

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 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 receive 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
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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