) or problem(s) studied**

Sense of belonging and mental health and wellbeing

## **Interventions**

### **DESIGN**

The study is a school-based trial in three countries. Three separate trials will be conducted concurrently in Portugal (PT), Czechia (CZ) and the United Kingdom (UK). Overall, these three parallel trials will employ the same design, although there will be some differences to accommodate local contexts. Pre-identified variations are highlighted in the protocol.

### **INTERVENTION**

The intervention under investigation (ASP#1, called Lina) is a newly developed software designed to enhance students' sense of social belonging through a blended approach of interactive gameplay facilitated by smartphones in a classroom setting. All necessary equipment, including smartphones, routers, headphones, and markers, will be provided by the trial team to the class.

The intervention is primarily user-driven but will be guided by the classroom teacher. Additionally, a researcher (or an Educational Psychologist in Portugal) will be present during every session to make observational notes and support usage, where required. The intervention consists of six sessions called "episodes". Four of these episodes will be delivered on a provided individual smartphone, whilst two will be "analogue episodes" and will be structured and interactive sessions within the classroom to enhance the sense of belonging and embed the psychotherapeutic principles inherent in the intervention. The order will be as follows:

- Lesson 1: Lina episode 1

- Lesson 2: Lina episode 2
- Lesson 3: Analogue session 1
- Lesson 4: Lina episode 3
- Lesson 5: Lina episode 4
- Lesson 5: Analogue session 2

Each episode will be followed by a short (5-10 minute) debrief, also facilitated by a smartphone.

During the four Lina episodes, each student plays a character in a fictional class. The episodes follow the story of a girl called Lina, a classmate who abruptly left the school. Lina had been secretive, and at times, Lina's behaviour seemed unusual or difficult to understand. The class collectively decides to uncover what happened to her. Players examine objects Lina left behind using augmented reality, revisit shared memories, and piece together the story. By the final episode, they learn that Lina has been caring for her mother, who struggles with a mental illness that has profoundly affected their daily lives. Lina and her mother have moved to live with Lina's aunt, allowing her mother to receive support while Lina returns to her previous school.

Gameplay emphasises collaboration and problem-solving, both individually and in varying group sizes. Students (and occasionally the teacher) work together to solve puzzles, exchange information, and help one another progress. Group compositions are intentionally mixed throughout the sessions to ensure every student interacts with their peers.

Using Lina's story, the teacher-led analogue sessions help students process the narrative and deepen their understanding of the themes explored (e.g., perspective taking, empathy, impact of mental health struggles). Students and their teacher reflect on the overall experience, their classroom dynamics and their sense of belonging within the group. This enables contextualisation of the main learning themes.

All necessary materials (PowerPoint slides, picture cards for grouping students, post-it notes, paper, and pens) for these analogue sessions will be supplied by the trial team.

It is recommended to schools that each of the six Lina sessions be delivered weekly for six weeks within a single term. However, due to the pragmatic nature of the trial and the understanding that schools (both within and between countries) structure lessons in different ways, schools may choose to deliver the sessions at different frequencies or across shorter or longer time periods (e.g., some schools may choose to deliver two sessions of Lina a week for three weeks). The variation in delivery will be collected as the observational data and form part of the analysis. Irrespective of the intervention delivery, follow-up outcome measures will be collected at 6-10 weeks after the date of baseline.

## CONTROL GROUP

Control group classrooms will receive routine lessons based on the established local curriculum as normal.

Classrooms that are randomised to the control arms of the three trials will be "wait-listed" and asked to complete Lina after the trial is completed, most likely at the start of the 2026/27 school year. Control classes and teachers who do use the intervention after trial completion will be followed up on as part of the implementation evaluation.

## RANDOMISATION AND ALLOCATION

The trial will employ a cluster randomised design, with class being the unit of randomisation. Whole classes will be randomised to either the Lina or the control group arm.

Randomisation will be conducted in blocks of 2 or 4 in all country sites. The randomisation scheme may be amended as and when the full list of participating trial schools is known, and how many classes per school will need to be randomised. Any future amendment to the randomisation scheme will be made to ensure that there is at least one class in the intervention arm per school and to ensure that while there may be some variations across schools, the allocations should be balanced within each country.

Randomisation will occur only when: schools have agreed to be part of the trial; appropriate classes that meet the inclusion criteria have been identified; adolescents have agreed to the study, and all students have been allocated to the class. Once these terms have been met, then randomisation can be triggered. Randomisation will occur before participant baseline data collection. The allocation ratio will be 1:1.

The randomisation will be carried out remotely by the trial statistician at Queen Mary, University of London, who will run the randomisation code to produce a STATA output randomly assigning the class to either intervention or control.

Classes within schools will be randomised at the same time (where possible), and the school and individual teachers will be informed of their allocation by the local research assistant or the trial manager. It is estimated that there will be an average of four classes per school involved in the trial (with a possible range of 2-7 classes per school).

#### **MASKING/BLINDING**

Due to the nature of the intervention under investigation and the cluster design of the trial, blinding participants (and teachers) to their allocation will not be possible. Baseline data will be collected post-randomisation, but before the start of the intervention, to avoid allocation bias. Participants in the class will not be informed of allocation before baseline data collection (although teachers might be aware due to pragmatic considerations around lesson planning, for example).

In the Czechia and UK trial, researchers facilitating the baseline, post-intervention, and 6-month follow-up will be blinded to allocation. Each group will remain blinded to the allocation of the schools assigned to the other group for the entire duration of the trial, allowing them to collect data in those schools without knowledge of allocation.

Due to researcher capacity in Portugal, blinding will not be possible at any of the post-intervention follow-ups (i.e., T1 and T2).

#### **IMPLEMENTATION EVALUATION**

Individual young people will be included in the trial if they are 12-13 years old, part of a class with similarly aged students and assent to the collection of personal data at key timepoints through the trial (baseline, 6-10 weeks post baseline, and 6 months post baseline). From this trial sample, a subsample of young people will be invited to attend an interview or focus group as part of the study's implementation evaluation.

#### **Intervention Type**

Behavioural

#### **Primary outcome measure**

Sense of belonging/ class climate as measured by the Delaware School Climate Survey- Student (DSCS-S) at post-intervention (6-10 weeks after baseline)

## Secondary outcome measures

The following is a list of core secondary outcome measures that will be collected across all three trials at post-intervention (6-10 weeks after baseline) and follow-up (6 months after baseline). All measures have been validated for use with adolescents, and in all 3 countries:

1. General well-being as measured using the WHO-5
2. Depression severity as measured using PHQ-8
3. Adolescents' social anxiety experiences in the context of peer relations as measured by the Social Anxiety Scale for Adolescents (SAS-A)
4. Loneliness as measured by UCLA Loneliness Scale
5. Children and adolescents' social awareness competency as measured by the SSIS Social Emotional Learning Scale-brief version. Social Awareness subscale
6. Peer stigma as measured by Peer Mental Health Stigmatisation Scale-Revised (PMHSS-R) Stigma Awareness subscale
7. Youth general quality of life (as part of economic evaluation) as measured by EQ-5D-Y-3L
8. Measure of health and a tool to calculate QALYs for adolescents as measured by CHU-9D

## Overall study start date

06/05/2025

## Completion date

31/12/2026

# Eligibility

## Key inclusion criteria

Schools will be included as 'trial schools' if they:

1. Are a school in Portugal, Czechia or the UK who have classes of students aged 12-13
2. Agree to support the delivery of Lina as part of routine school activities in the 2025/26 academic year
3. Agree to the process of randomisation, with the understanding that classes which are randomly allocated to the control group will have to wait until the 2026/27 school year to implement Lina

Individual young people will be included in the trial if:

1. They are 12-13 years old
2. They are part of a class with similarly aged students
3. Assent to the collection of personal data at key timepoints through the trial (baseline, 6-10 weeks post baseline, and 6 months post baseline)

## Participant type(s)

Employee, Learner/student

## Age group

Child

## Lower age limit

12 Years

## Upper age limit

13 Years



**Sex**  
Both

### **Target number of participants**

A full sample size calculation has been conducted by the trial statistical team. Based on an assumed small to medium effect size (Cohen's  $d = 0.4$ ), a conservative ICC of 0.1, which takes into account the clustering at the class and school level, and a design effect of 2.7, 40 classes per country will provide 90% power ( $\alpha = 0.05$ ). The analysable trial sample assumes an average cluster size of 18, (a total of 720 participants per country). To allow for an anticipated drop-out rate of 20%, an average cluster size of 22 will be recruited at baseline (i.e., average 22 adolescents per classroom), thus giving a total sample size of 880 per country. The cluster size of 22 at baseline takes into account the variability in class sizes within and across each country, and expected number of participants who opt out of the study. SIZE OF INTERVIEW AND FOCUS GROUP SAMPLE: For the post-trial interviews and focus groups it is predicted that there will be a maximum of 160 young people per country invited to participate in the evaluative qualitative work (up to 120 young people invited to a focus group, and 40 young people invited to be interviewed.) For teachers, there is predicted to be 20 teachers per country eligible to be interviewed or invited to a focus group.

### **Key exclusion criteria**

Young people will be excluded from the trial if:

1. They have a parent or guardian who explicitly requests that they be opted out of the trial
2. They do not assent (personally) to the collection of their personal data as part of trial outcome measures

Even if a young person, or a parent or guardian, requests that the young person be excluded from the study and they "opt out" of participation, the young person will still receive Lina as part of routine school activities. The "opt out" refers to the completion of the trial outcome measures and questionnaires only.

### **Date of first enrolment**

22/09/2025

### **Date of final enrolment**

30/01/2026

## **Locations**

### **Countries of recruitment**

Czech Republic

England

Portugal

United Kingdom

### **Study participating centre**

**Shireland Collegiate Academy**

Waterloo Road  
Smethwick  
United Kingdom  
B66 4ND

**Study participating centre****Windsor Academy Trust**

Trinity Point, High St  
Halesowen  
United Kingdom  
B63 3HY

**Study participating centre****Holyhead School**

Milestone Lane, Handsworth  
Birmingham  
United Kingdom  
B21 0HN

**Study participating centre****Small Heath School**

Muntz St, Small Heath  
Birmingham  
United Kingdom  
B10 9RX

**Study participating centre****Blue Coat Church of England Academy**

Birmingham Street  
Walsall  
United Kingdom  
WS1 2ND

**Study participating centre****Eden Girls' Leadership Academy, Birmingham**

256 Hob Moor Road  
Small Heath  
Birmingham  
United Kingdom  
B10 9HH

**Study participating centre**

**Alsager School**

Hassall Road

Alsager

Stoke-on-trent

United Kingdom

ST7 2HR

**Study participating centre**

**ZŠ Husova**

Husova 17

Brno

Czech Republic

602 00

**Study participating centre**

**ZŠ nám. Svornosti**

nám. Svornosti 7/2571, 616 00 Brno-Žabovřesky, Czechia

Brno

Czech Republic

616 00

**Study participating centre**

**ZŠ Heyrovského**

Heyrovského 611/32, 635 00 Brno-Bystrc, Czechia

Brno

Czech Republic

635 00

**Study participating centre**

**Tyršova ZŠ**

Kuldova 38, Zábrdovice, 615 00 Brno-Židenice, Czechia

Brno

Czech Republic

615 00

**Study participating centre**

**ZŠ Gajdošova**

Gajdošova 3, 615 00 Brno-Židenice, Czechia  
Brno  
Czech Republic  
615 00

**Study participating centre****ZŠ a MŠ Blažkova**

Blažkova 9, 638 00 Brno-sever-Lesná, Czechia  
Brno  
Czech Republic  
638 00

**Study participating centre****ZŠ a MŠ Jana Broskvy 3**

Jana Broskvy 3, 643 00 Brno-Chrlice, Czechia  
Brno  
Czech Republic  
643 00

**Study participating centre****ZŠ Arménská**

Arménská 21, 625 00 Brno-Bohunice, Czechia  
Brno  
Czech Republic  
625 00

**Study participating centre****ZŠ a MŠ nám. 28. října**

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Brno  
Czech Republic  
602 00

**Study participating centre****ZŠ Hroznová 1**

Hroznová 1, 603 00 Brno-střed, Czechia  
Brno  
Czech Republic  
603 00

**Study participating centre**

**Masarykova ZŠ a MŠ Zemědělská**

Zemědělská 29, 613 00 Brno-sever-Černá Pole, Czechia

Brno

Czech Republic

613 00

**Study participating centre**

**ZŠ Úvoz 55**

Úvoz 423/55, 602 00 Brno-střed-Veveří, Czechia

Brno

Czech Republic

602 00

**Study participating centre**

**ZŠ Řehořova**

Řehořova 3, 618 00 Brno-Černovice, Czechia

Brno

Czech Republic

618 00

**Study participating centre**

**ZŠ a MŠ Křenová**

Křenová 21, 602 00 Brno-střed-Trnitá, Czechia

Brno

Czech Republic

602 00

**Study participating centre**

**ZŠ Brno, Svážná 9**

Svážná 9, 634 00 Brno-Nový Lískovec, Czechia

Brno

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634 00

**Study participating centre**

**Masarykova ZŠ**

Kamenačky 4, 636 00 Brno-Židenice, Czechia

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**Study participating centre**

**ZŠ Slovanské náměstí 2**

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**Study participating centre**

**ZŠ Košínova**

Košínova 22, 612 00 Brno-Královo Pole, Czechia  
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**Study participating centre**

**Escola Básica e Secundária do Cadaval**

Rua Aristides de Sousa Mendes  
Cadaval  
Portugal  
2550-007

**Study participating centre**

**Escola Básica dos 2º e 3º Ciclos de Freiria**

Rua da Escola, nº15  
Freiria  
Portugal  
2565-321

**Study participating centre**

**Escola Básica de São Gonçalo**

Estrada da Serra da Vila

Torres Vedras

Portugal

2560 - 581

**Study participating centre**

**Escola Básica de 2º e 3º Ciclo Padre Francisco Soares**

Praça Dr. Sá Carneiro

Torres Vedras

Portugal

2560-295

**Study participating centre**

**Escola Básica de 2º e 3º Ciclo do Maxial**

Rua da Escola Preparatória, nº2

Maxial

Portugal

2565-463

**Study participating centre**

**Escola Básica 2º e 3º Gaspar Campello**

Avenida 21 de junho, nº29

Campelos

Portugal

2565-007

**Study participating centre**

**Escola Básica Padre Vítor Melícias**

Rua 25 de Abril nº1-Boavista-Olheiros

Torres Vedras

Portugal

2560-373

**Study participating centre**

**Escola Secundária Henriques Nogueira**

Rua Henriques Nogueira

Torres Vedras

Portugal

2560-341

**Study participating centre**

**Escola Secundária com 3.º ciclo de Francisco Simões**

Rua Jorge Pereira, nº2A

Almada

Portugal

2810-436

## **Sponsor information**

**Organisation**

University of Birmingham

**Sponsor details**

School of Psychology, Edgbaston

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B15 2TT

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psy-enquiries@contacts.bham.ac.uk

**Sponsor type**

University/education

**Website**

<https://www.birmingham.ac.uk/>

**ROR**

<https://ror.org/03angcq70>

## **Funder(s)**

**Funder type**

Government

**Funder Name**

HORIZON EUROPE Framework Programme

**Alternative Name(s)**

Horizon Europe, Horizon Europe Programme, Framework Programme, Horizon Europe, EU Framework Programme, Horizon



**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location****Funder Name**

UK Research and Innovation

**Alternative Name(s)**

UKRI

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

Trial findings will be disseminated following the dissemination policy established as part of the wider Horizon Europe-funded ASPbelong project.

The project comprises of a dedicated work package focussed on developing a high-level dissemination and communication strategy. This includes identifying barrier-beliefs, stakeholder mapping, and ongoing engagement with schools and wider networks across the project. We will use these networks to share findings with relevant actors, including schools, education authorities, and other stakeholders.

In addition, key study findings are planned for publication in peer-reviewed journals, to fulfil the wider Horizon Europe-funded ASPbelong project's deliverables.

**Intention to publish date**

31/08/2027

**Individual participant data (IPD) sharing plan****DATA STORAGE AND SHARING**

Research data will be retained and archived on a non-publicly available repository i.e. REDCap (on a secure local server called Research FIRST) at the University of Birmingham, in accordance with the Research Governance Framework.

The trial team will also regularly export the most up-to-date version of the database, therefore maintaining a local “backup” of the database on the University of Birmingham Research Data Store (RDS), a central storage service for active or working research data. The data will be exported as a STATA file for purposes of analysis.

All data from the three countries (Portugal, Czechia and the UK) will be maintained on the REDCap databases following the ASP-Belong Consortium Data Management Plan and formal data sharing agreements. The University of Birmingham will be the data controller for all three trials. Data from the three trials will be kept separate within the databases for data management and analysis.

#### END OF STUDY AND ARCHIVING

After the final version of the trial data has been exported from the REDCap database, it will be stored on the University of Birmingham Research Data Store (RDS). Once analysis is complete, the final dataset will be transferred to the Birmingham Environment for Academic Research (BEAR) hosted by the University of Birmingham, for long-term digital storage. Overseen and governed by the Research Computing Management Committee, the BEAR Archive offers secure archiving for longer-term storage of data. It is planned that the trial team will store up to 20TB of data for 10 years. Costs for long-term archiving are covered by the grant. The PI will be the custodian of the data.

#### ANONYMISATION

1. Personal information: All personal data will be pseudonymised to maintain confidentiality. All participants at the point of recruitment will be assigned a unique identifier (Subject ID) that will be used for all data management and processing purposes. Identifiable data (i.e. participants' names, contact details, socio-demographic data) and the list (cypher) linking these data with the Subject ID will be stored on the University of Birmingham RDS and will only be accessible to the approved members of the research team. All hard copies of data, including interview/ focus consent forms, will be kept in lockable filing cabinets on University of Birmingham premises.

2. Quantitative Data: Participant data collected as part of trial activities will be automatically entered onto an online REDCap database via secure API, from the study smartphones where the trial data is collected. All data stored on the database will be pseudonymised by using the Subject ID as the identifier. The database will be accessed by researchers working on the project, and user profiles will be assigned by the ITM ResearchFirst service at the University of Birmingham.

Although participant data will be collected electronically, researchers will carry paper copies of all surveys as a backup in case of technical issues (for example, no access to the internet). In the event of paper-based data collection, the raw participant data will be entered on REDCap and stored in a different storage unit at each implementing site (UoB, MU, ATV) than the consent forms to maintain confidentiality.

3. Qualitative Data: Qualitative data will be recorded and transcribed in the local language, and pseudo-anonymised and analysed by native speakers of that language, in the first instance. All audio recordings will be deleted after transcription. Transcribed data will be stored locally on password-protected University computers and analysed using NVivo software. All data will eventually be translated into English to allow for comparison across the three datasets. All references to names, locations or treatment teams will be removed and replaced with pseudonyms.

4. **Observational Data:** Researchers facilitating Lina will be collecting observational data as per a structured observational form. Observational data will not include any personal or identifiable details of any participants, and will include information on class-level engagement, activities, layout of the room, technical challenges, etc.

## CONSENT

As Lina will have been approved to be delivered by the schools as part of routine teaching, prior to recruitment of the classes, the consent-taking process will not follow usual procedures. Schools signing up to the trial will have already decided that the intervention does not differ significantly enough in terms of risk or content from standard school activities to require that any consent be required from individual students for them to partake in the Lina experience. This is critical to the successful delivery of the intervention as the intervention requires the inclusion of whole classes of young people. Thus, for the trial, consent will specifically mean consent for completing trial measures and the contribution of trial data.

1. **Effectiveness Evaluation:** A combination of opt-out parental consent along with opt-in young person's assent will be used, with context-specific variations across countries. Adolescents and their parents will be informed about the study and allowed to ask any questions about the research towards the end of the 2024-2025 academic year. The study team will organise information events and assemblies at each school to give information about the trial and outline what is involved so that adolescents and parents/carers are fully informed. We will also inform parents regarding procedures to mitigate stress - all measures have been refined and developed in close collaboration with young people. In order to do this in the best possible way, we will work with schools to identify the best way of reaching all relevant parents. For instance, in the UK, members of the research team might attend a parents' evening in the 2025 summer term to talk to all attending parents about the study, answer any concerns, share information on refinement and development of all measures with young people, and distribute information sheets. All written information will be sent to parents and adolescents again at the beginning of September 2025. A minimum of 1 additional week will be provided for parents or young people to opt out of the research.

"Opt-out" parental consent has been used in school studies of this type previously (e.g. DEER study [<https://doi.org/10.1186/ISRCTN12430839>]) to improve recruitment, reduce researcher burden and improve engagement and information-giving with participants and parents/carers. At the beginning of the baseline data-collection session, researchers will explain the study and encourage young people to ask any questions they have. Young people will also be provided with a summary of the study information, emphasising that participation is voluntary. Initial questions presented via the online questionnaire system will ask adolescents to indicate whether the study has been explained to them, whether they have had the opportunity to ask questions, whether they understand what they will be asked to do, and whether they wish to take part. The system will not allow progression if any of these questions are answered negatively. Researchers will make it clear to young people that if they want to ask more questions, they can just put their hand up. However, young people will not be asked to put their hand up if they do not wish to agree to the research. In such cases, we will arrange with the teacher in advance that all young people have something else with them (e.g. a book, some class work) that they can do during the lesson.

In Czech schools, a combination of opt-out parental consent along with opt-in young person's assent will be used.

2. **Implementation Evaluation:** Teachers will be given information sheets to elaborate on what participation will entail. Teachers will then be asked to sign and date a consent form to document that they are happy to complete measures, are able to opt out of any questions at their discretion, and participate in focus groups.

3. Qualitative Evaluation of Young People's Experiences: Young people volunteering to participate, or who are indicated by teachers to meet our inclusion criteria, will be provided with a written information sheet for themselves and their parents, parental consent and young person assent forms. Only those young people whose parents provide written consent and who provide written assent will participate. All documents will clearly inform participants about what participation in the study entails; how their data will be collected, used, and stored; and their rights to withdraw/request that their data be removed.

## DATA ANALYSIS

1. Statistical Analysis: Analysis for the three trials will be analysed separately (by country), before later being pooled for overall analysis. Participant level socio-demographic data and cluster level (classroom) data will be summarised at baseline for both arms of the trial. The primary outcome is the Delaware Class Climate score at the end of ASP#1 delivery (6-8 weeks post baseline). This will be compared between ASP#1 and control groups using a linear mixed effects model with a random effect for classroom and school, allowing for the clustering of children within classes and within schools. The model will include the baseline level of the Delaware Class Climate as a covariate, as well as demographics (which are known to affect the outcome). The analysis will use intention-to-treat by including all participants in the arm to which they were randomised, whether or not they completed the ASP#1 programme and including all students in the analysis by using multiple imputation. We will set out in the Statistical Analysis Plan (SAP) how missing data will be handled, including planned sensitivity analyses for the primary analysis. Secondary outcomes are WHO-5, PHQ-8, SAS-A, UCLA Loneliness Scale, SSIS SELb, the stigma measure, and EQ-5D-Y-3L, all measured at post-intervention (T1) and 6 months post baseline (T2). Each variable will be analysed using a generalised linear mixed effects model with a link appropriate to the outcome distribution, with random effects for classroom and school. All models will include the geographical location and baseline value of the outcome. A full statistical analysis plan (SAP) will be developed before exporting data from the database and reviewed by the trial steering committee. Data analysis will not be conducted before the final sign-off of the SAP. The SAP will be made publicly available before the data lock. Once country-level data has been analysed, then data from across the three countries will be pooled and analysed as one dataset. This will follow the analysis as described above, but with a further level of clustering at the country level. The full analysis plan for the pooled analysis will also be described in the SAP.

2. Economic Analysis: We will conduct an economic evaluation alongside the three trials. The time horizon for the evaluation will be from the point of randomisation until 6 months of follow-up. The analysis will be conducted from a school perspective.

The primary outcome measure for the economic evaluation is children's quality of life, measured by the EQ-5D-Y-3L instrument. The secondary outcomes are the CHU-9D and Delaware Class Climate score.

The resource data will include three types: i.e. delivering the ASP#1 and usual activities, supporting students' daily activities (beyond trial interventions), and school supports (provided beyond teachers). We will collect relevant unit costs to convert the quantity of resource use to monetary values. This refers to salary bands of school staff and unit costs for material uses. The cost data will be presented at the child and time point level (i.e. baseline, immediately after intervention, and 6 months follow-up).

We will assess the cost-effectiveness of the ASP#1 in comparison to usual activities from a school perspective, following the intention-to-treat principle. The economic analysis will be conducted in the first instance at the country level. A few sensitivity analyses will be conducted, including (1) applying the time period from randomisation until the end of intervention as the time horizon, (2) use CHU-9D and Delaware Class Climate score as outcome measures, (3)

conduct economic evaluation under alternative scenarios related to implementation (e.g. frequency of session delivery) to help contextualise the findings for future implementation. A Health Economic Analysis Plan (HEAP) will be signed off on before the start of the economic analysis.

3. Qualitative analysis of interviews and focus groups: Qualitative data that is generated as a result of interviews and focus groups with both young people and teachers will be transcribed in the local language and analysed by native speakers of that language, in the first instance. Transcribed data will be stored locally on password-protected University computers and analysed using NVivo software. All data will eventually be translated into English to allow for comparison across the three datasets.

Thematic analysis (Braun & Clarke, 2006) will be used to analyse the qualitative dataset. A coding frame will be created after the initial interviews and focus groups have taken place across all three countries. These coding frameworks will be country-specific, but commonalities and differences will be noted at this stage. This coding framework will then guide the analysis of the remaining data that is generated.

To ensure gender is considered throughout analysis, regular cross-site data analysis meetings will include young co-researchers and a gender champion.

4. Mixed methods analysis of implementation evaluation: The analysis of the implementation evaluation data will draw from different paradigms to gain a holistic picture of views and strategies of implementation. The first content analysis will be applied to the weekly data collected from the teacher. Thematic analysis (Braun & Clarke, 2006) will also be used, both inductively and deductively, to analyse data from the interviews and focus groups. The trial team will also look at individual-level characteristics in relation to completion rates, level of engagement and other implementational factors to understand who does and does not respond to intervention implementation and how this could be improved for certain groups. As is the case for all data analysis, analysis will happen on a country level first, followed by an overall pooled approach later on. A process evaluation analysis plan will be signed off on before the start of the analysis.

#### ACCESS TO THE FINAL DATASET

Access to the final (pseudo-anonymised) dataset will be made available to those researchers who request access following the completion and publication of the Lina trial findings. Access requests should be made formally to the study's Chief Investigator.

Details of making the final dataset publicly available will be outlined in more detail in the ASP Belong Data Management Plan.

#### LEGAL RESTRICTIONS

1. Ethics: The University of Birmingham Ethics Committee is the overall regulatory body that is responsible for giving a favourable ethical opinion for the three trials. Relatedly, the University of Birmingham will also act as the sole Sponsor for the three separate trials that are being completed as part of the ASP-Belong programme of research. Local approvals will be sought from institutional ethics committees (IECs) in Portugal and Czechia: Académico Torres Vedras and Masaryk University, respectively.

2. Risk Assessment and Management: A full risk assessment will be completed at the school level by the research team. A standardised risk assessment and mitigation form will be completed by the trial manager or local researcher for each trial school at the point they indicate interest in supporting the study. This form will identify any unique risks specific to that school, as well as general risks identified by the ASPBelong Consortium.

3. Regulatory Review and Compliance: All members of the trial team will comply with the requirements of the UK Data Protection Act 2018, as standard, about the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles throughout the study, and be GDPR compliant. As all trial data (from all three countries) will be stored in the UK, the relevant national legislation of the UK will be followed, as standard.

**IPD sharing plan summary**

Stored in non-publicly available repository