Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

Baghdad

Postal code

10001

Phone

+964 1 521 1494

Fax

Email

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

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

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

Baghdad

Postal code

10001

Phone

+964 1 521 1494

Fax

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

Nursing

Street address

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

City

Baghdad

Province

Baghdad

Postal code

10001

Phone

+964 1 521 1494

Fax

Email

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.