

# 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

##### City

Damahour

##### Postal code

22511

##### 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

##### City

Damahour

##### Postal code

22511

##### Phone

+20 45 3311679

##### Email

samihareda93@gmail.com

#### 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**  
Ph.D.  
**Other areas of specialty/work**  
Public Health/Community Medicine  
**Street address**  
Damanhour, ElBehira, Governorate, Egypt  
**City**  
Damahour  
**Province**  
Elbehira Governorate  
**Postal code**  
22511  
**Phone**  
+20 45 3311679  
**Email**  
samihareda93@gmail.com

## Person responsible for scientific 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**  
Ph.D.  
**Other areas of specialty/work**  
Public Health/Community Medicine  
**Street address**  
Damanhour, El-Behira, Governorate, Egypt  
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**Province**  
Elbehira Governorate  
**Postal code**  
22511  
**Phone**  
+20 45 3311679  
**Email**  
samihareda93@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Damanhour University- Faculty of Nursing  
**Full name of responsible person**

Samiha Hamdi Sayed Ramadan  
**Position**  
Assistant Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Public Health/Community Medicine  
**Street address**  
Damanhour, Elbehira, Governorate, Egypt  
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Damahour  
**Province**  
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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