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School-based waterpipe smoking cessation intervention program among Jordanian adolescents

Submission date	Recruitment status	[X] Prospectively registered
27/07/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/08/2015	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
10/08/2015	Other	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Recent studies showed that the popularity of tobacco smoking, particularly waterpipe, is high among Jordanian school students, but no school-based interventions to discourage waterpipe smoking have been tested. This study aims to test the effectiveness of a behavioral counseling waterpipe smoking cessation program using the 5As guidelines directed toward waterpipe-smoking Jordanian school students.

Who can participate?
Students enrolled in grade 9, 10, 11, or 12 who report smoking at least one puff of waterpipe in the last 30 days.

What does the study involve?
Eight schools from Zarqa Governorate First Educational District will be recruited to participate in the study and will be randomly allocated to deliver either a school-based counseling intervention or to hand out informational pamphlets regarding smoking cessation. Students will be assessed at the start of the study and 1, 3 and 6 months later to assess the short- and long-term effects of the intervention.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Zarqa Governorate First Educational District schools (Jordan).

When is the study starting and how long is it expected to run for?
March 2015 to April 2016.

Who is funding the study?
American University of Beirut (Lebanon).

Who is the main contact?
Dr Sukaina Alzyoud

Contact information

Type(s)
Public

Contact name
Dr Sukaina Alzyoud

Contact details
Faculty of Nursing
Hashemite University
P.O. Box 330127
Zrqa
Jordan
13115

Additional identifiers

Study information

Scientific Title
School-based waterpipe smoking cessation intervention program among Jordanian adolescents: a randomized controlled trial

Study objectives
To demonstrate a significantly 2.63, 2.99 and 4.01% increase in waterpipe smoking abstinence rates, defined as the percentage reporting no waterpipe smoking in the last 30 days, among students in the intervention compared to control schools at 1-, 3-, and 6-months follow-up assessments.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board - The Hashemite University, 26/03/2015

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied

Waterpipe smoking among youth

Interventions
Study intervention Includes two arms:

School-Based Counseling Intervention (CI)
The CI is based on the 5As intervention model, it is based on the Social Cognitive Theory [SCT] which incorporates cognitive-behavioral principles and posits that behavior and behavior change involve the following:
1. Knowledge of the risks and benefits of a behavior
2. Outcome expectations, that is expectations about positive and negative outcomes anticipated for the behavior, which are learned from prior experience, observing others, hearing about similar situations from others, and emotional or physical responses to the behavior
3. Self-control, or the ability to engage in goal-directed behavior including goal-setting, self-monitoring, problem-solving and self-reward
4. Behavioral capability, the knowledge and skills necessary to perform the given behavior to meet goals established, including addressing barriers to successfully engaging in the behavior
5. Self-efficacy, confidence in one's ability to successfully perform the behavior, including confidence in overcoming anticipated barriers.

Description of the Information Only (IO)
Students in the IO schools will have four weekly visits with the school counselor over the course of a month (equivalent to the CI condition). During these visits the school counselor will deliver a series of informational pamphlets regarding smoking and cessation (4 total) that was developed by the Jordanian Ministry of Health, check waterpipe smoking status and efforts at quitting, and ask if the student has any questions.

Intervention Type
Behavioural

Primary outcome(s)
Variables will be measured using questionnaires:
1. Waterpipe smoking in last 30 days: measured at baseline and 1-, 3- and 6-months follow-up
2. Waterpipe smoking in last 48 hours: measured at baseline and 1-, 3- and 6-months follow-up
3. Waterpipe smoking in last 24 hours : measured at baseline and 1-, 3- and 6-months follow-up
4. # of waterpipe smoking in last 30 days: measured at baseline and 1-, 3- and 6-months follow-up
5. Frequency of waterpipe smoking in last 30 days: measured at baseline and 1-, 3- and 6-months follow-up
6. Awareness of smoking health risks: measured at baseline and 1-, 3- and 6-months follow-up
7. Quit attempts: measured at baseline and 1-, 3- and 6-months follow-up

Key secondary outcome(s)
Cotinine assessment using cotinine saliva testing will be measured at baseline and 1-, 3- and 6-months follow-up

Completion date
30/04/2016

Eligibility

Key inclusion criteria

1. Enrolled in grade 9, 10, 11, or 12 at the time of study enrollment
2. Reporting smoking at least one puff of waterpipe in the last 30 days
3. Reporting willingness to participate in a smoking cessation intervention study
4. Able to complete the baseline questionnaire independently, indicating ability to complete study assessments and protocols
5. Intending to remain enrolled in the school for the remainder of the school year
6. Willing to provide contact information for the next 6 months

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Sex
All

Key exclusion criteria
None waterpipe smokers

Date of first enrolment
25/08/2015

Date of final enrolment
30/09/2015

Locations

Countries of recruitment
Jordan

Study participating centre
Zarqa Governorate First Educational District schools
Jordan
13133

Sponsor information

Organisation
American University of Beirut (Lebanon)

ROR

https://ror.org/04pznsd21

Funder(s)

Funder type
University/education

Funder Name
American University of Beirut (Lebanon)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Other