

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Influence of A Tailored Nurse-Led Intervention on Controlling Tobacco Smoking

#### Protocol summary

##### Study aim

To determine the dominant smoking trigger & the effects of a tailored nursing intervention on controlling such trigger.

##### Design

A quasi-experimental comparative design was employed to achieve the aforementioned objectives. 64 subjects will be assigned to Join the study group. The rest will be in the control group. The total sample size would be 128 subjects.

##### Settings and conduct

A 128 smokers with Non-communicable Chronic Diseases, who were visiting outpatient clinic in one major teaching hospital at Baghdad City. Study subjects were recruited when they were seeking the follow-up of their health problems and prescriptions refilling. The simple randomization procedure would involve throwing a dice (eg, below & equal to 3 = control, over 3 = treatment). No allocation concealment will be carried out.

##### Participants/Inclusion and exclusion criteria

Inclusion: \*Consent & compliance with all aspects of the study protocol, methods, providing data during follow-up phase.\*Contact male & female patients, who are 18-70 years old at the time of data collection phase  
Exclusion: \*Involvement with any other ongoing studies.  
\*Medically diagnosed with psycho-mental diseases  
\*Morbidly ill subjects, whereas their physical & mental capacity are impaired

##### Intervention groups

Intervention group: The starting point of the intervention phase will start by asking the subjects to respond to "why do you smoke" questionnaire (American Lung Association, 1993). This mandatory step will help in categorizing the subjects according to their smoking trigger. Intervention group subjects will be armed with orally & in a written form of simple, yet specific instructions to enable them managing their dominant smoking trigger. The intervention group will be contacted after 14 days to see the influence of the given instruction

on their smoking status.

##### Main outcome variables

Quitting or Reducing the Smoked Tobacco Cigarettes

#### General information

##### Reason for update

##### Acronym

Targeting Smoking Triggers Trial(TSTT)

##### IRCT registration information

IRCT registration number: **IRCT20190809044485N2**

Registration date: **2020-04-01, 1399/01/13**

Registration timing: **retrospective**

Last update: **2020-04-01, 1399/01/13**

Update count: **0**

##### Registration date

2020-04-01, 1399/01/13

##### Registrant information

##### Name

Sadeq AL-Fayyadh

##### Name of organization / entity

University of Baghdad, College of Nursing

##### Country

Iraq

##### Phone

+964 1 521 1494

##### Email address

s.al-fayyadh@conursing.uobaghdad.edu.iq

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-11-07, 1397/08/16

##### Expected recruitment end date

2019-01-27, 1397/11/07

##### Actual recruitment start date

2018-11-07, 1397/08/16  
**Actual recruitment end date**  
2019-01-27, 1397/11/07  
**Trial completion date**  
2019-01-27, 1397/11/07

**Scientific title**  
Influence of A Tailored Nurse-Led Intervention on Controlling Tobacco Smoking

**Public title**  
Targeting Smoking Triggers: A Tailored Nurse-led Intervention for Controlling Tobacco Smoking

**Purpose**  
Supportive

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Consent & compliance with all aspects of the study protocol, methods, providing data during follow-up phase  
Contact male & female patients, who are 18-70 years old at the time of data collection phase  
**Exclusion criteria:**  
Involvement with any other ongoing studies. Medically diagnosed with psycho-mental diseases Morbidly ill subjects, whereas their physical & mental capacity are impaired

**Age**  
From **18 years** old to **70 years** old

**Gender**  
Both

**Phase**  
N/A

**Groups that have been masked**  
*No information*

**Sample size**  
Target sample size: **750**  
Actual sample size reached: **128**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
In order to maintain a transparent & scientific-based randomization process, simple randomization will be used in assigning participants (individuals: Active smokers), to treatment & control groups, assuming that each participant has an equal chance of being assigned to any group. The simple randomization procedure would involve throwing a dice (eg, below & equal to 3 = control, over 3 = treatment). No allocation concealment will be carried out.

**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

Research Ethical Approval Committee, at the College of Nursing

##### Street address

Bab AL-Muadum

##### City

Baghdad

##### Postal code

10001

##### Approval date

2017-12-21, 1396/09/30

##### Ethics committee reference number

2395

## Health conditions studied

### 1

#### Description of health condition studied

Tobacco Cigarettes Smoking Dependence

#### ICD-10 code

F17.21

#### ICD-10 code description

Nicotine dependence, cigarettes

## Primary outcomes

### 1

#### Description

Smoking Tobacco Cigarettes (Quitting or Reducing)

#### Timepoint

Subjects response to the educational intervention will be within two weeks of the first meeting to examine the effectiveness of the intervention on smoking habit

#### Method of measurement

Self-report of smoking status after being exposed to the educational intervention

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: The starting point of the intervention phase will start by asking the subjects to respond to "why do you smoke" questionnaire (American Lung Association, 1993). This mandatory step will help in categorizing the subjects according to their smoking trigger. Intervention group subjects will be armed with orally & in a written form of simple, yet specific instructions to enable them managing their dominant smoking trigger. The intervention group will be contacted

after 14 days to see the influence of the given instruction on their smoking status.

**Category**

Lifestyle

**2**

**Description**

Control group: In order to be matched with subjects in the intervention group, control group subjects smoking dominant trigger will be determined. No instructions will be given to them during the study course.

**Category**

N/A

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

The outpatient clinic of the Baghdad Teaching Hospital at Medical City Complex

**Full name of responsible person**

Sadeq AL-Fayyadh

**Street address**

Bab AL-Muadum Medical City Complex

**City**

Baghdad

**Postal code**

10001

**Phone**

+964 1 415 0076

**Email**

s.al-fayyadh@conursing.uobaghdad.edu.iq

**Web page address**

<https://www.medicalcity.gov.iq/ar/contact-us>

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

College of Nursing, University of Baghdad

**Full name of responsible person**

Professor Iqbal Ghanim Muala, PhD. Dean

**Street address**

Bab AL-Muadum campus

**City**

Baghdad

**Postal code**

10001

**Phone**

+964 1 521 1494

**Email**

s.al-fayyadh@conursing.uobaghdad.edu.iq

**Grant name**

**Grant code / Reference number**

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

No

**Title of funding source**

The author of the trial is the funding source

**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**

Other

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

University of Baghdad, College of Nursing

**Full name of responsible person**

Sadeq AL-Fayyadh

**Position**

Faculty member-An Associate Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nursing

**Street address**

Al Karkh, Ajnadine neighborhood, House No 3, Street No 62, Section No 863

**City**

Baghdad

**Province**

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**Postal code**

10001

**Phone**

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

University of Baghdad, College of Nursing

**Full name of responsible person**

Sadeq AL-Fayyadh

**Position**

Faculty member-An Associate Professor

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**Email**  
s.al-fayyadh@conursing.uobaghdad.edu.iq

## Person responsible for updating data

### Contact

**Name of organization / entity**  
University of Baghdad, College of Nursing  
**Full name of responsible person**  
Sadeq AL-Fayyadh  
**Position**  
Faculty member-An Associate Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
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No 62, Section No 863  
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s.al-fayyadh@conursing.uobaghdad.edu.iq

## 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

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Not applicable

### Analytic Code

Not applicable

### 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

The researcher is acknowledging the scientific community to have verifiable findings of the study. sharing plan includes making all the related data available through publishing the study report in peer-reviewed reputable journals.

### When the data will become available and for how long

God willing, once finishing the process of data collection, analysis and successfully publishing the manuscript, all the related files will become available for 6 months after publications

### To whom data/document is available

All the related files will be shared with any scientific interested parties.

### Under which criteria data/document could be used

It may be used after seeking the author's permission and acknowledging his contribution.

### From where data/document is obtainable

The author's professional e-mail that will be available with the published manuscript can be used to contact the author. e-Mail: s.al-fayyadh@conursing.uobaghdad.edu.iq

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

N/A

### Comments

Profound appreciations are due to the IRCT members for their genuine efforts in helping researchers fulfilling their academic endeavors.