The effect of an interpersonal communication campaign on increasing knowledge and reducing use of khat, amphetamine and tobacco among male students of high schools in Jazan City

Submission date 09/10/2018	Recruitment status No longer recruiting	[X] Prospectively registered [] Protocol
Registration date	Overall study status	☐ Statistical analysis plan
16/10/2018	Completed	Results
Last Edited	Condition category	☐ Individual participant data
17/01/2019	Other	Record updated in last year

Plain English summary of protocol

Background and study aims

Substance abuse is a global youth health problem that has high social and economic burdens. This is a major problem among Saudi youth. The most prevalent substances used by Saudi youth are tobacco, amphetamine, and khat. Although khat use is restricted to the South of the Kingdom of Saudi Arabia, amphetamine and tobacco are used all over the country. Substance abuse is one of the major health problems, causing more deaths, illness, and disabilities than any other preventable cause today. These legal and illegal substances cause many diseases ranging from gastrointestinal disease, psychiatric disorders, cardiovascular, cancers, and many others. They also cause academic under-performance, and negative impacts economically and in terms of the families of students.

Based on other countries experiences where such practice is widely spread, we hypothesise that an effective health campaign to raise awareness about the health effects of the use of khat, amphetamines, and smoking will increase the knowledge about their danger, and consequently decrease their use. A school-based interpersonal communication intervention program (IPC) to raise awareness about the use of khat, amphetamines, and smoking, as derived from the health belief model, will be implemented and evaluated in high schools in Jazan city.

The aim of this study is to assess the effectiveness of the school-based interpersonal communication intervention program (IPC) on the level of knowledge about the health effects of khat, amphetamines and smoking and their use among male students of high schools in Jazan.

Who can participate?

Males aged 15-25 attending high school in Jazan, Saudi Arabia

What does the study involve?

The main concept of this intervention is to focus on peer pressure theory. Three schools will have the main intervention, another three schools will have standard intervention and the last

three schools will have intervention about road traffic accidents. The educational campaign will be delivered by students. Selected students will be trained and supervised by the research team, and they will conduct most of the education campaign. This main intervention will involve lectures, brochures and videos. This will be compared to the standard education campaign, conducted by an expert using printed materials, without any interactive sessions or videos. The control group will receive printed materials about road traffic accidents. Participants will complete questionnaires before and after the intervention.

What are the possible benefits and risks of participating?

Information about the harm effect of the substance abuse disseminated during the health education campaign will benefit in the control of substance abuse. Moreover, the national health policy makers will benefit from the receipt of definitive evidence of how to increase awareness and decrease use of substances within communities. There are no known risks to participants taking part in this study.

Where is the study run from?
The study is run from Jazan University and take place in 9 high schools in Jazan, Saudi Arabia

When is the study starting and how long is it expected to run for? May 2012 to April 2019

Who is funding the study? Saudi Ministry of Education (Saudi Arabia)

Who is the main contact? Dr Anwar Makeen dr.makeen@gmail.com

Contact information

Type(s)

Scientific

Contact name

Dr Anwar Makeen

Contact details

6285 - villa B11 Faculty Housing, Jazan University Jazan Saudi Arabia 82912

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

JAZ00001

Study information

Scientific Title

Unblinded cluster-randomised controlled trial on the effect of an interpersonal communication campaign on increasing knowledge and reducing use of khat, amphetamine and tobacco among male students of high schools in Jazan City

Acronym

IPCISA

Study objectives

Students aged 14-25 years who are exposed to a high-intensity interpersonal communication campaign will have more knowledge or less substance abuse after six months than students who receive low intense or left untreated.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Research Ethics Committee at Jazan University, 14/05/2018, ref: REC39/9-S046

Study design

Interventional three-armed unblinded cluster randomised controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

School

Study type(s)

Prevention

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Use of khat, amphetamine and tobacco

Interventions

Current interventions as of 17/01/2019:

This study has 3 arms. Nine male schools in Jazan city will be randomised to one of the three arms using the close envelope technique.

The first arm will receive an intensive dose of the health education campaign, Jazan University

Model For Peer Education (JUMP). The second arm will receive a low dose of the health education campaign. The third arm be the control group, and instead receive an educational campaign about road traffic accidents.

Intensive dose of JUMP:

Within schools, the intensive JUMP intervention will take place for one month followed by weekly educational visits for five months. The moderators will be senior students and advisors from high schools who will be trained specifically for this program (training of trainees). The program will be delivered by a student from each school after they have received short training to ensure uniformity of the interventions. The educational material will consist of written material created by a specialized team. The video, lectures and group discussion will be presented in equipped classrooms in each intervention school. The intervention will be given over a period of one month as follows:

- 1. The lectures will be given by the moderator (instructor) and contain information about the global, regional and local situation regarding khat,
- amphetamines and smoking, and talk about that are making these products
- 2. We will show 3 videos for khat, amphetamine and smoking. The first educational video will provide educational messages about the risks and damages related to the use of psychotropic substances (stimulants and drugs) and methods of prevention in a scientific manner. The second educational video will provide educational messages on the harmful effects of tobacco consumption. Third educational video will present awareness-raising messages about the harmful effects of khat.
- 3. A printed brochure will be structured to include several components, including risks and damages related to the use of psychotropic substances (stimulants and drugs), tobacco, and khat use.
- 4. Group discussions will focus on developing two life skills including time management and effective communication
- 5. Time management will be delivered through one video session that show the target students a motion graphic
- 6. An interactive activity on (effective communication skill) will be conducted on the form of a pamphlet that contains simple instructions and illustrates practical methods to conduct an interactive activity session that on skill of effective communication.

Low dose of JUMP:

All printed materials will be distributed for all students in this arm, without interactive session and videos. Baseline data will be collected before the intervention and follow up after 24 weeks.

Control group:

Printed materials about road traffic accidents will be distributed for all students in this arm. Baseline data will be collected before the intervention and follow up after 24 weeks.

Previous interventions:

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Intensive dose of health education campaign:

Within schools, the intensive health education campaign intervention will take place for one month followed by weekly educational visits for five months. The moderators will be senior students and advisors from high schools who will be trained specifically for this program

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Control group:

Printed materials about road traffic accidents will be distributed for all students in this arm. Baseline data will be collected before the intervention and follow up after 24 weeks.

Intervention Type

Behavioural

Primary outcome measure

Current:

The following will be assessed using the Youth Tobacco, Khat and Amphetamine Prevalence and Knowledge Questionnaire at the baseline, 12 and 36 week follow-up:

- 1. Proportion of participants who report using khat, amphetamines or smoking tobacco products (each substance will be considered individually, as well as aggregated use)
- 2. Proportion of participants who report having knowledge about the harmful effects of khat, amphetamines or smoking tobacco products (each substance will be considered individually, as well as aggregated use)

Previous:

The following will be assessed using the Youth Tobacco, Khat and Amphetamine Prevalence and Knowledge Questionnaire at the baseline and at the 24 week follow-up:

1. Proportion of participants who report using khat, amphetamines or smoking tobacco products (each substance will be considered individually, as well as aggregated use)

2. Proportion of participants who report having knowledge about the harmful effects of khat, amphetamines or smoking tobacco products (each substance will be considered individually, as well as aggregated use)

Secondary outcome measures

Current:

Changes in the following will be assessed using the Youth Tobacco, Khat and Amphetamine Prevalence and Knowledge Questionnaire at the baseline, 12 and 36 week follow-up:

- 1. Proportion of participants who perceive the dangers of khat, amphetamine and tobacco, yet still report using substances (each substance will be considered individually, as well as aggregated perceptions)
- 2. Proportion of participants who have quit using khat, amphetamine and tobacco at 6 months (this will be split into years ago and since the onset of the intervention)

Previous:

Changes in the following will be assessed using the Youth Tobacco, Khat and Amphetamine Prevalence and Knowledge Questionnaire at the baseline and the 24 week follow-up:

- 1. Proportion of participants who perceive the dangers of khat, amphetamine and tobacco, yet still report using substances (each substance will be considered individually, as well as aggregated perceptions)
- 2. Proportion of participants who have quit using khat, amphetamine and tobacco at 6 months (this will be split into years ago and since the onset of the intervention)

Overall study start date

10/05/2012

Completion date

20/01/2020

Eligibility

Key inclusion criteria

- 1. Enrolled in one of the selected schools
- 2. Aged 15-25
- 3. Willing and able to provide informed consent
- 4. Proxy consent from guardians

Participant type(s)

Other

Age group

Adult

Sex

Male

Target number of participants

2625

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment 04/11/2018

Date of final enrolment 31/01/2019

Locations

Countries of recruitmentSaudi Arabia

Study participating centre Al razi school Alhassan Albasry Street Jazan Saudi Arabia 8272

Study participating centre Al Ahfad Private School 25th Street Jazan Saudi Arabia 82812

Study participating centre
Prince Abdullah Alfisal School
Ibn Alqayem Street
Jazan
Saudi Arabia
82617

Study participating centre
Manarat Almajed Private School
3330 Prince Metibb Bin Abdul Aziz Road
Jazan
Saudi Arabia
82812

Study participating centre Khwarizmi High School

Ibn Kholdon Street Jazan Saudi Arabia 82812

Study participating centre Moa'ad Bin Jabal High School

As Suways King Abdullah Street Jazan Saudi Arabia 82616

Study participating centre Alrawdah School

Prince Fawaz Bin Abdulazis Street Alrawdah District Jazan Saudi Arabia 82727

Study participating centre Al Maarfa Private School

19th D Street Jazan Saudi Arabia 82731

Study participating centre Al Karbous School

2691 King Faysal Road Al Arak 7653 Jazan Saudi Arabia 82635

Sponsor information

Organisation

Jazan University

Sponsor details

Block 8, Jazan University campus Jazan Saudi Arabia 45142

Sponsor type

University/education

Website

http://www.jazanu.edu.sa/Pages/Default.aspx

ROR

https://ror.org/02bjnq803

Funder(s)

Funder type

Government

Funder Name

Ministry of Education Saudi Arabia

Results and Publications

Publication and dissemination plan

The results will be disseminated at scientific conferences, seminars and presentations, and by publication in peer-reviewed scientific journals.

Intention to publish date

20/01/2021

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary

Data sharing statement to be made available at a later date