Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of Motivational Interviewing on decisional conflict, stress and hopelessness after one IVF failure of infertile women referring to molud infertility center in Zahedan in 2020

Protocol summary

Study aim

Determining the effect of motivational interviewing on decisional conflict, stress, and hopelessness after one failed in vitro fertilization attempt among infertile women referring to the Moloud Infertility Center in Zahedan in 2020

Design

This study was a randomized controlled parallel clinical trial conducted on 60 infertile women. Participants were allocated to intervention and control groups using simple randomization (lottery method). This was an educational interventional study and had no drug trial phase.

Settings and conduct

This trial was conducted at the Moloud Infertility Center in Zahedan. Participants were recruited by convenience sampling and randomly allocated using simple randomization after written consent. The intervention group received four motivational interviewing sessions and the control group received routine care.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Infertile women aged 20–45 living in Zahedan; living with spouse; at least one year of infertility and six months since diagnosis; at least two months after one failed IVF; no living or adopted child; having frozen embryos and no contraindication for repeat IVF; no remarriage; no severe psychosocial crisis in the past six months; no history of psychiatric disorder; no psychiatric medication use. Exclusion criteria: Absence from more than one session; spontaneous pregnancy during the study; occurrence of a serious adverse event.

Intervention groups

ntervention group: Four 90-minute group motivational interviewing sessions over two weeks (two sessions per week) were conducted at the Moloud Infertility Center by a trained MSc counselor in midwifery under specialist supervision. Control group: Received routine care only.

Main outcome variables

Decision conflict; stress; hopelessness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260610069746N1**
Registration date: **2026-06-29, 1405/04/08**
Registration timing: **retrospective**

Last update: **2026-06-29, 1405/04/08**
Update count: **0**

Registration date

2026-06-29, 1405/04/08

Registrant information

Name

Maryam Navaee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 54 3344 4510

Email address

navaee.m@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-21, 1399/07/30

Expected recruitment end date

2020-11-19, 1399/08/29

Actual recruitment start date

2020-11-07, 1399/08/17

Actual recruitment end date

2021-05-20, 1400/02/30

Trial completion date

2021-06-03, 1400/03/13

Scientific title

Effect of Motivational Interviewing on decisional conflict, stress and hopelessness after one IVF failure of infertile women referring to molud infertility center in Zahedan in 2020

Public title

Effect of Motivational Interviewing on decisional conflict, stress and hopelessness after one IVF failure

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria for the study: resident of Zahedan city; living with her spouse; having at least literacy in reading and writing; age between 20 and 45 years; at least 2 months passed since the failure of in vitro fertilization; having no living child or adopted child; not experiencing severe psychosocial crises during the past 6 months; not participating in any counseling program; having no history of psychological disorders and not using psychiatric medications; having frozen embryos stored at the infertility center; having no contraindication for performing in vitro fertilization again; having no history of remarriage; currently belonging to a monogamous family; at least one year has passed since their decision to become pregnant and they have not been successful; at least 6 months have passed since the diagnosis of infertility.

Exclusion criteria:

Exclusion criteria from the study: not participating in more than one counseling session; occurrence of spontaneous pregnancy in the woman during the study; occurrence of any unpleasant event such as the death of loved ones.

Age

From **20 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: In this study, simple randomization was used. After assessing the inclusion and exclusion criteria and obtaining written informed consent, participants were randomly allocated to either the intervention group or the control group. Unit of randomization: The individual participant was considered as the unit of randomization. Stratification: Stratified randomization was not used in this study. Randomization tool and generation of random sequence: The random sequence was generated using the lottery method. For this purpose, 60 identical folded papers were prepared, including 30 labeled “intervention group” and 30 labeled “control group”. All papers were placed in a container, and each participant randomly selected one paper. Based on the label on the paper, the participant was assigned to either the intervention or control group. Allocation concealment:To ensure allocation concealment, the papers were identical, unmarked, and folded before being placed in the container. Therefore, neither the participants nor the researcher were aware of the group allocation until the paper was selected.

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 Zahedan University of Medical Sciences

Street address

Zahedan University of Medical Sciences, Khalije Fars Boulevard, Zahedan, Iran

City

zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2020-07-18, 1399/04/28

Ethics committee reference number

IR.ZAUMS.REC.1399.149

Health conditions studied

1

Description of health condition studied

stress

ICD-10 code

F43.1

ICD-10 code description

Post-traumatic stress disorder (PTSD)

2

Description of health condition studied

Infertility

ICD-10 code
N97
ICD-10 code description
Female infertility

Primary outcomes

1

Description
Decision conflict
Timepoint
Before and one month after the intervention
Method of measurement
O'Connor's Decision Conflict Questionnaire

2

Description
stress
Timepoint
Before and one month after the intervention
Method of measurement
Newton's Infertility Stress Questionnaire (Fertility Problem Inventory)

3

Description
hopelessness
Timepoint
Before and one month after the intervention
Method of measurement
Beck hopelessness scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:This study was conducted at the Moloud Infertility Center in Zahedan. Participants were selected by convenience sampling from infertile women with one failed IVF attempt. After obtaining written informed consent, participants were randomly allocated to intervention and control groups using simple randomization (lottery method). The intervention group received four motivational interviewing sessions.
Category
Prevention

2

Description
Control group:
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Moloud Infertility Center
Full name of responsible person
Maryam Navaee
Street address
Moloud Infertility Center, Ali Ibn Abitaleb Specialized Hospital, Persian Gulf Highway, Salamat Boulevard, Zahedan, Iran
City
zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3329 5570
Email
info@zaums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Dr. Mohsen Taheri
Street address
Zahedan University of Medical Sciences, Khhalije fars Square
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816743463
Phone
+98 54 3329 5796
Email
taheri@zaums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zahedan 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
Zahedan University of Medical Sciences
Full name of responsible person
Maryam Navaee
Position
Assistant Professor, Faculty Member
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Mashahir Square
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816838192
Phone
+98 54 3344 4510
Email
helennavaee@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Maryam Navaee
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Mashahir
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816838192
Phone
+98 54 3344 4510
Fax
Email
Navaee.M@zaums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Zahedan University of Medical Sciences
Full name of responsible person
Maryam Navaee
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Midwifery
Street address
Mashahir
City
Zahedan
Province
Sistan-va-Balouchestan
Postal code
9816838192
Phone
+98 54 3344 4510
Fax
Email
Navaee.M@zaums.ac.ir

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