Behavior change intervention design to control vaping and tobacco use in secondary students in As Seeb

Submission date	Recruitment status	[X] Prospectively registered
04/04/2025	Not yet recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
22/04/2025	Ongoing	Results
Last Edited	Edited Condition category	Individual participant data
22/04/2025	Other	[X] Record updated in last year

Plain English summary of protocol

Background and study aims

This research project aims to understand how many grade 11 students in Muscat, Oman, use tobacco and vape, and what factors influence these behaviors. It also aims to test a school-based program designed to help students quit smoking.

Who can participate?

Grade 11 students from schools in A Seeb area of Muscat can participate in the first part of the study. Students identified as smokers from the first part will be invited to participate in the second part.

What does the study involve?

In the first part, students will take part in face-to-face interviews conducted by school health nurses using a survey from the World Health Organization. In the second part, students who smoke will receive monthly counseling sessions for four months to help them quit smoking.

What are the possible benefits and risks of participating? Participants may benefit from gaining a better understanding of their smoking habits and receiving support to quit smoking. There are minimal risks involved, mainly related to the time commitment for the interviews and counseling sessions.

Where is the study run from? Ministry of Health, Oman

When is the study starting and how long is it expected to run for? March 2025 to September 2027

Who is funding the study? Ministry of Health, Oman

Contact information

Type(s)

Public, Scientific, Principal Investigator

Contact name

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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

Behavior change intervention design to control vaping and tobacco use in secondary students in As Seeb area: a pre-post intervention study

Study objectives

Is Motivational Interviewing counselling effective in helping high school students to quit tobacco use including vaping?

Ethics approval required

Ethics approval required

Ethics approval(s)

Submitted 12/03/2025, Research Ethics Committee in Sultan Qaboos University (The Dean's Office P.o. Box 20; Al Khodh Postal Code 123, Muscat, 123, Oman; +968 2443407; t.alghafri@squ. edu.om), ref: -

Study design

Interventional non randomized

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

School

Study type(s)

Other

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

Motivational Interviewing counselling for smoking cessation

Interventions

For study 1: a cross-sectional study in which structured face-to-face interview (survey) will be conducted by trained school health nurses utilizing the World Health Organization (WHO) Global Youth Tobacco Survey (GYTS) questionnaire, including data on the demographics, behavioral intentions, attitudes, subjective norms and perceived behavioral control on smoking (constructs of the Theory of Planned Behavior - TPB). A representative sample (n=886) from all schools of A Seeb area in Muscat, the capital of Oman, will be included (12 x schools). Logistic regression models will be done to determine factors associated with tobacco use and change in the constructs of the TPB. A team from the Ministry of Health and Education will be trained on project objectives, measurement tools, recruitment procedures, and data collection.

For study 2, a pilot quasi-experimental single arm pre- and post-study will be used (n=28, students identified as smokers from study 1). School health nurses (n=12) will be trained to deliver the behavior change intervention monthly for 4 months. School nurses will deliver monthly school-based interventions to the students over 4 months. The monthly intervention is composed of a 30-40 minutes counselling session guided by Motivational Interviewing (MI) strategies widely used for adolescent smoking cessation. Motivational interviewing (MI) is a brief, client-centered approach focused on resolving doubts regarding quitting and increasing self-efficacy for change.

Intervention Type

Behavioural

Primary outcome measure

Tobacco use behaviour will be assessed using GYTS WHO constructs before and after the intervention.

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

12/03/2025

Completion date

01/09/2027

Eligibility

Key inclusion criteria

A sample of grade 11 students in 13 secondary schools in A Seeb area in Muscat region will be included. All students willing to participate in an interview based one to one interview will be included.

Participant type(s)

Learner/student

Age group

Child

Lower age limit

15 Years

Upper age limit

18 Years

Sex

Both

Target number of participants

Total of 886 students will be randomly selected 74 students per school except for one school n=72

Key exclusion criteria

Not willing to participate

Date of first enrolment

01/10/2025

Date of final enrolment

28/10/2025

Locations

Countries of recruitment

Study participating centre

Sultan Qaboos University, Ministry of higher education, research and innovation, Ministry of health and ministry of education

The Dean's Office P.o. Box 20; Al Khodh Muscat Oman 123

Sponsor information

Organisation

Ministry of Health

Sponsor details

Co-ordinator Centre of Studies & Research Ministry of Health Headquarters Muscat Oman

+968-22357280 centre.s.r2017@gmail.com

Sponsor type

Government

Website

https://mohcsr.gov.om

ROR

https://ror.org/0362za439

Funder(s)

Funder type

Government

Funder Name

Oman Ministry of Health

Results and Publications

Publication and dissemination plan

Results will be shared with all stake holders and published in Q1 or Q2 Scopus indexed journals

Intention to publish date

01/12/2027

Individual participant data (IPD) sharing plan

Anonymized individual participant data can be made available upon request to the Principal Investigator, subject to approvals from the Ministry of Education and the Ministry of Health thamra74@yahoo.com

IPD sharing plan summary

Available on request