

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of Group Consulting with Positive Psychological Approach on Psychological Capital and Quality of Life in Pregnant Women

Protocol summary

Study aim

Determining the Effect of Group Consulting with Positive Psychological Approach on Psychological Capital and Quality of Life in Pregnant Women

Design

Positive Psychological Interventions will be offered twice a week in 8 sessions of 90-60 minutes. The number of participants in each session is 10 people. In the beginning and after the consultation sessions, the questionnaires will be provided to the participants. The questionnaires will be re-submitted to the participants six weeks after the last consultation. The control group will receive routine pregnancy care.

Settings and conduct

The research population is pregnant women referring to Prenatal Preparatory Counseling Centers, Comprehensive Health Centers, Women's Clinics.

Participants/Inclusion and exclusion criteria

Entry criteria: Pregnancy age 14 to 28 weeks of gestation, Completion of informed consent form, No history of complications and problems associated with pregnancy, No medical and surgical diseases, no mental illness and cognitive impairment, no psychiatric drugs, no drugs And fluent, having at least third-level guidance, familiarity with Persian language, non-attendance at training sessions and similar consultations. Exclude criteria: Exit criteria include: reluctance to continue to participate in the study, non-attendance at more than two counseling sessions, birth-related complications or termination of pregnancy, medical and surgical complications. The occurrence of major stressful events during the research.

Intervention groups

In this research, an easy sampling method was used and then 60 people with the inclusion criteria of randomly assigned blocking method would be divided into two groups of intervention and control. The number of members in each group is 30.

Main outcome variables

Psychological capital and quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160521027994N6**

Registration date: **2019-01-28, 1397/11/08**

Registration timing: **prospective**

Last update: **2019-01-28, 1397/11/08**

Update count: **0**

Registration date

2019-01-28, 1397/11/08

Registrant information

Name

Taraneh Emamgholi khooshehchin

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 24 3314 8318

Email address

khoosheh@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01

Expected recruitment end date

2019-04-19, 1398/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Group Consulting with Positive Psychological Approach on Psychological Capital and Quality of Life in Pregnant Women

Public title

Impact of counseling on psychological capital and quality of life

Purpose

Education/Guidance

Inclusion/Exclusion criteria**Inclusion criteria:**

Gestational age 14 to 28 weeks of pregnancy Completion of informed consent form Absence of history of complications and problems associated with pregnancy Absence of medical and surgical diseases Non-occurrence of mental illness and cognitive impairment Non-use of psychiatric drugs, narcotics and psychotropic drugs Having at least third-level guidance Familiarity with Persian language Non-attendance at training sessions and similar consultations

Exclusion criteria:

Gestational age less than 14 and older than 28 weeks of gestation Failure to complete informed consent form History of complications and problems associated with pregnancy Medical and surgical diseases Mental illness and cognitive impairment Use of psychiatric drugs, drugs and psychotropic substances Participation in training sessions and similar consultations

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The collected samples will be divided into two intervention and control groups using randomized block 4. In each block, two assignments will be assigned to the intervention group and two allocations for the control group, which will create a total of 6 modes, each of which will be assigned a number from 1 to 6, then the random selection of numbers 1 to 6 will continue to be continued. It found the sample size to reach 60.

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**

Zanjan Medical University

Street address

Zanjan Azadi Square

City

zanjan

Province

Zanjan

Postal code

4513956113

Approval date

2019-01-10, 1397/10/20

Ethics committee reference number

IR.ZUMS.REC.1397.308

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

Psychological capital

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

Quality of Life

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

Psychological capital

Timepoint

Before the intervention, the last consultation session and six weeks after the end of the intervention

Method of measurement

Psychological Capital Questionnaire

2**Description**

quality of life

Timepoint

Before the intervention, the last consultation session and six weeks after the end of the intervention

Method of measurement

Quality of Life Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Consultation with a positive psychology approach for the intervention group in a group and eight sessions of 60-90 minutes, will be held a weekly two sessions. The number of members in the group consultation will be 10, and at the end of each session homework assignments will be given to participants.

Category

Other

2

Description

Control group: In the control group, routine pregnancy care will be performed. Positive psychological counseling sessions will be held for them if they wish the participants in the control group after the intervention.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Pre-natal Preparatory Counseling Centers,
Comprehensive Health Centers, Women's Clinics

Full name of responsible person

Mansureh Mostafai

Street address

Zanjan

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4513665758

Phone

+98 24 3344 4280

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mostafai554@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Doctor Alireza Shoghli

Street address

Zanjan University of Medical Sciences, Azadi Square,
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Grant name

tesis

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

Mansureh Mostafai

Position

Senior Counselling Student In Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

School Of Nursing and Midwifery, Carmandan
Boulevard, Zanjan

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Taraneh Emamgoli Khooshehchin

Position

Faculty

Latest degree

Ph.D.

Other areas of specialty/work

Midwifery

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Person responsible for updating data

Contact

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Full name of responsible person

Mansureh Mostafai

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Latest degree

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Other areas of specialty/work

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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

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

Title and more details about the data/document

The release program is not yet known

When the data will become available and for how long

The release program is not yet known

To whom data/document is available

The release program is not yet known

Under which criteria data/document could be used

The release program is not yet known

From where data/document is obtainable

The release program is not yet known

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

The release program is not yet known

Comments