Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of counseling with hope therapy approach on improving perceived stress and quality of life of women suffering from pregnancy nausea and vomiting

Protocol summary

Study aim

The effect of counseling with hope therapy approach on improving quality of life and perceived stress of women suffering from pregnancy nausea and vomiting

Design

The study is a phase 3 of parallel randomized clinical trial, with a control group which will be conducted on 68 patients (34 intervention and 34 control). Women suffering from pregnancy nausea and vomiting will be selected in the convenience sampling method and then will be allocated in two groups with the block random allocation method with a block size of 4. Random blocks will be selected from the table of random numbers. There is no blinding.

Settings and conduct

The setting of study includes the all comprehensive health centers of Zanjan city and the research population includes all pregnant women suffering from pregnancy nausea and vomiting who referring to the mentioned centers. The women will be will be allocated in two groups with the block random allocation method with a block size of 4. There is no blinding.

Participants/Inclusion and exclusion criteria

Inclusion criteria: gestational age of 6 to 12 weeks, obtaining a score of 17-32 from the Rhodes Nausea and Vomiting Questionnaire and a score of 18-36 based on the Cohen Stress Questionnaire. Exclusion criteria: suffering from chronic diseases, suffering from gastrointestinal disease, depression, taking psychiatric drugs, narcotics and psychotropic drugs, experiencing traumatic and stressful events in the last 3 months, symptoms of miscarriage, presence of molar pregnancy , and ectopic

Intervention groups

The intervention group" Hope therapy counseling will be held in 8 sessions with intervals of twice a week and each session lasts 90 minutes in the comprehensive health centers of Zanjan city. The control group: the usual prenatal care and adherence to diet will be ordered

Main outcome variables

Quality of life, perceived stress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150731023423N22**
Registration date: **2023-07-11, 1402/04/20**
Registration timing: **prospective**

Last update: **2023-07-11, 1402/04/20**
Update count: **0**

Registration date

2023-07-11, 1402/04/20

Registrant information

Name

Azam Maleki

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-23, 1402/05/01

Expected recruitment end date

2024-01-31, 1402/11/11

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of counseling with hope therapy approach on improving perceived stress and quality of life of women suffering from pregnancy nausea and vomiting

Public title
The effect of counseling with hope therapy approach on improving perceived stress and quality of life of women suffering from nausea and vomiting of pregnancy
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Gestation age 6 to 12 weeks Low risk pregnancy Wanted pregnancy Obtaining a score of 17-32 based on the Rhodes Nausea and Vomiting Questionnaire Obtaining a score of 18-36 based on Cohen's Perceived Stress Questionnaire Singleton pregnancy based on ultrasound
Exclusion criteria:
Suffering from chronic diseases Suffering from depression (getting a score of 12 or more from the Edinburgh Questionnaire) Suffering from digestive diseases Taking psychiatric drugs Drug and psychedelic use Experiencing traumatic and stressful events in the last 3 months Symptoms of miscarriage Presence of molar or ectopic pregnancy Presence of ectopic pregnancy
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **68**
Randomization (investigator's opinion)
Randomized
Randomization description
Eligible women will be selected during routine prenatal care and then will be allocated into two intervention ans control groups using the block random allocation method with a block size of 4; For this purpose, blocks of 4 will be selected using a table of random numbers in the size of 17 blocks so that the sample size reaches 68 people. Blocking will be done by a person not involved in sampling. Each of the generated random sequences will be recorded on a card and the cards will be placed in the envelopes in order. Finally, the lids of the envelopes will be glued and placed inside a box. At the start of the intervention to identify the order of the participants, one of the envelopes will be opened in order and the assigned group of that participant will be revealed.
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 Zanjan University of Medical Sciences
Street address
Jomhori Eslami Ave, Azadi Square,The first floor of Deputy of research and technology of Zanjan University of Medical sciences
City
Zanjan
Province
Zanjan
Postal code
4515613191
Approval date
2023-06-27, 1402/04/06
Ethics committee reference number
IR.ZUMS.REC.1402.080

Health conditions studied

1

Description of health condition studied
Quality of life in women with pregnancy nausea and vomiting
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Perceived Stress
ICD-10 code
F43.9
ICD-10 code description
Reaction to severe stress, unspecified

Primary outcomes

1

Description
Quality of Life
Timepoint
Before the intervention, 8 weeks after the end of the

intervention

Method of measurement

The Pregnancy Nausea and Vomiting Quality of Life

2

Description

Perceived Stress

Timepoint

Before the intervention, 8 weeks after the end of the intervention

Method of measurement

Cohen's Perceived Stress Questionnaire

Secondary outcomes

1

Description

Hope for Life

Timepoint

Before intervention and 8 weeks after the completion of counseling sessions

Method of measurement

Hope for Life Scale

Intervention groups

1

Description

Intervention group: Hope counselling will be conducted in a group format. It will consist of 8 sessions, held twice a week, with each session lasting 90 minutes at the Comprehensive Health Centers in Zanjan City. The content of the sessions will be designed based on the developed treatment plan by Snyder. In the hope therapy sessions, women will become familiar with concepts such as hope, understanding the growth of hope, and the necessity of hope in life. Individuals will be encouraged to express their life stories, current events, and important dimensions of life. They will prioritize life events based on their importance, set goals for each area of life, develop pathways and appropriate strategies to achieve the set goals and transform these pathways into small steps and motivating pathways. Ultimately, individuals are expected to practice positive thinking in their daily lives.

Category

Prevention

2

Description

Control group: The control group will be received the usual prenatal care and diet.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive health centers in Zanjan city

Full name of responsible person

Mahsa Piri

Street address

All health centers in Zanjan city

City

Zanjan

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Postal code

4515613191

Phone

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mahsapiri3226006@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Samad Nadri

Street address

Jomhouri Street, Azadi Boulevard, University Headquarters, 1st floor, Deputy of Research and Technology, Zanjan 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

Zanjan 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
Zanjan University of Medical Sciences

Full name of responsible person
Mahsa Piri

Position
Master's student in counseling in midwifery

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Zanjan University of Medical Sciences

Full name of responsible person
اعظم ملکی

Position
Assistant Professor in reproductive health

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Person responsible for updating data

Contact

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Azam Maleki

Position
Assistant Professor in reproductive health

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
The possibility of dissatisfaction of the participants

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available