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# A feasibility study to test the feasibility and acceptability of a peer-led school-based smoking prevention intervention for adolescents


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| **Submission date**<br>06/06/2023 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[X] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[X] Record updated in last year |
| **Registration date**<br>28/09/2023 | **Overall study status**<br>Completed | |
| **Last Edited**<br>30/06/2025 | **Condition category**<br>Other | |


## Plain English summary of protocol

Background and study aims

Tobacco is the world's leading cause of avoidable poor health and premature death; around 50% of smokers will die from smoking. Smoking rates in Indonesia and the Philippines are (very) high. WHO trend models (based on existing survey data and current tobacco control initiatives) project steep increases by 2025 in adult male rates (in Indonesia [to 83%] and stable rates in the Philippines [34%]). The very high smoking rates in these countries highlight the need for youth prevention, given the evidence that few people begin smoking or become habitual smokers in adulthood. Research from the United Kingdom (UK) shows that preventing people from starting to smoke when they are young can be an effective way to tackle future adult smoking rates, as few people start smoking as adults.

ASSIST is a 'peer-led', school-based smoking prevention intervention, developed in the UK and shown to be effective there. ASSIST Global is a project to assess whether the ASSIST intervention is feasible for schools to implement, likely to make a difference in students' attitudes and behaviours and is acceptable to young people, schools and parents in Indonesia and the Philippines. The project will also test if the methods that will be used to assess ASSIST (e.g., the questionnaires participants complete) are acceptable and feasible. The evaluation will provide essential evidence to support a full-scale trial.

Who can participate?

Both state and privately funded schools in each of the two countries will be eligible. All students who are active in school (whether smokers, non-smokers or experienced smokers) will be potentially eligible to take part. ASSIST is a whole school year-group intervention, thus all students in the target school year (aged 13-14 years) will be potentially eligible to participate in the intervention and research. Students in the target school year who are outside of the 13-14 age group will not be excluded as students in the target class in Indonesia may be age 15 by public school regulation, and some students in the Philippines may have had to pause or delay their studies due to socioeconomic hardship or challenges in completing their schoolwork.

What does the study involve?
The participating schools will be allocated randomly to the intervention (to receive ASSIST) or control group (to continue with usual smoking education). The ASSIST Global approach involves recruiting Peer Supporters from the target year group who have been voted as 'most influential' by their year group (via a short questionnaire). Around 18% of the students who receive the most nominations, stratified by gender, will be invited to a recruitment meeting. Those who choose to take on the role will attend a 2-day training run by specialist trainers. Over a defined period of 10 weeks, Peer Supporters will use social media and face-to-face interaction to disseminate messages aimed at preventing smoking. They will encourage their friends/peers in their year group not to take up smoking. They will be supported – through regular meetings and via social media – by the professionals who trained them. They will also have access to ASSIST Global resources (website and moderated forum) for further support. Although only about 18% of the cohort will be trained to be Peer Supporters, the effect of the program is likely to be seen across the year group.
The researchers will conduct baseline and follow-up questionnaires in all schools. At follow-up, they will repeat the same questionnaires but also measure recent smoking exposure by exhaled carbon monoxide (eCO) measures, collected non-invasively via blowing into safe, single-use mouthpieces on Smokelyser Micro+ devices. They will also talk to students, teachers and parents about their experience of being involved in ASSIST Global. The researchers are interested in whether the intervention improves attitudes, knowledge, and risk-reduction skills, and whether these, in turn, affect self-reported weekly smoking. If the intervention is successful, they will seek funds for a full-scale evaluation in more schools.

What are the possible benefits and risks of participating?
The risk of smoking is well documented. Rates of smoking are high among young people in Indonesia and the Philippines. The potential benefits of the study include being more fully informed about the risks of smoking and if the intervention is successful, feeling confident to avoid smoking in the future. Participants will also be contributing to an international research project on an important public health problem.
Being a peer supporter is a great way to gain new knowledge and experience around smoking. The role and training may help improve confidence, communication skills, problem-solving and peer leadership skills which can be useful now (both within and outside of school) and in the future. This can also be a great addition to a young person's CV which may benefit future job applications.
ASSIST is a low-risk intervention and therefore we do not expect any serious risks to participants. This intervention has been delivered in several studies around the world, as well as in real-world settings and there have been virtually no incidences of the risks described below.
1. During the interviews there is a slight possibility young participants may become upset and local guidance will be followed in dealing with this.
2. Peer supporters may send inappropriate messages on the forum or Facebook/Whatsapp /other groups. To mitigate this the ASSIST Global trainer will moderate the forum/group.
3. Completing the questionnaires may take around an hour during school time but this will be agreed with the schools not to disrupt learning time.
4. For those students who agree to take on the Peer Supporter role (with their parent's consent), the 2-day training and subsequent activities to talk to friends in the year group, will also require some time commitment but they will learn valuable skills. The schools will ensure that provision is made for the peer supporters to catch up on anything missed.
The school will have policies in place to deal with problematic behaviours. The ASSIST Global research team and trainers will inform the school if any such behaviour occurs and expect that the School will respond as per their policy.

Where is the study run from?
University of Glasgow (UK) in collaboration with Universitas Gadjah Mada (Indonesia) and De La Salle University (Philippines)

When is the study starting and how long is it expected to run for?
May 2022 to December 2025

Who is funding the study?
Medical Research Council (UK)

Who is the main contact?
Prof. Sharon Simpson, Sharon.Simpson@glasgow.ac.uk

# Contact information


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Principal investigator

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## Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### Protocol serial number
MR/T040416/1

## Study information

### Scientific Title
Feasibility study of a peer-led, school-based, adolescent smoking prevention intervention (ASSIST) in culturally different middle-income countries

### Acronym
ASSIST Global

### Study objectives
Current study hypothesis as of 04/10/2023:
The main research question of this study relates to whether it is feasible to conduct a full-scale effectiveness evaluation of an adapted version of the ASSIST intervention in two Asian middle-income countries with different cultural, political, social and educational systems.

The hypotheses of the ASSIST study intervention are:
1. That secondary students, nominated as influential by their peers and trained as peer supporters, can prevent smoking uptake, affect improvements in smoking behaviour (their own and that of friends and family), smoking-related attitudes and knowledge.

2. That social media and informal conversations provide effective means through which peer supporters can disseminate messages about the risks of smoking and the benefits of not smoking.

Previous study hypothesis:
The main research question of this study relates to whether it is feasible to conduct a full-scale effectiveness evaluation of an adapted version of the ASSIST intervention in three Asian middle-income countries with different cultural, political, social and educational systems.

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## Ethics approval required
Ethics approval required

## Ethics approval(s)
approved 09/12/2022, College of Medical, Veterinary & Life Sciences (MVLS) Ethics Committee (University of Glasgow, Room B313, Sir Graeme Davies Building, University Avenue, Glasgow, G12 8TA, United Kingdom; +44 (0)141 330 5206; mvls-ethics-admin@glasgow.ac.uk), ref: 200210204

## Study design
Feasibility mixed methods cluster randomized controlled trial

## Primary study design
Interventional

## Study type(s)
Prevention

## Health condition(s) or problem(s) studied
Adolescent smoking prevention

## Interventions
Current interventions as of 04/10/2023:
This study will use cluster randomisation at the school level, with 10 schools being randomised to the intervention or control arms (six intervention and four control) in each country. Stratification by school year size (where necessary) and an academic measure of a school's overall performance will be used to reduce the potential for any sizeable differences between intervention and control arm baseline characteristics. Randomisation will be conducted by a member of staff at the University of Glasgow who is independent from the study team. Those in the intervention arm will receive the ASSIST intervention + usual school education on smoking and the control group will receive usual school education on smoking only.

In intervention schools, the researchers will identify (via a peer nomination process) and recruit the most influential students aged 13-14 years in Indonesia and the Philippines. These students

(called peer supporters) will attend a 2-day training run by specialist trainers which provides education on the risks of smoking and how best to disseminate anti-smoking messages and influence peers. Over a defined period of 10 weeks, the peer supporters will use social media and face-to-face interactions to spread messages among their friendship networks via informal conversations about the risks of smoking and the benefits of not smoking. They will be supported – through regular meetings and through moderated forums – by the professionals who trained them.

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In intervention schools, the researchers will identify (via a peer nomination process) and recruit the most influential students aged 13-14 years in China, Indonesia and the Philippines. These students (called peer supporters) will attend a 2-day training run by specialist trainers which provides education on the risks of smoking and how best to disseminate anti-smoking messages and influence peers. Over a defined period of 10 weeks, the peer supporters will use social media and face-to-face interactions to spread messages among their friendship networks via informal conversations about the risks of smoking and the benefits of not smoking. They will be supported – through regular meetings and through moderated forums – by the professionals who trained them.

## Intervention Type
Behavioural

## Primary outcome(s)
Current primary outcome measure as of 04/10/2023:
1. Attainment of pre-set progression criteria to progress to a full trial measured using different sources of evidence including baseline and follow-up questionnaires, a peer supporter questionnaire, interviews, attendance logs, social network analysis, researcher records, and data collection records at various timepoints throughout the study.

The progression criteria are as outlined below and there will be red/amber/green cut-offs:
1.1. Intervention acceptability and feasibility (in intervention schools)
1.1.1. Feasibility to recruit and train peer supporters measured using attendance monitoring at recruitment meetings and with training attendance logs and social network analysis
1.1.2. Ability of peer supporters to carry out the role measured using peer supporter questionnaire, follow-up attendance log, and peer supporter interviews
1.1.3. Usefulness of the ASSIST intervention to the wider target group measured using study study-developed questionnaire at a 7-month follow-up
1.1.4. Acceptability of the ASSIST Global intervention to parents/careers of peer supporters measured using peer supporter questionnaire, teacher interviews, and peer supporter interviews
1.1.5. Acceptability of the ASSIST Global intervention to participating schools measured using teacher interviews

1.2. School and participant recruitment and retention
1.2.1. Recruitment of the required number of schools measured using researcher records
1.2.2. Acceptability of the ASSIST Global study methodology to participating schools measured using teacher interviews
1.2.3. Retention of schools measured using retention records

1.3. Primary outcome measurements
1.3.1. Acceptability of opt-out rates measured using school records, and study records of opt-out (data collection records)
1.3.2. Acceptability and feasibility of questionnaires to students measured using a study-developed questionnaire at baseline and 7-month follow-up
1.3.3. Likelihood of primary outcome to be accurately measuring smoking measured using interviews; CO/self-report comparison; CO acceptability and comparison to other country data on smoking rates if available

2. Primary effectiveness outcome: self-reported weekly smoking (i.e. those reporting they smoke 1+ cigarettes weekly) measured using a study-developed questionnaire at baseline and 7 months follow-up.

All of these and the secondary outcomes will be analysed after the 7-month follow-up.

Previous primary outcome measure:
The main outcome is the attainment of preset progression criteria in order to progress to a full trial. The primary effectiveness outcome is self-reported weekly smoking measured via questionnaire (i.e. those reporting they smoke 1+ cigarettes weekly).

### Key secondary outcome(s))
1. Smoking behaviour of friends and family measured using a study-developed questionnaire at baseline and 7 months
2. E-cigarette/vaping and other forms of tobacco use measured using a study-developed questionnaire at baseline and 7 months
3. Smoking-related attitudes and knowledge measured using a study-developed questionnaire at baseline and 7 months
4. Smoking norms measured using a study-developed questionnaire at baseline and 7 months
5. Self-esteem measured using a study-developed questionnaire at baseline and 7 months
6. Spillover effects on parents and other family members they live with, measured using a study-developed questionnaire at 7 months
7. Self-efficacy measured using the Smoking Abstinence Self-Efficacy Questionnaire (SASEQ) at baseline and 7 months
8. Socio-demographics measured using a study-developed questionnaire at baseline
9. Exhaled carbon monoxide (eCO) measured using Smokelyser Micro+ at 7 months

### Completion date
31/12/2025

## Eligibility

### Key inclusion criteria
Current inclusion criteria as of 14/10/2024:

Both state and privately funded schools in each of the three countries will be eligible. All students in the target year group who are active in school (whether smokers, non-smokers or experience of smoking) will be eligible to take part

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Previous participant inclusion criteria as of 04/10/2023:

1. State and privately funded schools in each of the two countries
2. All students (aged 13-14 years old) who are active in school (whether smokers, non-smokers or experience of smoking)

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## Participant type(s)
Learner/student

## Healthy volunteers allowed
No

## Age group
Child

## Lower age limit
12 years

## Upper age limit
19 years

## Sex
All

## Total final enrolment
3389

## Key exclusion criteria
Current exclusion criteria as of 14/10/2024:

Schools:
1. For reasons of practicality school year group size will be limited to 500
2. Schools with school year groups smaller than 100 will be excluded
3. Schools with limited or poor internet access due to potential requirement to run study remotely if the COVID-19 situation dictates.
4. No single-sex schools (due to the low rates of girls smoking in some countries and also the important influence of the other gender on smoking behaviour).

Individual students:
1. Any student identified by the researchers, in consultation with teaching staff, as not having the mental and emotional capacity to consent and fully engage in the research will not be included. If a change in mental or emotional capacity occurs during the course of the study, making it difficult for students to take part, then they can be withdrawn from the research process on advice from teaching staff.
2. Other reasons for student ineligibility to consent may include learning difficulties, level of literacy and language comprehension issues.

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### Date of first enrolment
16/10/2023

### Date of final enrolment
26/11/2024

## Locations

### Countries of recruitment
China

Indonesia

Philippines

### Study participating centre
**Peking University**
Health Science Center
No. 38 Xue Yuan Rd
Haidian District
Beijing

China
100191

**Study participating centre**
**Universitas Gadjah Mada**
Bulaksumur
Yogyakarta
Indonesia
55281

**Study participating centre**
**De la Salle University**
2401 Taft Avenue
Manila
Philippines
1004

# Sponsor information

**Organisation**
University of Glasgow

**ROR**
https://ror.org/00vtgdb53

**Organisation**
De La Salle University

**ROR**
https://ror.org/04xftk194

**Organisation**
Gadjah Mada University

**ROR**
https://ror.org/03ke6d638

# Funder(s)

### Funder type
Research council

### Funder Name
Medical Research Council

### Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, Medical Research Committee and Advisory Council, MRC

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location
United Kingdom

# Results and Publications

### Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository (UK Data Archive).
The type of data that will be shared: Quantitative questionnaire and social network data after deidentification.
When the data will become available and for how long: Data available after publications are completed around March 2027 and for 10 years.
By what access criteria the data will be shared including with whom: Data will be shared with genuine researchers whose proposed use of the data has been discussed and agreed upon by the Principal Investigator with the Country Lead(s), with the requirement that any outputs generated from the data access should acknowledge the project and the MRC and cite the data using the DOI.
For what types of analyses: To achieve the aims in the proposed proposal.
By what mechanism: Access will be through the archive's standard procedures where people need to register and agree to a standard end-user licence
Whether consent from participants was obtained: Consent from participants was obtained.
Comments on data anonymisation: Data will be anonymised.

### IPD sharing plan summary
Stored in publicly available repository

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | | 22/06/2025 | 24/06/2025 | Yes | No |