

Development and evaluation of a school-based smoking prevention intervention for 13-14 year old adolescents in Malaysia

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| Submission date 23/05/2016 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 25/05/2016 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 02/03/2022 | Condition category Mental and Behavioural Disorders | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Cigarette smoking is the primary cause of premature death in Malaysia. Adolescent smoking is a particular problem, at around 20.2%. Preventing teenagers from smoking and encouraging them to stay off cigarettes are particularly important public health objectives for the Malaysian government. It is possible that adolescents may listen to their peers more with regards to smoking attitudes and behaviour than to adults. The aim of this study is to develop a school-based peer-led anti-smoking programme for 13-14 year olds in the Malaysian state of Sabah and evaluate its effectiveness in relation to smoking-related attitudes and behaviour.

Who can participate?

All Form 1 pupils attending the eight selected schools who attended school on the day of questionnaire administration.

What does the study involve?

Participating schools are randomly allocated to one of two groups. Schools in the first group continue with their usual practice of health promotion, such as health talks targeted at the whole school. A selection of pupils attending schools in the second group, take part in the three day training programme to be anti-smoking peer supporters. This involves watching videos, having talks and discussions and taking part in role playing and team building exercises. On returning to school, the pupils are asked to have informal anti-smoking conversations with their classmates. For pupils who took part in the peer educator programme, immediately before, at the start of the third day and at the end of the third day, a number of questionnaires are completed about their attitudes to smoking. Additionally, at the start of the study and then again after 7 months, all Form 1 pupils complete a number of questionnaires about whether they have talked to a peer educator about smoking and their attitudes towards smoking.

What are the possible benefits and risks of participating?

Participants may benefit from the training which included tips on how to communicate with other people. There is a small risk that some participants may experience mocking by their classmates for attempting to promote non-smoking.

Where is the study run from?

The study is run from the Sabah Health Department and takes place in eight schools located in Sabah (Malaysia)

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

March 2011 to March 2012

Who is funding the study?

1. Ministry of Health Malaysia (Malaysia)
2. The Health Promotion Unit, Sabah Health Department (Malaysia)
3. The Non-Communicable Disease Unit, Sabah Health Department (Malaysia)

Who is the main contact?

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Contact information

Type(s)

Public

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

UPE:40/200/19/2761

Study information

Scientific Title

A pilot pragmatic cluster randomised control trial of a school-based peer-led anti-smoking intervention for 13-14 year olds in Malaysia

Study objectives

Trained anti-smoking peer supporters will promote non-smoking among their 13-14 year old Malaysian classmates through informal conversations.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. Research Promotion and Co-ordination Committee of the Economic Planning Unit of The Prime Minister's Department in Malaysia
2. Biomedical Research Ethics Committee, University of Warwick

Study design

Pilot pragmatic cluster randomised control 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 the contact details below to request a patient information sheet.

Health condition(s) or problem(s) studied

Adolescent smoking

Interventions

Schools are randomly allocated to one of two groups through concealed stratified randomisation.

Control arm: Schools in the control arm receive usual care in the form of health promotion activities such as health talks that targeted the whole school, delivered by designated Health Promotion Officers who had attended a briefing session that focussed on guidelines for these activities.

Intervention arm: Schools in the Intervention arm receive usual care plus the intervention. The intervention focuses on training pupils over three days off school premises to be anti-smoking peer supporters. Examples of activities during the training programme are:

1. Watching videos of the contents of cigarettes
2. Role plays of a variety of scripted scenarios some of which were smoking-related scenarios

3. Lectures on for example the important elements of communication and tips on how to be a good listener
 4. Team building exercises
 5. Reflection session on commitment to family
 6. Practicing how to use the log book to record their smoking-related activity on their return to school after training
- On return to school peer educators are asked to have informal anti-smoking conversations with their classmates.

Baseline and follow-up questionnaires were administered to all form 1 pupils in the control and intervention arms of the study who were present on the day of administration. Follow up questionnaires were administered 7 months after baseline questionnaires and 6 months after the peer supporters had been trained.

Intervention Type

Behavioural

Primary outcome measure

Smoking is measured via self-report questions at baseline and 7 months.

Secondary outcome measures

Peer educators:

1. Smoking-related knowledge is measured using a questionnaire specifically designed for the purpose of this study immediately before the peer educator training at the beginning of the three day peer educator training programme and at the end of the three day peer educator training programme
2. Smoking-related attitudes are measured using a questionnaire specifically designed for the purpose of this study immediately before the peer educator training at the beginning of the three day peer educator training programme and at the end of the three day peer educator training programme

All Form 1 pupils:

1. Proportion of pupils who have had one-to-one conversations about smoking at 7 months is measured via the follow-up questionnaires that were administered to all Form 1 students who were present on the day of administration
2. Components of the Theory of Planned Behaviour (Attitudes, Subjective Norms, Perceived Behavioural Control and Smoking Intention) are measured using a questionnaire specifically designed for the purpose of this study at baseline and 7 months

Overall study start date

01/05/2011

Completion date

31/03/2012

Eligibility

Key inclusion criteria

All Form 1 students attending the 8 selected schools who attended school on the day that the baseline and follow-up questionnaires were administered at their school.

Participant type(s)

Other

Age group

Child

Sex

Both

Target number of participants

Schools n=8. Schools in intervention arm n=4, Schools in control arm n=4. Total number of students on class registers; Intervention schools n=1122; Control schools n=996

Key exclusion criteria

Pupils who were absent on the day of questionnaire administration.

Date of first enrolment

25/05/2011

Date of final enrolment

28/02/2012

Locations**Countries of recruitment**

Malaysia

Study participating centre**Sabah Health Department**

Level 3, Federal House

Mat Salleh Street

Sabah

Kota Kinabalu

Malaysia

88590

Study participating centre**SMK Shantao**

Batu 3, Jalan Tuaran, Likas

P.O.Box 11080

Sabah

Kota Kinabalu

Malaysia

88811

Study participating centre

SMK Kolombong

Jalan Nountun, Inanam
P.O.Box A-155
Sabah
Kota Kinabalu
Malaysia
89357

Study participating centre

SMK Likas

Jalan Kompleks Likas
P.O.Box 235
Sabah
Kota Kinabalu
Malaysia
88856

Study participating centre

SMK Inanam

Jalan Tuaran Lintas Kg Kalansanan
P.O.Box A-290
Sabah
Inanam
Malaysia
89357

Study participating centre

SMK Apin Apin

KM20, Jalan Keningau Kota Kinabalu
P.O.Box 464
Sabah
Keningau
Malaysia
89008

Study participating centre

SMK Kenhwa

KM3, Jalan Bariawa
P.O.Box 55
Sabah

Keningau
Malaysia
89007

Study participating centre

SMK Gunsanad II

KM1, Jalan Bariawa
P.O.Box 2085
Sabah
Keningau
Malaysia
89008

Study participating centre

SMK Sook

KM 40, Jalan Keningau Sook Nabawan
P.O.Box 1613
Sabah
Keningau
Malaysia
89008

Sponsor information

Organisation

Ministry of Health Malaysia

Sponsor details

Economic Planning Unit
Prime Minister's department
Block B5 & B6
Putrajaya
Malaysia
62502

Sponsor type

Government

ROR

<https://ror.org/05ddxe180>

Funder(s)

Funder type

Government

Funder Name

Ministry of Health Malaysia

Funder Name

The Health Promotion Unit, Sabah Health Department

Funder Name

The Non-Communicable Disease Unit, Sabah Health Department

Results and Publications

Publication and dissemination plan

Planned publication in a peer reviewed journal.

Intention to publish date

01/06/2017

Individual participant data (IPD) sharing plan

Not provided at time of registration

IPD sharing plan summary

Stored in repository

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | | 02/10/2017 | 02/03/2022 | Yes | No |