Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

The Study of the effectiveness of Group Quality of life Therapy on Anxiety, Perceived Stress, General Health and Quality of life of Pregnant Women

Protocol summary

Study aim
Determine the effectiveness of quality of life therapy on anxiety, perceived stress, general health and quality of life in pregnant women in Isfahan.

Design
This study had semi experimental design with pre-test, post-test and follow-up measurements comparing with attention control group. From pregnant women to Shaid Behshti Hospital in Isfahan. 50 participants were available sampling method selected and assigned to the group quality of life therapy intervention or attention control randomly using concealed cards.

Settings and conduct
This study examined the effectiveness quality of life therapy on psychological pregnant women. This study was performed on pregnant women referred to Shahid Behshti Hospital of Isfahan. Measurements were performed at pre-test, post-test and follow-up. The intervention was created theory of psychotherapy based on Frsch quality of life improvement. Experimental group received quality of life therapy during 8 sessions(90 minutes, for 8 weeks) and control group received routine medical education for pregnancy period without any psychological trainings. participants were blind to grouping. Statistical analysis were also blind to grouping.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1- Pregnancy 2- Inclination to participat in research Exclusion criteria: 1- Acute psychiatric disorders 2- Get other psychological interventions

Intervention groups
Experimental group received group quality of life therapy during 8 sessions (90 minutes, for 8 weeks) and attention control group received routine medical education for pregnancy period without any psychological trainings.

Main outcome variables
Effectiveness of quality of life therapy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190620043956N1**
Registration date: **2019-09-03, 1398/06/12**
Registration timing: **retrospective**

Last update: **2019-09-03, 1398/06/12**
Update count: **0**

Registration date
2019-09-03, 1398/06/12

Registrant information

Name
Nooshin Heidari

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3535 4001

Email address
nooshinheidari@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-02-19, 1395/12/01

Expected recruitment end date
2017-03-05, 1395/12/15

Actual recruitment start date
2017-02-19, 1395/12/01

Actual recruitment end date
2017-03-10, 1395/12/20

Trial completion date
2017-07-06, 1396/04/15

Scientific title
The Study of the effectiveness of Group Quality of life Therapy on Anxiety, Perceived Stress, General Health and Quality of life of Pregnant Women

Public title
The Study of the effectiveness of Group Quality of life Therapy on Pregnant Women

Purpose
Health service research

Inclusion/Exclusion criteria

Inclusion criteria:
Pregnant women Reading and writing education Inclination to participat in research

Exclusion criteria:
Acute psychiatric disorders Unwillingness to complete the research process Get other psychological interventions

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **50**
Actual sample size reached: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
This is a randomized trial that examine Quality of life Therapy intervention among pregnant women who were randomly selected from among referrals to Shahid-Beheshti Hospital in Isfahan. Participants were then randomized to the psychological wellbeing intervention or the control condition using concealed cards with group assignment listed that were only accessed by research team members following completion of baseline assessments.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study participants were blind about the groupings. Also group assignment listed were only accessed by research team members following completion of baseline assessments. Statistical analysts were also blind to the groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
islamic azad university khorasgan branch

Street address
University Blvd, Arghavanieh, The East Jey St.,Isfahan

City
Isfahan

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Isfehan

Postal code
۸۶۱۷۷۴۳۱۱۱

Approval date
2018-09-12, 1397/06/21

Ethics committee reference number
IR.IAU.KHUISF.REC.1397.055

Health conditions studied

1

Description of health condition studied
Pregnant women

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Quality of Life Score for Pregnant Women in the World Health Organization Quality of Life Questionnaire (2004)

Timepoint
Measurements were performed at pre-test (Before the intervention), post-test (9 weeks after the intervention) and follow-up (15 weeks after the intervention).

Method of measurement
Measurement tools included the World Health Organization Quality of Life Questionnaire - Short Form (WHOQOL-BREF)(2004).

Secondary outcomes

1

Description
Anxiety

Timepoint
Measurements were performed at pre-test (Before the intervention), post-test (9 weeks after the intervention) and follow-up (15 weeks after the intervention).

Method of measurement
Instruments included beck anxiety inventory(1990)

2

Description

Perceived Stress

Timepoint

Measurements were performed at pre-test (Before the intervention), post-test (9 weeks after the intervention) and follow-up (15 weeks after the intervention).

Method of measurement

Instruments included Cohen perceived stress questionnaire (1983)

3

Description

General health

Timepoint

Measurements were performed at pre-test (Before the intervention), post-test (9 weeks after the intervention) and follow-up (15 weeks after the intervention).

Method of measurement

Instruments included Goldberg and Hiller general health questionnaire (1979)

Intervention groups

1

Description

Intervention group received Group Quality of Life Therapy based on Frisch Quality of Life Therapy during 8 sessions (weekly, 90 minutes, for 8 weeks).

Category

Lifestyle

2

Description

Control group received routine medical education for pregnancy period without any psychological trainings during 8 sessions (weekly, 90 minutes, for 8 weeks).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti hospital

Full name of responsible person

Nooshin Heidari

Street address

Shahid Beheshti hospital, Shahid Motahari St, Isfahan City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Majid Toghiani

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Email

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Web page address

Grant name

Grant code / Reference number

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

No

Title of funding source

Islamic Azad University

Proportion provided by this source

1

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

Islamic Azad University

Full name of responsible person

Nooshin Heidari

Position

M.A.Student

Latest degree

Master

Other areas of specialty/work

Psychology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is 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 total potential data can be shared after being "unidentifiable"
When the data will become available and for how long
Start the access period 6 months after publishing of the results
To whom data/document is available
It will be accessible for everyone
Under which criteria data/document could be used
There will be no specific condition
From where data/document is obtainable
nooshinheidari@yahoo.com
What processes are involved for a request to access data/document
There will not be any specific process, we will be responsive after receiving an email
Comments