Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of Smoking Educational Intervention Based on Trans-theoretical Model on Egyptian Male Smokers' Knowledge, and Smoking Behavior

Protocol summary

Study aim
Examine the effect of Smoking Educational Intervention Based on Trans-theoretical Model on Egyptian Male Smokers' Knowledge, and Smoking Behavior

Design
Randomized controlled trial (Not blinded) with a parallel-group design. 170 Adult male smokers will be enrolled in both intervention and control groups in April 2022 and followed up for 6 months.

Settings and conduct
The central building of the ministry of health-El-Beheira Governorate-Egypt. An educational intervention based on the transtheoretical model will be conducted for the study group using multimedia educational tools to enrich the learning. They will be followed for 6 months to monitor the stage of change in their smoking behavior and knowledge.

Participants/Inclusion and exclusion criteria
Inclusion Criteria -Regular smoke of minimally one cigarette daily - Being in the stages of pre-contemplation, contemplation, and preparation based on TTM, - Aged at least 20 years - Enthusiastic to take part in the study. Exclusion criteria -Smoke another type of nicotine than cigarettes - Actively share in any other smoking programs quitting - Diagnosed with psychological health problems, - Addicts to any other drugs were excluded from the study.

Intervention groups
The study group will be 85 male smokers who will recieve the TTM based education The control group will be 85 male smokers who will not given no education

Main outcome variables
Smoking Knowledge and behavior

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210612051555N4**
Registration date: **2022-03-12, 1400/12/21**
Registration timing: **registered_while_recruiting**

Last update: **2022-03-12, 1400/12/21**
Update count: **0**

Registration date
2022-03-12, 1400/12/21

Registrant information

Name
Samiha Hamdi

Name of organization / entity
Dmanhour University, Faculty of Nursing

Country
Egypt

Phone
+20 45 3538264

Email address
samihareda93@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-15, 1400/11/26

Expected recruitment end date
2022-03-15, 1400/12/24

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Smoking Educational Intervention Based on Trans-theoretical Model on Egyptian Male Smokers' Knowledge, and Smoking Behavior

Public title
Effect of Smoking Educational Intervention Based on Trans-theoretical Model on Egyptian Male Smokers' Knowledge, and Smoking Behavior
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
-Regular smoke of minimally one cigarette daily Being in the stages of pre-contemplation, contemplation, and preparation based on TTM Aged at least 20 years Enthusiastic to take part in the study.
Exclusion criteria:
-Smoke another type of nicotine than cigarettes Actively share in any other smoking programs quitting Diagnosed with psychological health problems Addict to any other drugs were excluded from the study
Age
From **20 years** old to **50 years** old
Gender
Male

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **170**
Randomization (investigator's opinion)
Randomized
Randomization description
Those who meet the study criteria, will be randomized between the study and control groups using the randomization block technique using five successive steps: 1) establishing a list of numbers (1-170) in advance, 2) these numbers were written in small papers and turned to be hidden then combined in a ball, 3) all the 170 papers were randomly split to 17 blocks/10 per each. 4) from each block, five papers were pulled out to be randomly allocated to the study group and the other five papers were allocated to the control group, 5) the word "study" or " control" was written by the researchers beside each number in the pre-prepared list based on to the randomization block results. This respective list was kept until the start of data collection with a total of (85) participants were allotted to each group. Masking of the participants' allocation to the study group or the control group was not feasible.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic's committee of the Faculty of Nursing-Damanhour University
Street address
Damanhour, Elbehira, Governorate, Egypt
City
Damahour
Postal code
22511
Approval date
2022-01-10, 1400/10/20
Ethics committee reference number
08-09-01-2022 EC

Health conditions studied

1

Description of health condition studied
Smoking behavior and nicotine dependence level
ICD-10 code
F17.29
ICD-10 code description
Nicotine dependence, other tobacco product

Primary outcomes

1

Description
Knowledge about smoking
Timepoint
Before and 6 months after intervention
Method of measurement
Smoking Knowledge scale

2

Description
Smoking behavior
Timepoint
Before and 6 months after intervention
Method of measurement
TTM constructs questionnaire---stage of change, processes of change, decisional balance, self efficacy

3

Description
Nicotine dependence level
Timepoint
Before and 6 months after intervention
Method of measurement
Fagerstrom Tolerance Questionnaire (FTQ)

Secondary outcomes

empty

Intervention groups

1

Description

For the study group: 85 male smokers employees in the main building of the ministry of health in El-Beheira Governorate. The educational intervention using TTM will be designed and implemented throughout five phases. - Ice-breaking phase: the researchers visit the participants in their workplace and introduce themselves to each other in a trial to establish a trustful relationship with them. This phase also aided in initiating the recruitment process-Assessment phase: it will assess the participants' basic and smoking-related data, knowledge, nicotine dependence level, and TTM constructs to specify the participants' stages and process of change, decisional balance, and self-efficacy to quit smoking even if exposed to triggering situations (pre-test). - Planning phase: considering the recent and reliable literature, the researchers designed an educational intervention about smoking based on TTM (PPT, informational brochures, educational videos, and booklet). These materials were further evaluated and approved by external peer reviewers. -Implementation phase: the participants will split into groups according to their respective stages of change. Motivational interviews and counseling will be implemented initially and repeated after 3 and 6 months at the group level, then they will be conducted at the individual level on monthly basis using phone interviews. The educational activities will be tailored to the stage of change while considering the psychological constructs of the TTM model and applying the motivational interview principles to foster the behavioral change process. e.g., those who will be in the pre-contemplation stage will be instructed about the negative consequences of smoking in every life aspect (physical, psychological, and social) to enhance their readiness to quit smoking. Whereas those who are in other stages were offered the functionally feasible strategies to foster quitting of smoking and enhance their smoking resistant techniques and problem-solving skills. A weekly motivating message for quitting smoking was delivered on WhatsApp to boost motivation.

Category

Behavior

2

Description

Control group: 85 male smokers employees in the main building of the ministry of health in El-Beheira Governorate. they will not receive any education but ethically, all the educational materials will be given for them at the end of the study to maximize the benefits and protect their health rights.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

The ministry of health central building (male smoker employees)

Full name of responsible person

Samiha Hamdi Sayed Ramadan

Street address

Damanhour, Elbehira, Governorate, Egypt

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Phone

+20 45 3311679

Email

samihareda93@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Damanhour University- Faculty of Nursing

Full name of responsible person

The Vice Dean of Academic Research

Street address

Damanhour, El-Behira, Governorate, Egypt

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Damanhour University- Faculty of Nursing

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
Damanhour University- Faculty of Nursing
Full name of responsible person
Samiha Hamdi Sayed Ramadan
Position
Assistant Professor
Latest degree
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Other areas of specialty/work
Public Health/Community Medicine
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Published research report that contains all the findings of the study.
When the data will become available and for how long
within one year and will be available long life
To whom data/document is available
for public
Under which criteria data/document could be used
for scientific use and public education
From where data/document is obtainable
Scientific ranked health journal
What processes are involved for a request to access data/document
none
Comments
none