Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

alinavidian@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

goverment

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
Tobaco
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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr. Noor Mohammad Bakhshani

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Dr Hesabi Square, Zahedan University of Medical Sciences

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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

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

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Person responsible for scientific inquiries

Contact

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Dr. Ali Navidian
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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
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 emil: nesamojahed@gmail.com
What processes are involved for a request to access data/document
10 days
Comments