Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The design, implementation and evaluation of The effect of educational campaign on smoking prevention behaviors based on protection motivation theory (PMT) in the students

Protocol summary

Study aim
Determining the effect of educational campaign on smoking prevention behaviors based on protection motivation theory (PMT) in students of Yazd universities

Design
Project implementation method (steps and methods accurately) This study is a pre- and post-intervention study that aims to determine the effect of educational campaign using protection motivation theory (PMT) on smoking prevention on students in Yazd universities.

Settings and conduct
The method of conducting research in this research in 5 interconnected phases will be as follows: 1- Needs assessment and determination of the current situation 2- Construction of tools 3- Design of educational intervention (educational campaign) 4- Execution of educational program 5- Performing educational evaluation (pre Test-post-test), measuring the salivary cotinine level of a smoking student

Participants/Inclusion and exclusion criteria
All students of Yazd universities, including national, free, non-profit and ... Inclusion criteria include: attending college at least until the end of the research, student's willingness to participate in the study, being a student Exclusion criteria included: drug addiction, less than six months of being a student and absence in more than 10% of training sessions, their unwillingness to participate in research.

Intervention groups
Interventional study before and after

Main outcome variables
Knowledge, Attitude and Functional Score and Protection Motivation Model (PMT) structures ; Reduce smoking exposure ; Improve lifestyle ; Prevent health problems such as cancer, increase cardiovascular disease and other chronic diseases; reduce treatment costs and Increase a person's life expectancy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200908048656N1**
Registration date: **2020-10-18, 1399/07/27**
Registration timing: **prospective**

Last update: **2020-10-18, 1399/07/27**
Update count: **0**

Registration date
2020-10-18, 1399/07/27

Registrant information

Name
Salime Zare Abdollahi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 35 3730 5879

Email address
salimezare2319@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-10-22, 1399/08/01

Expected recruitment end date
2020-12-21, 1399/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The design, implementation and evaluation of The effect of educational campaign on smoking prevention behaviors based on protection motivation theory (PMT) in the students

Public title
The design, implementation and evaluation of The effect of educational campaign on smoking prevention behaviors based on protection motivation theory (PMT) in students
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Being a student Attend college at least until the end of the research The student's desire to participate in the study
Exclusion criteria:
Their unwillingness to participate in research Drug addiction Being a student for less than six months Absence from more than 10% of training sessions
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **300**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features
Implementation of an extensive educational campaign +community based

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
School of Public Health - Shahid Sadoughi University of Medical Sciences
Street address
No. 62, Sarnabesh, Second Crossroads, Vahdat Alley, Between First and Second Square, Azadshahr St., Yazd
City
Yazd
Province
Yazd
Postal code
8917864633
Approval date
2020-09-29, 1399/07/08
Ethics committee reference number
IR.SSU.SPH.REC.1399.174

Health conditions studied

1

Description of health condition studied
Prevention of smoking
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Knowledge, attitude and practice score and structures of protection motivation model (PMT) - Reduce students' exposure to smoking - Percentage of smoking students
Timepoint
Before the intervention of the educational campaign with questionnaires and tests
Method of measurement
Protection Motivation Questionnaire + Salivary cotinine test

Secondary outcomes

1

Description
Lifestyle Improvement - Prevent health problems such as cancer, increase cardiovascular disease and other chronic diseases, reduce treatment costs and increase life expectancy
Timepoint
3 months after the training campaign
Method of measurement
Protection Motivation Questionnaire + saliva cotinine test

Intervention groups

1

Description
The method of conducting research in this research in 5 interconnected phases will be as follows: 1- Needs assessment and determination of the current situation 2- Construction of tools 3- Design of educational intervention (educational campaign) 4- Execution of educational program 5- Performing educational evaluation (pre- Test-post-test) To conduct a research

project, people who meet the inclusion criteria will be selected to participate in the study. After selecting these people, the purpose of the study will be explained to them and then informed consent will be obtained. Phase 1: Needs Assessment and determining the status of this stage, first the necessary communication to form a planning team with Key people, established with influence and experts. The projected members fall into two categories. The first category of this team includes key decision makers and those in power (student-related officials) including university deans, deans, security guards of the governorate university, municipality, health deputy and city health center, representative of the Radio and Television Organization, faculty members and members Faculty, predecessors of the university, seller of the university or college store, service managers; The second group of volunteer students and the student committee, which will be the same members of the target community, ie the representatives of the students of each university. The role of this group is to provide advice, support, participation in the program design, implementation and evaluation stages. The group will also have effective oversight of intervention strategies and training materials in terms of eloquence, cultural appropriateness and comprehensiveness, manner and duration of intervention, and selection and use of facilitators. During the group meetings that will be held, the goals of the program and the role of organizations and individuals in this program will be explained to the members of the planning team.Phase 2: Instrumentation Then the data related to the stages of face validity, content validity (CVI, CVR), reliability (internal consistency) and determination of the structures of predictors of protection motivation theory are done. Questionnaire After reviewing the relevant texts, articles and journals, a questionnaire will be designed accordingly, its validity and reliability will be obtained through a panel of experts. This questionnaire has 2 parts; The first part of demographic characteristics (including: age, grade point average, parents 'education level, smoking in the student - parents and friends of parents' occupation, residence status, native and non-native, financial status, etc.), the second part of the researcher questionnaire The construct will be designed and completed based on the theory of protection motivation. The analysis of the results in the descriptive section will identify the main components of the intervention. Interventions and messages designed in a session with the presence of the planning team and a number of members of the target community, will be pre-tested and examined by factors such as audience perception of the message, relevance to the level of education and culture of the audience, attractiveness, credibility and acceptance as The final message will be considered.Phase 3: Designing an educational intervention (educational campaign) to start entering the target community and better access to the target group and also to help implement interventions in the target group, people will be selected and trained as facilitators. These people from both groups will be selected voluntarily to work with the presenter with the necessary interest and motivation in all stages of the program. Campaigns: One of the strategies of community-based training programs is health information mobilization (campaign), which has increased in recent years and aims to convey persuasive messages to perform specific behaviors in the target group. A set of coordinated information, communication and educational activities using a combination of multiple and diverse information channels in order to convey the desired and specific messages to a specific population in a specific and limited period in line with the objectives of the program to mobilize information Say. Health campaigns invite people and officials to participate publicly and to pay attention to the common good, but it cannot achieve this goal if the information is not correct. The campaign measures include two categories: 1- Action to strengthen the collective action of engaging with partner organizations in health: to prevent and reduce smoking through holding joint coordination meetings to increase cross-sectoral cooperation and coordinated action between organizations Related to health (municipality, radio and television, health deputy, deans of universities, colleges, faculty members, etc.) and their participation. 2- Facilitators' cooperation with the facilitator: Holding educational sessions with educational methods used in educational classes based on lectures along with PowerPoint, questions and answers, group discussions with showing videos and photos related to the harmful effects of smoking on a person's health and Secondhand smoke for those around you and a risk factor for increasing the risk of coronary heart disease, forming self-help groups to educate peers and reducing the target group's access to cigarettes.Phase 4: Implementation of the educational program In this section, the designed educational intervention (educational campaign) will be implemented on the students of the studied universities. The statistical population of the study includes all students studying at Yazd universities in the academic year 1399-1400 (which is approximately equal to 43,600 people. The sample size considering the significance level of 5% and test power 80% and according to the study Similar and standard deviation of preventive behavior score s = 1.5 and to achieve a significant difference of at least 7 units in the mean score of behavior in the intervention group compared to the control of 265 people, which with 10% of the fall, 300 people in each group will be calculated Sampling is probably a multi-stage random class in that after preparing a list of university names in a random class, three selected universities including a national non-medical university, a medical university and a free university Or non-profit are selected, then one faculty in each university is randomly determined and after preparing a list of graduate and faculty education department, students will be selected by random sampling method and this sample size is 300 people according to the university population. Will be divided and thus the random sample size with the names in hand Students required for research will be selected. With the data collection tool (researcher-made questionnaire), a pre-test will be conducted of students eligible to enter the study, and then based on the design, an educational campaign will be conducted and designed interventions

and messages that include messages- Designed to mobilize information (campaign) in the lesson plan (including the use of mass media, health exhibitions, competitions, walking conferences, lectures with PowerPoint, group discussions, pamphlets, posters and text messages, online education and spaces Virtual, etc.) will be implemented for one month with the participation of facilitators. Phase 5: Educational evaluation will be done two months after the intervention of the post-test educational campaign based on the questionnaire of protection motivation theory and the collected results of the educational campaign on The basis is compared and analyzed before and after the educational campaign, and in order to evaluate the effect of implementing programs designed to prevent the second type in smoking students, in addition to performing post-test in them, measuring the salivary cotinine level of smoking students and comparing before and after The training will be done using appropriate statistical tests.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Central Laboratory

Full name of responsible person

Mr. Rouh A. Beigi

Street address

Taleghani Boulevard

City

Yazd

Province

Yazd

Postal code

۸۹۱۶۶۵۷۳۵۵

Phone

+98 35 3724 6665

Fax

+98 35 3724 6665

Email

centrallab@ssu.ac.ir

Web page address

https://bankpezeshkan.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. Seyed Saeed Mazloumi

Street address

Alam Square, campus of Shahid Sadoughi University of Medical Sciences, Yazd

City

Yazd

Province

Yazd

Postal code

8989898989

Phone

+98 35 3820 9110

Email

mazloomy.mm@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Yazd University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Salime Zare Abdollahi

Position

PhD student and Deputy Minister of Health

Latest degree

Ph.D.

Other areas of specialty/work

Health Promotion

Street address

No .62,koy Vahdat ,West Azadshahr.

City

Yazd

Province

Yazd

Postal code

8917864633

Phone

+98 35 3721 3280

Email

salimezare2319@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Salime Zare Abdollahi

Position

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Phone

+98 35 3721 3280

Email

salimezare2319@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Salime Zare Abdollahi

Position

PhD student and Deputy Minister of Health

Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Demographic data of study participants + total potential data after unidentifiable individuals

When the data will become available and for how long

1399

To whom data/document is available

Everyone and everyone who needs data.

Under which criteria data/document could be used

Unidentifiable personal data or other documentation

From where data/document is obtainable

Researcher articles and dissertation

What processes are involved for a request to access data/document

No process

Comments