

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

The effect of resiliency training on mental health of pregnant women with unwanted pregnancy

Protocol summary

Study aim

Investigating the effect of resiliency training on mental health of pregnant women with unwanted pregnancy

Design

Clinical trial with control group, with parallel groups, randomized, on 60 pregnant women with unwanted pregnancies.

Settings and conduct

After obtaining written consent, they enter the research. First, the Goldberg mental Health Questionnaire and the Connor Davidson Resilience Scale will be completed. The control group will receive the routine pregnancy care. In the intervention group, in addition to routine pregnancy care, a resilience training program will be held once a week of 6 group training sessions with 10 to 15 people, lasting 60- 90 minutes; with educational methods of scheduled lectures, working group, question and answer, and group discussion. Immediately and one month after the completion of the educational intervention, the resilience scale and the mental health questionnaire will be completed. The data will be analyzed by SPSS Software Editing 16 at a significance level of 0.05.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women with unwanted pregnancy, age 18 to 35 years, gestational age 12 to 20 weeks, no medical contraindications to maintain pregnancy, no use of drugs and psychotropic drugs, resilience score less than 50, general health score 23 to 60; Conditions of non-admission: Pregnant women with a history of serious mental illness, pregnant women with a history of recurrent miscarriage, women with multiple pregnancies .

Intervention groups

Including 30 women attending to the comprehensive health center assigned to the intervention group and 30 women attending to the health center assigned to the control group

Main outcome variables

Mental health, Resilience

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200630047968N1**

Registration date: **2020-08-05, 1399/05/15**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-05, 1399/05/15**

Update count: **0**

Registration date

2020-08-05, 1399/05/15

Registrant information

Name

Marjan Naderpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4422 1651

Email address

naderpourm@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2020-11-20, 1399/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of resiliency training on mental health of pregnant women with unwanted pregnancy

Public title

The effect of resiliency training on mental health of pregnant women with unwanted pregnancy

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnant women with unwanted pregnancies Age 18 to 35 years Mild and/or moderate problem of mental health based on the mental health questionnaire (score of 23 to 60) Low resilience based on the resilience scale (score less than 50) Written consent form

Exclusion criteria:

Failure to diagnose abnormalities in the fetus (according to screening of the first or second trimester or anomaly scan of fetus Lack of medical prohibition to maintain pregnancy

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to prevent interaction and exchange of information between individuals in the two groups, three centers were assigned to each group by random allocation. Random allocation was done in such a way that the selected health centers (6 centers) were randomly divided into two groups (3 centers in each group). The names of the centers were written on a piece of paper and placed in a lottery bag. The first sheet that was randomly removed from the bag was assigned to the intervention group and the second sheet to the control group and continued until the end of the sheets.

Blinding (investigator's opinion)

Single blinded

Blinding description

Outcome assessor and data analyser of the outcomes will be unaware of the study groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق دانشگاه علوم پزشکی مشهد

Street address

opposite to University Street 18, University Street, Mashhad University of Medical Sciences, Khorasan Razavi, Iran.

City

Mashhad

Province

Razavi Khorasan

Postal code

051 38412081

Approval date

2020-06-02, 1399/03/13

Ethics committee reference number

IR.MUMS.NURSE.REC.1399.022

Health conditions studied

1

Description of health condition studied

unwanted pregnancy

ICD-10 code

Z64.0

ICD-10 code description

Problems related to unwanted pregnancy

Primary outcomes

1

Description

Mental health

Timepoint

The beginning of the study, immediately after the consultation sessions and one month after consultation sessions

Method of measurement

General Health Questionnaire

Secondary outcomes

1

Description

Resilience

Timepoint

The beginning of the study, immediately after the consultation sessions and one month after consultation sessions

Method of measurement

Connor Davidson Resilience Scale

Intervention groups

1

Description

Intervention group: First, the general health questionnaire and the screening scale of Connor and Davidson will be completed. Educational topics include resilience training, first session: pre-test, unwanted pregnancy, resilience generalities, second session: self-acceptance, emotion control and anger management, recognizing strengths and weaknesses, third session: boosting self-esteem, communication and dating, Session 4: Determining purpose and purposeful life, Session 5: cultivating a sense of spirituality and faith, Session 6: providing a summary of all sessions. Immediately and one month after end of the educational intervention, the Resilience Scale and the General Health Questionnaire will be completed.

Category

Lifestyle

2

Description

Control group: Control Group: First, the General Health Questionnaire and the Connor and Davidson Resilience Scale will be completed. The Control Group will receive only the routine pregnancy care. Immediately and one month later, the Resilience Scale and the General Health Questionnaire will be completed.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Comprehensive health centers in Sabzevar

Full name of responsible person

Marjan Naderpour

Street address

Between Taleghani 25 and 27, Taleghani Street, Khorasan Razavi, Iran

City

Sabzevar

Province

Razavi Khorasan

Postal code

9614765836

Phone

+98 51 4422 1651

Email

naderpourm1@mums.ac.ir

Web page address

<https://nurse.mums.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Opposite to University Street 18, University Street
Mashhad University of Medical Sciences, Khorasan
Razavi, Iran

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 2081

Fax

+98 51 3843 0249

Email

vcresearch@mums.ac.ir

Web page address

<http://v-research.mums.ac.ir>

Grant name

Grant code / Reference number

981626

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Marjan Naderpour

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

Street address

School of Nursing and Midwifery, Crossroad of the
Doktora, Khorasan Razavi, Iran

City

Mashhad

Province
Razavi Khorasan
Postal code
9614765836
Phone
+98 51 4422 1656
Email
naderpourm1@mums.ac.ir
Web page address
<https://nurse.mums.ac.ir>

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Maryam Moradi
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
School of Nursing and Midwifery, Crossroad of the
Doktora, Khorasan Razavi, Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51 3859 1511
Email
moradim@mums.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Marjan Naderpour
Position
Masters student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
School of Nursing and Midwifery, Crossroad of the
Doktora, Khorasan Razavi, Iran
City

Mashhad
Province
Razavi Khorasan
Postal code
9137913199
Phone
+98 51138591511
Email
naderpourm1@mums.ac.ir
Web page address
<https://nurse.mums.ac.ir/>

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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is 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 results of this study will be provided to the library of the Faculty of Nursing and Midwifery of Mashhad for the use of students and research units as well as enthusiasts as the senior dissertation on midwifery. A copy of this study was also made available to relevant authorities upon request. Publication of the results in prestigious scientific and research journals will be done in compliance with the authors' rights in all publications resulting from this research project.

When the data will become available and for how long

Probably from the end of 1399

To whom data/document is available

Researchers, students and research units as well as other enthusiasts

Under which criteria data/document could be used

The use of thesis in articles or any scientific article is subject to the mention of the source and in accordance with the publication regulations of Mashhad University of Medical Sciences.

From where data/document is obtainable

Library of the School of Nursing and Midwifery of Mashhad

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

Contact e-mail with supervisor and registered author

Comments