

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Determination of the Effect of Narrative writing on Maternal Depression, Anxiety and Stress in women referring to Prenatal care units of Tehran University Of Medical Sciences

Protocol summary

Study aim

Determine the impact of narrative writing on stress, anxiety and depression on pregnant women who refer to prenatal care of Tehran medical health centers

Design

At first, to determine the sample size, a pilot study was performed on 30 pregnant women who had entered the study at the South University Health Center in Tehran. A sample size of 120 cases was calculated for both groups. Sample will be collected from pregnant women referring to the South Tehran Medical Health Centers. In each center, mothers who come to the clinic on Saturday, Monday, or Wednesday will be in the control group in the intervention group and mothers who visit on Sunday, Tuesday or Thursday.

Settings and conduct

This study is a quasi-experimental trial that will be conducted in two groups of intervention and control. The researcher will visit the prenatal care Units of the health centers of Tehran University of Medical Sciences every other week. Participant's eligibility for inclusion criteria will be checked by a researcher-made questionnaire. Individuals will be screened for depression using a Beck Depression Scale, and if they score between 17 and 10, they will complete the DASS 21 questionnaire and will enter the study if they get acceptable score.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Pregnant women with gestational age between 25 and 28 weeks. age between 18 and 45 years old. Having literacy and ability to read and write. Not taking drugs that cause depression (such as Anti-epileptic drugs, Anti hypertensive drugs, Corticosteroids, Digoxin, Diuretics, Potent tranquilizers, Anti-Parkinson agents). Singleton pregnancy. Being Primiparous. Having a telephone number. Wanted pregnancy. Earning score of 10-17 (mild depression) from Beck Depression questionnaire mild depression, mild to medium anxiety,

mild to medium stress from DASS21 questionnaire.

Exclusion criteria: Change of location. Stressful events during the study (Death of a close Relative, spouse, newborn, economic problems, marital problems and divorce). Intrauterine Fetal Death in current pregnancy. preterm labor. Death of mother. Unwillingness to continue the study for any reason. Narrative writing less than twice a week. Having chronic illness. Having diseases that cause depression (such as Epilepsy, Migraine, Multiple Sclerosis). Taking psychotropic drugs (Opium, Crack, Heroin, Cigarette). Fetal Anomaly in current pregnancy. Abortion history.

Intervention groups

The mothers of the intervention group will be given a protocol and they will be asked to write in accordance with this instruction. This protocol is based on PanBaker's model. According to it, mothers are required to write twice a week or two about their deep thoughts and feelings about pregnancy, fetus and issues that cause their anxiety and joy during this period. It is important that they really write about their deepest thoughts and feelings on paper and not worry about grammar or spelling of words. Mothers are advised to perform narration in a relaxed environment and can do the narration at any time they want. The only law in writing narratives is that they continue to write for 20 to 15 minutes when they start writing. The mothers receive the routine care control group.

Main outcome variables

Stress; anxiety; depression

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170815035722N2**

Registration date: **2018-03-04, 1396/12/13**

Registration timing: **registered_while_recruiting**

Last update: **2018-03-04, 1396/12/13**
Update count: **0**
Registration date
2018-03-04, 1396/12/13

Registrant information
Name
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 69371655980
Email address
f_khalili@razi.tums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-02-24, 1396/12/05
Expected recruitment end date
2018-05-21, 1397/02/31
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Determination of the Effect of Narrative writing on Maternal Depression, Anxiety and Stress in women referring to Prenatal care units of Tehran University Of Medical Sciences

Public title
The Effect of narrative writing on depression, anxiety and stress

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women with gestational age between 25 and 28 weeks age between 18 and 45 years old Having literacy and ability to read and write Not taking drugs that cause depression (such as Anti-epileptic drugs, Anti hypertensive drugs, Corticosteroids, Digoxin, Diuretics, Potent tranquilizers, Anti-Parkinson agents) Singleton pregnancy Being Primiparous Having a telephone number Wanted pregnancy Earning score of 10-17 (mild depression) from Beck Depression questionnaire mild depression, mild to medium anxiety, mild to medium stress from DASS21 questionnaire
Exclusion criteria:
Change of location Stressful events during the study (Death of a close Relative, spouse, newborn, economic problems, marital problems and divorce) Intrauterine Fetal Death in current pregnancy preterm labor Death of mother Unwillingness to continue the study for any reason Narrative writing less than twice a week Having chronic illness Having diseases that cause depression (such as Epilepsy, Migraine, Multiple Sclerosis) Taking

psychotropic drugs (Opium, Crack, Heroin, Cigarette)
Fetal Anomaly in current oregnancy Abortion history

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Not randomized

Randomization description
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 Tehran University of Medical Sciences

Street address

Enghelab Street, Ghods Street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417614411

Approval date

2017-08-15, 1396/05/24

Ethics committee reference number

IR.TUMS.FNM.REC.1396.3197

Health conditions studied

1

Description of health condition studied

depression

ICD-10 code

F32.0

ICD-10 code description

Major depressive disorder, single episode, mild

2

Description of health condition studied

anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

3

Description of health condition studied

stress

ICD-10 code

F43.2

ICD-10 code description

Adjustment disorders

Primary outcomes

1

Description

Depression

Timepoint

Before intervention, 4 weeks after intervention, 8 weeks after intervention

Method of measurement

DASS21 Questionnaire (depression-anxiety and stress)

2

Description

Anxiety

Timepoint

Before intervention, 4 weeks after intervention, 8 weeks after intervention

Method of measurement

DASS21 questionnaire (depression-anxiety and stress)

3

Description

Stress

Timepoint

Before intervention, 4 weeks after intervention, 8 weeks after intervention

Method of measurement

DASS21 questionnaire (depression-anxiety and stress)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The narrative writing group that follows the instructions should write two times a week for two months about their deep thoughts and feelings about pregnancy, fetuses and issues that cause their

anxiety in this period.

Category

Behavior

2

Description

Control group: They will only receive routine prenatal care.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

South Tehran Health Center

Full name of responsible person

Fatemeh khalili

Street address

No.2, Abbas Shafei Aleey, Taleghani Ave, Vesale Shirazi Ave, Enghelab Ave.

City

Tehran

Province

Tehran

Postal code

1417863181

Phone

+98 21 6695 0069

Email

nedakhalili1370@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Esmat Karimi

Street address

No23, Valiasr Avenue, Dameshgh Street, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1417863181

Phone

+98 21 8163 3685

Email

nedakhalili1370@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 21 6105 4312
Fax
Email
mirmolaei@sina.tums.ac.ir
Web page address

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University Of Medical Sciences, School Of Nursing And Midwifery
Full name of responsible person
Fatemeh Khalili
Position
MS Student in reproductive health
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
East Nosrat Avenue, Towhid square, Nursing and Midwifery Faculty, Tehran University Of Medical Science
City
Tehran
Province
Tehran
Postal code
1419733171
Phone
+98 21 6692 7171
Fax
Email
nedakhalili1370@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Tehran University Of Medical Science
Full name of responsible person
Dr Seyedeh Tahereh Mirmolaei
Position
Phd in reproductive health
Latest degree
Ph.D.
Other areas of specialty/work
Reproductive Health
Street address
East Nosrat Avenue, Towhid square, Nursing and Midwifery Faculty, Tehran University Of Medical Science

Person responsible for updating data

Contact

Name of organization / entity
Tehran University Of Medical Sciences, School Of Nursing And Midwifery
Full name of responsible person
Fatemeh khalili
Position
Student Master Of Reproductive Health
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
East Nosrat Avenue, Towhid square, Nursing and Midwifery Faculty, Tehran University Of Medical Science
City
Tehran
Province
Tehran
Postal code
1345764418
Phone
+98 21 6692 7171
Fax
Email
nedakhalili1370@yahoo.com
Web page address

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

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