Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of art therapy on anxiety and quality of life following pregnancy loss

Protocol summary

Study aim
Determining the effect of art therapy on anxiety and quality of life following pregnancy loss

Design
Clinical trial with control and intervention groups, randomized with blocking methodSample number 60 (30 people in each group)

Settings and conduct
Individuals enter the study if they wish and have inclusion criteria. At the beginning of the referral, the prenatal grief scale of Putin et al will be completed by clients and included in the study if the grief is confirmed. Random allocation will be done by blocking method. Samples will then be informed of the subject and the informed consent form will be completed. And they complete the demographic, mourning, anxiety, and quality of life questionnaires. Samples will be divided into 4 90-minute sessions of two sessions per week of painting and pottery as planned, and the anxiety and mourning questionnaires will be completed after two sessions of art therapy and after the course is completed. Eight weeks after the intervention, all three questionnaires will be completed again. During the intervention period, no intervention will be performed in the control group except for routine medical care following pregnancy loss.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 1. Having a history of miscarriage or stillbirth in the last 6 weeks 2. Minimum literacy 3. Willingness to participate in the study 4. Confirm grief by PGS questionnaire 5. Residence in Tehran Exclusion criteria: 1. Mental illness 2. Severe psychiatric reactions that require referral to psychiatry and basic interventions. 3. Current use of antidepressants 4. Unwillingness to participate in the study 5. Failure to attend at least one art therapy session

Intervention groups
Art Therapy Recipient Group Control group (not receiving art therapy)

Main outcome variables
Quality of life; anxiety.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200104046002N1**
Registration date: **2020-01-07, 1398/10/17**
Registration timing: **registered_while_recruiting**

Last update: **2020-01-07, 1398/10/17**
Update count: **0**

Registration date
2020-01-07, 1398/10/17

Registrant information
Name
masumeh zahmatkesh
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 26 3464 5913
Email address
masumezahmatkesh64@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-10-23, 1398/08/01
Expected recruitment end date
2020-02-20, 1398/12/01
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of art therapy on anxiety and quality of life following pregnancy loss

Public title
The effect of art therapy on anxiety and quality of life following pregnancy loss

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Having a history of miscarriage or stillbirth in the last 6 weeks Minimum literacy Willingness to participate in the study Mourning confirmation by PGS questionnaire Residence in Tehran

Exclusion criteria:
Developing mental illness Severe psychological reactions that require referral to psychiatry and basic interventions. Current use of antidepressants Unwillingness to participate in the study Failure to attend at least one art therapy session

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
This will be done by blocking method. For this purpose, the four blocks selected will be assigned to the intervention group letter A and the control group letter B. The 6 possible modes will be written on separate cards and assigned to each card a number (from one to six), then the numbers will be written on the paper and randomly removed. Until the expected sample number is completed. Sequence concealment will be carried out using envelopes in a package such that one of the letters is placed in the order specified and then the envelope is closed and provided to the researcher. The process of random allocation and concealment is performed by the statistical consultant.

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
No 55,12th Ave, first dehghanvilla.

City
Karaj

Province
Alborz

Postal code
3139913939

Approval date
2019-09-04, 1398/06/13

Ethics committee reference number
IR.TUMS.FNM.REC.1398.102

Health conditions studied

1

Description of health condition studied
Anxiety after pregnancy loss

ICD-10 code

ICD-10 code description

2

Description of health condition studied
Mourning after losing pregnancy

ICD-10 code

ICD-10 code description

3

Description of health condition studied
Quality of life following pregnancy loss

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Quality of Life: According to the World Health Organization Questionnaire, the short version of 26 questions indicates a score of 26 to 59 inadequate quality of life, 60 to 89 average quality of life, and a score of 90 to 130 appropriate quality of life.

Timepoint
At first, after two sessions of intervention, at the end of the intervention and 8 weeks after the intervention

Method of measurement
WHO questionnaire, short version 26 questions

2

Description
Explicit anxiety: 20 to 31 mild anxiety score, 32 to 42 moderate to low anxiety score, 43 to 53 moderate to high anxiety score, 54 to 64 moderately severe anxiety, 65 to 75 severe anxiety score, and 76 to 80 very severe anxiety score, respectively. Show.

Timepoint
At first, after two sessions of intervention, at the end of the intervention and 8 weeks after the intervention

Method of measurement
State-Trait Anxiety Inventory (STAI) questionnaire

3

Description
Hidden anxiety: 20 to 31 mild anxiety score, 32 to 42 moderate to low anxiety score, 43 to 52 moderate to high anxiety score, 53 to 62 moderately severe anxiety, 63 to 72 severe anxiety score, and 73 to 80 very severe anxiety scores, respectively. Show.

Timepoint
At first, after two sessions of intervention, at the end of the intervention and 8 weeks after the intervention

Method of measurement
State-Trait Anxiety Inventory (STAI) questionnaire

4

Description
Mourning: Earning a score of 92 or higher on an overall score of 34 or higher on the Active Mourning subscale or a score of 30 or higher on the Hard Coping subscale and a score of 27 or higher on the Despair subscale indicates a high degree of mourning.

Timepoint
At first, after two sessions of intervention, at the end of the intervention and 8 weeks after the intervention

Method of measurement
prenatal grief scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: Samples of this group will be divided into 4 sessions of 90 minutes, two sessions per week of painting and pottery, and the anxiety and mourning questionnaire will be completed after two sessions of art therapy and after the end of the course. Eight weeks after the intervention, all three questionnaires will be completed again.

Category
Rehabilitation

2

Description
Control group: Control group: Samples In this group, there will be no art therapy intervention.

Category
Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center
Baharloo Hospital

Full name of responsible person
Masoume Zahmatkesh

Street address
Railway Square, Behdari Street

City
tehran

Province
Tehran

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12299

Phone
+98 21 5565 8500

Email
Hosp_baharloo@tums.ac.ir

Web page address
http://medicine.tums.ac.ir/baharlou

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Masoumeh Zahmatkesh

Street address
No 55,12th Ave, first dehghanvilla.

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Email
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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
Masoumeh Zahmatkesh
Position
student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
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Person responsible for scientific inquiries

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Person responsible for updating data

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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
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
Undecided - It is not yet known if there will be 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