Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Aug 2026

Compering The Impact Of Writing On Two Types Of Narrative Writing And writing Daily Activity On Stress, Anxiety And Depression Of Pregnant Women

Protocol summary

Study aim
Compering The Impact Of Writing On Two Types Of Narrative Writing And Writing Daily Activity On Stress, Anxiety And Depression Of Pregnant Women

Design
Clinical trials , triple blocking , two intervention groups and one control group with blinded samples.

Settings and conduct
This study is a clinical trial trial that will be conducted in two intervention groups and one control group. The researcher will visit the prenatal care Units of the South Tehran Health Center. Participant's eligibility for inclusion criteria will be checked by a researcher-made questionnaire. Individuals will be screened by 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.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Being Primiparous, gestational age between 25 and 28 weeks age between, Having literacy and ability to read and write, Singleton pregnancy, Acceptedallowed scores from questionnaires. Exclusion criteria: Stressful events during the study, Narrative writing or writing less than twice a we.

Intervention groups
The mothers of group A are given protocol and will require them to write twice a week for two month about their deep thoughts and feelings about pregnancy, fetus. they do not worry about grammar or spelling of words. The only law in writing narratives is that they continue to write for 20 to 15 minutes when they start writing. give a protocol to mothers of group b and will ask pregnant mothers that write about daily activities and do this for 2 times a week without time limit and avoid getting involved with your thoughts and feelings when writing.The mothers receive the routine care in control group.

Main outcome variables
Stress;Anxiety; Depression

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170815035722N3**
Registration date: **2019-05-18, 1398/02/28**
Registration timing: **prospective**

Last update: **2019-05-18, 1398/02/28**
Update count: **0**

Registration date
2019-05-18, 1398/02/28

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
2019-05-22, 1398/03/01

Expected recruitment end date
2020-04-21, 1399/02/02

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Compering The Impact Of Writing On Two Types Of Narrative Writing And writing Daily Activity On Stress, Anxiety And Depression Of Pregnant Women

Public title
Compering The Impact Of Writing On Two Types Of Narrative Writing And Writing Daily Activity On Stress, Anxiety And Depression

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
En 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 do not have history of infertility do not have Fetal Anomaly in current pregnancy do not Taking psychotropic drugs (Opium, Crack, Heroin, Cigarette) do not have mental and psychological disease before pregnancy do not Having diseases that cause depression (such as Epilepsy, Migraine, Multiple Sclerosis) do not Having chronic illness do not have Abortion history

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

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

Gender
Female

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
The samples are classified into three groups by random allocation method. Thus, the letter A is assigned to the narrative group, letter B is assigned to the group writing daily activity and the letter C is assigned to the control group.Then the possible modes of placing these three letters on the three blocks are written on the card and selected by samples.

Blinding (investigator's opinion)
Single blinded

Blinding description
This is a clinical trial study Since the nature of the study is writing, it is not possible to blind people. Only the statistics specialist will be unaware of this matter that, which person belongs to which group (intervention or control).

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
2018-09-17, 1397/06/26

Ethics committee reference number
IR.TUMS.FNM.REC.1397.116

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: 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
Mothers of the second intervention group are required that write about their daily activities. Do this for 2 times a week without time limit and Avoid getting involved with your thoughts and feelings when writing
Category
Behavior

3

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
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1417863181
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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.
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Tehran
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1417863181
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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
Full name of responsible person
Fatemeh Khalili
Position
MS in reproductive health
Latest degree
Master
Other areas of specialty/work
Midwifery
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East Nosrat Avenue, Towhid Square, Nursing and Midwifery Faculty, Tehran University Of Medical Science
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Person responsible for updating data

Contact
Name of organization / entity
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Full name of responsible person
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Student Master Of Reproductive Health
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nedakhalili1370@yahoo.com

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