Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of family-based counseling on the basis of the BASNEF model on the frequency of smoking among smokers in pregnant women

Protocol summary

Summary

The effect of family-based counseling on the basis of the BASNEF model on the frequency of smoking among smokers in pregnant women. Objective: The effect of family-based counseling on the basis of BASNEF model constructs on the frequency of smoking among smokers in the pregnant mother's family Design: This is a pretest-posttest randomized not blind clinical trial study with two groups. Sampling will be done randomly and available among pregnant women referring to Hamedan comprehensive health centers and will have all the criteria for entering the research. A total of 106 female smokers of pregnant women will be randomly divided into two groups of 53 people. Setting and conduct: In the intervention group, educational-consultation program smoking cessation in the presence of a pregnant woman and will not be intervened in the control group.The criteria for entry into the gestational age are not below 30 weeks of pregnancy, the pregnant mother is a smoker and not a hookah. The mother is exposed to tobacco smoke during the night by his or her partner in a closed home, and the smoker is not addicted to any type of drug. Exit criteria: The participant for any reason and at any time to discontinue cooperation, the pregnant mother needs hospitalization due to physical or psychological problems. Intervention: Intervention in four sessions of the Bessenfocus Counseling Group for non-smoking in the presence of pregnant women in groups of ten for individuals in the intervention group for 60 minutes.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017072235133N1**
Registration date: **2017-08-06, 1396/05/15**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2017-08-06, 1396/05/15

Registrant information

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Recruitment status

Recruitment complete

Funding source

Hamadan University of Medical Sciences

Expected recruitment start date

2017-08-27, 1396/06/05

Expected recruitment end date

2017-10-27, 1396/08/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of family-based counseling on the basis of the BASNEF model on the frequency of smoking among smokers in pregnant women

Public title

Impact of family-centered counseling on the smoker's mother-in-law

Purpose

Prevention

Inclusion/Exclusion criteria

Entry criteria: 1) Gestational age is less than 30 weeks of pregnancy. 2) The pregnant mother is not a smoker or a hookah. 3) Mom is exposed to smoke during the day by his or her partner in a closed home. 4) A smoker is not addicted to any type of drug. Exit criteria: 1) Participant for any reason and at any time to opt out of cooperation. 2) The pregnant mother needs hospitalization due to physical or psychological problems.

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **106**

Randomization (investigator's opinion)

Randomized

Randomization description

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

Hamadan University of Medical Sciences

Street address

Nursing and Midwifery Faculty, Hamadan University of Medical Sciences, in front of Mardom Park, Shahid Fahmide Avenue, Hamadan

City

Hamadan

Postal code

Approval date

2017-05-23, 1396/03/02

Ethics committee reference number

IR.UMSHA.REC.1396.309

Health conditions studied

1

Description of health condition studied

Tobacco abuse counselling

ICD-10 code

Z71.6

ICD-10 code description

Person consulting on behalf of another person

Primary outcomes

1

Description

Succeeding in quitting a pregnant woman's presence

Timepoint

Before intervention to 1 mounths after intervention

Method of measurement

Success Stomach Quitting Questionnaire based on BASNEF Model

Secondary outcomes

1

Description

Success of smoking cessation

Timepoint

Before intervention to 1 mounths after intervention

Method of measurement

A researcher-made questionnaire measuring smoking cessation based on the BASNEF model

Intervention groups

1

Description

Intervention group:Of the 53 pregnant women, the smoker's home will be used as an intervention group. Intervention in smokers will also house pregnant women and there will be no intervention in pregnant women. By telephone, the consultation timetable is coordinated with the intervention group and the time for the consultation sessions is determined. In this research, intervention will be family-centered counseling. Meetings will be grouped by a maximum of 10 people. The duration of each session is about 60 minutes and the number of sessions of 4 sessions will be at least 1 week. The counseling will be conducted by the researcher in all groups based on counseling steps on reproductive health services (GATHER). The objectives of our study are as follows: Session 1: A counseling session to introduce a smoker to smoke and harmful substances to a smoker and his relatives, especially pregnant and fetus, which is synonymous with GATHER steps 1, 2 and 3. Session 2: Counseling for a smoker A few cigarette smoke explanations, including second hand smoke, active smoker and active smoker, are synonymous with steps 2 and 5 of GATHER counseling. Session 3: A counseling session for a smoker to know about the effects of cigarette smoking during childbirth, childhood and adolescence on exposure to cigarette smoke and the options available to prevent exposure of pregnant women with cigarette smoke is synonymous with

GATHER steps 3, 4 and 5. Session 4: Mention the summary of the contents of the past sessions and provide queries and answers to help eliminate the ambiguities of smokers, which is synonymous with step 6 of GATHER counseling. Then, the test group will be asked to apply the principles that they are trained when attending the home and the pregnant woman. After completion of the follow-up period (one month later), the initial questionnaire is again completed by the two groups. The obtained data will be analyzed by statistical analysis.

Category

Lifestyle

2

Description

Intervention group 2:The control group, like the intervention group, will consist of 53 pregnant women with a smoker's home, and there will be no intervention or training for smokers at their home.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada Health and Treatment center

Full name of responsible person

Barzegar Fariba

Street address

Takhti Street, next the SHahid Hajibabaii High School

City

Hamadan

2

Recruitment center

Name of recruitment center

Khezr Center

Full name of responsible person

Barzegar Fariba

Street address

Khezr Center, Shahid Sardari Street

City

Hamadan

3

Recruitment center

Name of recruitment center

Navvab Safavi Center

Full name of responsible person

Barzegar Fariba

Street address

Navvab Safavi Street, in front of Manuchehri Hammam

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamadan University of Medical Sciences

Full name of responsible person

Dr. Sangestani Gita

Street address

Nursing and Midwifery Faculty, Hamadan University Medical Sciences

City

Hamadan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Hamadan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty