Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 reffer 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 laber. 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.

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, fetuse 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 laber 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

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

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 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