

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Effect of hope therapy counseling on psychological well-being of mothers after abortion: a randomized controlled trial

Protocol summary

Study aim

Determining the effect of hope therapy on psychological well-being in mothers after abortion

Design

Randomized controlled trial with two parallel arms

Settings and conduct

This study will be performed in Al-Zahra and Taleghani educational and therapeutic centers in Tabriz on 52 women aged 15 to 49 whose pregnancy has led to abortion. In the study, informed written consent will be obtained and initial evaluations will be performed. Participants will be assigned to the intervention and control groups using a block randomization method with block sizes of 4 and 6 and with a 1:1 allocation ratio.

Participants/Inclusion and exclusion criteria

inclusion criteria: Women with loss of pregnancy less than 20 weeks of pregnancy, Minimum secondary education and living in Tabriz exclusion criteria: Suffering from mental illnesses and taking any psychological medication, having a history of chronic physical diseases and experiencing a severe psychological crisis during the last 3 months, such as the death of relatives

Intervention groups

For the intervention group, group counseling with hope therapy approach will be held in 8 sessions of 45 minutes, twice a week. The control group will receive routine post-abortion care.

Main outcome variables

Mean score of psychological well-being

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120718010324N60**

Registration date: **2020-12-17, 1399/09/27**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-17, 1399/09/27**

Update count: **0**

Registration date

2020-12-17, 1399/09/27

Registrant information

Name

Mojgan Mirghafourvand

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-09, 1399/09/19

Expected recruitment end date

2021-03-19, 1399/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of hope therapy counseling on psychological well-being of mothers after abortion: a randomized controlled trial

Public title

The effect of hope therapy on psychological well-being of mothers after abortion

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 15 to 49 years
Not participation in similar studies
Loss of pregnancy less than 20 weeks of pregnancy
Having at least secondary education
Living in Tabriz
Having a phone number
Non-addiction to drugs, alcohol and cigarettes according to the self-report

Exclusion criteria:

Suffering from mental illnesses and taking any psychological medication according to the person's own statement
Having a history of chronic physical diseases (diabetes, heart disease, high blood pressure, cancer, kidney disease, lung disease, iron deficiency anemia, thyroid diseases and epilepsy) according to her statement
Experiencing a severe psychological crisis during the last 3 months, such as the death of relatives, according to her statement

Age

From **15 years** old to **49 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be assigned to the intervention (counseling) and control groups using stratified random blocking method (Stratification based on abortion history and type of abortion (spontaneous or induced)) with the block sizes of 4 and 6 and with a 1: 1 allocation ratio. The allocation sequence will be determined by a person not involved in the study using Randomizer software. In order to hide the allocation (Allocation Concealment), the type of intervention is written on paper and sealed in opaque envelopes. The envelopes will be opened in order of the participants entering the study and the type of group will be determined.

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 Tabriz University of Medical

Sciences

Street address

Faculty of Nursing Midwifery, South Shariati Street

City

Tabriz

Province

East Azarbaijan

Postal code

5138947977

Approval date

2020-11-25, 1399/09/05

Ethics committee reference number

IR.TBZMED.REC.1399.815

Health conditions studied

1

Description of health condition studied

Psychological well being after abortion

ICD-10 code

Z00.4

ICD-10 code description

General psychiatric examination, not elsewhere classified

Primary outcomes

1

Description

Psychological well-being

Timepoint

Before, right after and four weeks after the intervention

Method of measurement

Psychological Well-being Questionnaire

Secondary outcomes

1

Description

Quality of Life

Timepoint

Before, right after and four weeks after the intervention

Method of measurement

WHO Quality of Life (WHOQOL) Standard Questionnaire

Intervention groups

1

Description

Intervention group: In this study, counseling will be provided with each of the participants in the intervention group through hope therapy approach in 8 sessions of 45 minutes twice a week in native language. Hope therapy is done in 2 main stages, each of which consists of 2 steps. The first stage is hope-building, which includes recognizing hope by telling your story and consolidating hope. In the next stage, hope-rising includes increasing hope through goal-improvement techniques, creating a

framework for revealing goals, creating clear and practical goals, management of obstacles placed on the path of hope and finally the retention of hope.

Category

Other

2

Description

The control group will receive routine post-abortion care.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Educational and Medical Centers

Full name of responsible person

Fatemeh Rafi

Street address

Alzahra Educational and Treatment Center, South
Artesh street, Tabriz

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2

Recruitment center

Name of recruitment center

Taleghani Educational and Medical Centers

Full name of responsible person

Fatemeh Rafi

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Talegani hospital, Rah Ahan square, Tabriz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mohammad Samiei

Street address

Research department, third floor, central construction
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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Fatemeh Rafi

Position

MSc student of counseling in midwifery

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Mojgan Mirghafourvand

Position

PhD of Reproductive Health

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Participant data is confidential

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not 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

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available