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Community-based quit-smoking intervention using 5As and 3As approaches in Sarawak, Malaysia

Submission date
12/02/2022

Registration date
15/02/2022

Last Edited
25/03/2022

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Mental and Behavioural Disorders

✓ Retrospectively registered
? Protocol not yet added
? SAP not yet added
? Results not yet added and study completed for more than 2 years
? Raw data not yet added
✓ Study completed

Plain English Summary

Current plain English summary as of 23/03/2022:
Background and study aims
There is a lack of data on the effectiveness of adolescent smoking cessation programs in Malaysia so more research is needed on effective non-pharmacological interventions. This breakthrough novel study compared the effectiveness of various non-pharmacological interventions using carbon monoxide levels and nicotine dependence as outcome measures. Due to complex behaviours and various variables, most adult smokers started smoking as teenagers and persisted into adulthood. As adolescent smoking has been connected to preventable chronic problems, the current research findings could target adolescent smokers and the risk of adult diseases. The findings will help the Malaysian Ministry of Health, practitioners, and policymakers to develop innovative quit-smoking policies and programmes. It is critical to identify effective behavioural interventions for smoking cessation and fund them adequately. In this context, this study aims to determine the effectiveness of the 5As or 3As smoking cessation interventions among Malaysian secondary school-aged teenagers. The findings will add to the body of knowledge regarding the effectiveness of smoking cessation programmes among Malaysian secondary school students using the 5As or 3As models.

Who can participate?
Male adolescent smokers aged 13-17 years living in Samarahan and Asajaya districts

What does the study involve?
Cluster were randomly allocated to one of three groups. 3As and 5As smoking cessation behavioural interventions treated smokers in the experimental groups, whereas the control group received no intervention. During the initial village visit, all respondents met face-to-face with facilitators. The baseline survey inquired about respondents' socio-demographics, smoking characteristics, nicotine dependence, and stage of change on the contemplation ladder. In addition, all participants were followed-up by phone or WhatsApp in the first and third months. Each respondent was examined in person 6 and 9 months later and tested for carbon monoxide

in their breath. The intervention was repeated during the 6-month follow-up, surveying participants' motivation stage, nicotine dependence, monthly cigarette consumption, and quit-smoking status, accompanied by a carbon monoxide assessment. During the 9-month follow-up, participants in the 3A and 5A groups received no intervention only surveying participants' motivation stage, nicotine dependence, monthly cigarette consumption, and quit-smoking status, accompanied by a carbon monoxide assessment.

What are the possible benefits and risks of participating?
Quitting smoking may reduce the risk of heart attack, improve lung function, reduce stress levels and mood disorders, and increase happiness levels and general life satisfaction. There are no risks associated with participation in this study.

Where is the study run from?
Universiti Malaysia Sarawak (Malaysia)

When is the study starting and how long is it expected to run for?
December 2019 to July 2021

Who is funding the study?
Universiti Malaysia Sarawak (Malaysia)

Who is the main contact?
Dr Muhammad Siddiq bin Daud
19040005@siswa.unimas.my

Previous plain English summary:
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was on their last month's daily cigarette consumption and progress in quitting smoking. Each respondent was examined in person 6 months later and tested for carbon monoxide in their breath. The intervention was repeated during the 6-month follow-up, surveying participants' motivation stage, nicotine dependence, daily cigarette consumption, and quit-smoking status, accompanied by a carbon monoxide assessment. During the 9-month follow-up, participants in the 3A and 5A groups received no intervention.

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Universiti Malaysia Sarawak (Malaysia)

When is the study starting and how long is it expected to run for?
December 2019 to October 2022

Who is funding the study?
Universiti Malaysia Sarawak (Malaysia)

Who is the main contact?
Dr Muhammad Siddiq bin Daud
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Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Protocol/serial number
F05/CDRG/1822/2019

Study information

Scientific Title
Behavioural intervention for quitting smoking among secondary school students in Samarahan

Study hypothesis
Current study hypothesis as of 23/03/2022:
1. The 5As intervention is more effective compared to the 3As intervention in minimising tobacco use among secondary schoolboys.
2. The 3As intervention is more effective compared to the 5As intervention in minimising tobacco use among secondary schoolboys.

Previous study hypothesis:
1. The 5As model (Ask, Advise, Assess, Assist and Arrange) is more practical at minimizing tobacco use among form four secondary schoolboys, compared to the 3As (Ask, Advise and Act) behavioural intervention model
2. The 5As and 3As models are practical as smoking cessation interventions among mild to severe nicotine addicts

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/01/2020, UNIMAS Ethics Committee (Faculty of Medicine and Health Sciences, 94300 Kota Samarahan, Sarawak, Malaysia, +60 (0)82581 000; medicalethics@unimas.my), ref: # UNIMAS/NC-21.02/03-02 Jld.4 (51)

Study design
Cluster randomized controlled trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Prevention

Participant information sheet
Not available in web format

Condition
Smoking cessation among adolescents

Interventions
Current intervention as of 25/03/2022:
5As: Ask, Advise, Assess, Assist and Arrange
3As: Ask, Advise and Act
Control: no intervention

The study utilised a parallel design of a three-arm cluster randomised controlled trial. The experimental groups were divided into two treatment groups of smokers who received 5As and 3As smoking cessation behavioural intervention approaches, respectively, and one control group that received no intervention.

During the initial village visit, all the respondents met with facilitators face-to-face. A baseline survey was conducted, and the intervention was divided into three groups: 3As, 5As, and the control group. The questionnaires consisted of several sections: the respondents' sociodemographic status, smokers' characteristics, level of nicotine dependence, and stage of change as indicated by the contemplation ladder. Throughout the first and third months of the study, all respondents in the intervention and control groups were followed-up via telephone calls or WhatsApp messages.

All participants were surveyed about their last month's daily cigarette consumption and quitting smoking progress during follow-ups. Additionally, each participant was scheduled for a face-to-face evaluation and carbon monoxide in breath analysis six and nine months later. The intervention was repeated according to their groups during the 6-month follow-up. In addition, respondents were surveyed about their motivation stage, nicotine dependence level, daily cigarette consumption and quit-smoking status. However, during the 9-month follow-up, no intervention was provided to participants in the 3As and 5As groups.

Samarahan and Asajaya districts situated in the Samarahan Division were selected. The criteria for inclusion were a village population of at least 1000 people and consent from the village head. 45 villages in the Samarahan district were evaluated for eligibility, but only 17 villages met the criteria. In contrast, 54 villages in the Asajaya district were assessed for eligibility, but only 12 villages met the criteria. SPSS's randomisation technique selected six villages meeting the eligibility criteria for each district and determined the intervention for each village. Furthermore, the one-stage cluster sampling method selected participants.

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Intervention Type
Behavioural

Primary outcome measure
Success of male secondary school students in quitting smoking measured using a questionnaire at the 1-, 3-, 6- and 9-month follow-ups

Secondary outcome measures
Current secondary outcome measures as of 24/03/2022:
1. Level of nicotine dependence measured using the Fagerstrom Test for Nicotine Dependence (FTND) at baseline, 1-, 3-, 6- and 9-month follow-ups
2. Motivation level and stage of change measured using the Contemplation Ladder questionnaire at baseline, 1-, 3-, 6- and 9-month follow-ups
3. Carbon monoxide levels measured using the piCO Smokerlyzer (ppm) at baseline, 6- and 9-month follow-ups
4. Monthly cigarette consumption measured using a questionnaire at baseline, 1-, 3-, 6- and 9-month follow-ups

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1. Level of nicotine dependence measured using the Fagerstrom Test for Nicotine Dependence (FTND) at baseline, 1-, 3-, 6- and 9-month follow-ups
2. Motivation level and stage of change measured using the Contemplation Ladder questionnaire at baseline, 1-, 3-, 6- and 9-month follow-ups
3. Carbon monoxide levels measured using the piCO Smokerlyzer (ppm) at baseline, 1-, 3-, 6- and 9-month follow-ups
4. Monthly cigarette consumption measured using a questionnaire at baseline, 1-, 3-, 6- and 9-month follow-ups

Overall study start date
17/12/2019

Overall study end date
01/07/2021

Eligibility

Participant inclusion criteria
1. Current smoker or diagnosed by piCO analyser (carbon monoxide breath test monitor)
2. Age 13-17 years old
3. Male
4. Enthusiastic about participating in the study voluntarily
5. Positive parental consent

Participant type(s)
Healthy volunteer

Age group
Child

Lower age limit
13 Years

Upper age limit
17 Years

Sex
Male

Target number of participants
800

Total final enrolment
600

Participant exclusion criteria
1. Non-Malaysian students
2. Participants of other tobacco cessation programme
3. Students who were mentally disorientated or had severe illnesses
4. Ex-smoker

Recruitment start date
18/02/2020

Recruitment end date
10/09/2020

Locations

Countries of recruitment
Malaysia

Study participating centre
Universiti Malaysia Sarawak
Department of Community Medicine and Public Health
Faculty of Medicine and Health Sciences
Kota Samarahan
Malaysia
94300

Sponsor information

Organisation
Universiti Malaysia Sarawak

Sponsor details
Research, Innovation and Enterprise Centre
Faculty of Medicine and Health Sciences
Kota Samarahan
Malaysia
94300
+60 (0)82 58 1117
riec@unimas.my

Sponsor type
University/education

Website
http://www.unimas.my/

ROR
https://ror.org/05b307002

Funder(s)

Funder type
University/education

Funder Name
Universiti Malaysia Sarawak

Alternative Name(s)
University of Malaysia, Sarawak

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Malaysia

Results and Publications

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

Intention to publish date
01/04/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository (Universiti Malaysia Sarawak). The datasets generated during and /or analysed during the current study are not expected to be made available due to the sensitive issue of smoking among adolescents in Malaysia. All information obtained in this study will be kept and handled confidentially, in accordance with applicable laws and/or regulations. When publishing or presenting the study results, identity will not be revealed. Individuals involved in this study, qualified monitors and auditors, and governmental or regulatory authorities may inspect the study data, where appropriate and necessary.

IPD sharing plan summary
Stored in non-publicly available repository, Not expected to be made available