Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of supportive- educational counseling with men on distress of their pregnant wives: A randomized controlled clinical trials..

Protocol summary

Study aim
The effect of supportive- educational counseling with men on distress of their pregnant wives: A randomized controlled clinical trials.

Design
To assign the participants to the study groups, the random block method will be used with blocks of 4 and 6 and with an allocation ratio of 1:1.Allocation of people in the study and control groups will be done by a person not involved in the project.

Settings and conduct
Considering the importance of the role of spouses in the pregnancy process and the importance of women's health during pregnancy this study was carried out in a quarter of the health centers (total of 84 centers) of Tabriz health centers that were randomly selected using selected from the website www.random.org, will be executed.

Participants/Inclusion and exclusion criteria
Inclution criteria: Gestational age 18 to 24 weeks, husband's willingness to participate, couple's literacy, not taking antidepressants and sedatives, no accidents during the last 6 months, people with a distress score of 24 or higher. exclusion criteria: having obstetrical problems

Intervention groups
Intervention group: Educational counseling will be done for the intervention group. In this regard, 4 counseling sessions of 45 to 60 minutes will be held at intervals of one week in groups of 8 to 10 people. In all counseling sessions, only fathers will be present,Allocation of people in the study and control groups will be done by a person not involved in the project.Allocation of people in the study and control groups will be done by a person not involved in the project. The place and time of educational counseling will be based on the desire of the participants. Control group: No special intervention will be done. After the study is completed, the counseling content will be given to the control group in the form of a booklet.

Main outcome variables
distress of pregnant wemen

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110524006582N38**
Registration date: **2023-03-11, 1401/12/20**
Registration timing: **prospective**

Last update: **2023-03-11, 1401/12/20**
Update count: **0**

Registration date
2023-03-11, 1401/12/20

Registrant information

Name
Mahin Kamalifard

Name of organization / entity
Tabriz University of Medical Sciences and Health Services

Country
Iran (Islamic Republic of)

Phone
+98 414796770

Email address
kamalifardm@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-03, 1402/01/14

Expected recruitment end date
2024-04-02, 1403/01/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of supportive- educational counseling with men on distress of their pregnant wives: A randomized controlled clinical trials..

Public title

The effect of supportive- educational counseling with men on distress of their pregnant wives.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnancy age 18 to 24 weeks husband's desire to participate in counseling classes husbands' reading and writing literacy Not taking antidepressants and sedatives No accidents during the last 6 months People with a distress score of 24 and above

Exclusion criteria:

Having an obstetric problem including the possibility of premature birth, diabetes, hypertension Known congenital abnormalities Receiving counseling services outside the study by couples before the study Twins

Age

No age limit

Gender

Both

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **102**

Randomization (investigator's opinion)

Randomized

Randomization description

Sampling will be done after obtaining the necessary permits. A quarter of the health centers (a total of 84 centers) will be randomly selected using the www.random.org website.Since the sampling is multi-stage, first the health centers will be randomly selected, in this way, we number the centers from 1 to 84 and in the random.org software, we order a random selection of a quarter, the numbers selected in The list will show randomly selected centers. From the selected centers, sampling will be done in an easy way, then participants will be assigned to study groups (supportive counseling with fathers and control group).Random block method will be used for the random allocation of the study subjects using RAS software and through blocks of four and six and with an allocation ratio of 1:1. Allocation of people in the study and control groups will be done by a person not involved in the project. In order to hide the allocation (allocation concealment), the type of intervention will be written by a person not involved in the study in a paper and placed inside numbered opaque envelopes. After obtaining informed consent, the relevant envelope will be opened in the order of entry into the study and the intervention will be implemented.

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 Research in Tabriz University of Medical Sciences

Street address

Central Organization No. 2 - Vice Chancellor for Research TABRIZ, Tabriz University of Medical Sciences, Tabriz, Iran

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Approval date

2023-02-18, 1401/11/29

Ethics committee reference number

IR.TBZMED.REC.1401.907

Health conditions studied

1

Description of health condition studied

distress of pregnant wemen

ICD-10 code

F43.2

ICD-10 code description

Adjustment disorders

Primary outcomes

1

Description

The amount of distress of pregnant women

Timepoint

Before and 4 weeks after the study

Method of measurement

Tilberg Pregnancy Distress Scale Questionnaire

Secondary outcomes

1

Description
The amount of violence among pregnant women
Timepoint
four weeks after the end of the intervention in two intervention and control groups
Method of measurement
Questionnaire of conflict resolution strategy scale used for domestic violence

Intervention groups

1

Description
Intervention group: Educational counseling will be done for the intervention group. In this regard, 4 counseling sessions of 45 to 60 minutes will be held at intervals of one week in groups of 8 to 10 people. The counseling will be in Azeri language. In all counseling sessions, only fathers will be present. The place and time of educational counseling will be based on the desire of the participants.The contents of counseling sessions include: introduction, stating the goals of the plan, listening to clients, paying attention to the main point of problems and mental conflicts and listening to their opinions, the concept of supportive educational counseling and the impact of distress on the mother and fetus during pregnancy.The role of the father in supporting the pregnant mother, expressing the complications of the lack of support for pregnant women and its consequences after birth, the importance of the role of fathers during pregnancy, the importance of the father's bond with the fetus and the duties of fathers during pregnancy and childbirth, sexual relations and the changes surrounding it in Pregnancy, mental health during pregnancy,Violence in pregnancy and its effects on the mother and the fetus and the distress of the pregnant woman, anatomical, physiological and hormonal changes during pregnancy and the impact of these changes on the body and especially the mother's psyche and providing solutions to adapt more to these changes, the role of the father in helping the mother adapt With these changes, familiarity with the stages of fetal development during pregnancy, the effect of mother's nutrition and the father's attention to the nutrition of his pregnant wife and his wife's distress during pregnancy and the effect of prenatal care on the health of the mother and fetus, signs and symptoms of violence during pregnancy and how to deal with them,The process of childbirth and the stages of childbirth (natural cesarean) and the advantages and disadvantages of each, how the father and his pregnant wife prepare for childbirth will be described.The last fifteen minutes of each session will be devoted to questions and answers, and at the end of the session, individual counseling will take place if requested by each participant.
Category
N/A

2

Description
Control group: The content of the consultation will be provided to the control group in the form of a booklet.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz health centers
Full name of responsible person
Mahin Kamalifard
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Shariati street, Faculty of Nursing and Midwifery
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https://nursing.tbzmed.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Parviz Shahabi
Street address
Research office, No 2 central building, Golgasht street, Tabriz university of medical science riz
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Grant name
Grant code / Reference number
دانشگاه علوم پزشکی تبریز
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
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Position
Assistant professor
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Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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

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

Analytic Code

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

Data Dictionary

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