

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

The effect of motivational interviewing on self-efficacy, craving and hookah dependency in pregnant women.

Protocol summary

Study aim

The purpose of the study was to determine the effect of motivational interview on self-efficacy, craving and addiction to hookah in pregnant women referring to health care centers in Zahedan city in 1396.

Design

At first, among pregnant women who use the hookah in the health centers of the city of Zahedan, who are pregnant and who are referred to these centers for prenatal care, 140 people are eligible for inclusion criteria, then with The random allocation is divided into two groups: intervention and control.

Settings and conduct

The place of study is the health centers of Zahedan suburbs. How to conduct a motivational interviewing group counseling session during four 45-90 minute sessions of two sessions.

Participants/Inclusion and exclusion criteria

Criteria for entering the study: 1- At least 6 times a month for hookahs. 2. No psychiatric disorder. Exit criteria: 1. Failure to attend or absent more than one session in the motivational counseling program. 2. Pregnancy problems during the course of the implementation. Intervention (abortion, and

Intervention groups

The intervention group will provide motivational interviewing group counseling sessions in four sessions of 45 to 90 minutes a week, two sessions at the clinic and at agreed time with women in groups of 4 to 9 people. The control group will only receive routine pregnancy training and advice and training on the harm and consumption of hookah.

Main outcome variables

Self-efficacy of reducing hookah consumption; Reducing dependence on hookahs; Reducing hookah craving.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160924029954N5**
Registration date: **2018-01-22, 1396/11/02**
Registration timing: **retrospective**

Last update: **2018-01-22, 1396/11/02**

Update count: **0**

Registration date

2018-01-22, 1396/11/02

Registrant information

Name

Ali navidian

Name of organization / entity

Zahedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 54 3344 2482

Email address

alnavidian@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

government

Expected recruitment start date

2017-06-20, 1396/03/30

Expected recruitment end date

2017-11-21, 1396/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of motivational interviewing on self-efficacy,

craving and hookah dependency in pregnant women.

Public title

Impact of Motivational Interview on reducing hookah consumption

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

gestational age less than 22 weeks have been used regularly for at least 6 months. The lack of psychiatric disorders Non-addiction to any substance other than the smoking hookah is not subject to a specific training program.

Exclusion criteria:

Failure to attend or absent more than one session in the Motivational Counseling Program pregnancy complications during the intervention (abortion, etc.)

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment to intervention and control groups. Participants in the study are randomly assigned to two groups of intervention and control. First, the envelope containing the study groups will be sorted out and randomly ordered. Gradually, by identifying the eligible person, one of the envelopes will be allocated to the selected individuals, respectively.

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**

Ethics Committee of Zahedan University of Medical Sciences

Street address

Dr hesabi's Square,Zahedan University of Medical Sciences

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

98167-43463

Approval date

2017-06-12, 1396/03/22

Ethics committee reference number

IR.ZAUMS.REC.1396. 57

Health conditions studied**1****Description of health condition studied**

Tobacco

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Self-efficacy of reducing hookah consumption in pregnant women

Timepoint

Before the intervention and eight weeks after the intervention

Method of measurement

Self-efficacy inventory of hookah consumption

2**Description**

Dependence on hookah in pregnant women

Timepoint

Before the intervention and eight weeks after the intervention

Method of measurement

Dependence on hookah consumption questionnaire

3**Description**

Hookah craving for pregnant women

Timepoint

Before intervention and 8 weeks after intervention

Method of measurement

Indicator of Craving

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group : For the intervention group,

motivational interviewing group counseling sessions will be conducted in five sessions of 45 to 90 minutes a week, at the clinic and at agreed time with women in groups of 4 to 9 people.

Category

Behavior

2**Description**

Control group: The control group will only receive routine pregnancy training and advice and training on the hookah's health.

Category

Behavior

Recruitment centers**1****Recruitment center****Name of recruitment center**

Shahid barazande Health Center

Full name of responsible person

Zahra jodaei

Street address

Murad Qolli 30, Shahid barazande Health Center

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9814675465

Phone

+98 54 3331 9553

Fax

+98 54 3331 9553

Email

zahrajodaei@gmail.com

Web page address

http://zaums.ac.ir/

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Dr. Noor Mohammad Bakhshani

Street address

Dr Hesabi Square, Zahedan University of Medical Sciences

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 1341 6708

Fax

+98 54 1341 6708

Email

public@zaums.ac.ir

Web page address

http://zaums.ac.ir/

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Zahedan University of Medical Sciences

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**

Zahedan University of Medical Sciences

Full name of responsible person

Kheirolnesa Mojahed

Position

Midwifery Bachelor

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Dr hesabi Square, Zahedan University of Medical Sciences

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816913396

Phone

+98 54 3344 2482

Fax

+98 54 3344 2481

Email

nesamojahed@gmail.com

Web page address

http://zaums.ac.ir/

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Dr. Ali Navidian

Position

P.H.D

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Dr Hesabi Square, Zahedan University of Medical Sciences

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816913396

Phone

+98 54 3344 2482

Fax

+98 54 3344 2481

Email

alinavidian@gmail.com

Web page address

<http://zaums.ac.ir/>

Province

Sistan-va-Balouchestan

Postal code

9816913396

Phone

+98 54 3344 2482

Fax

+98 54 3344 2481

Email

nesamojahed@gmail.com

Web page address

<http://zaums.ac.ir/>

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Information about study implications

When the data will become available and for how long

Starting the access period from 2018

To whom data/document is available

academic researchers

Under which criteria data/document could be used

There are no special conditions

From where data/document is obtainable

by email: nesamojahed@gmail.com

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

10 days

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Kheirolnesa Mojahed

Position

Midwifery Bachelor

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

Dr Hesabi Square, Zahedan University of Medical Sciences

City

Zahedan