Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparing the effectiveness of integrated care versus usual care on maternal grief in mothers with perinatal loss: a randomized clinical trial

Protocol summary

Study aim
Evaluation of the effect of integrated care compared to usual care on maternal greif in bereaved mothers with perinatal loss

Design
A single-blind, parallel-group clinical trial with a control group, randomized by a randomization computer program with 128 participants, 64 in each group.

Settings and conduct
The setting of the study will be the maternity ward of Bahar Hospital in Shahroud city of Semnan province. The study population is hospitalized mothers with perinatal fetal loss. Blinding will be done centrally by a statistician and the list of blocks will be made available to someone outside the research. This person will prepare envelopes containing the name of intervention or control in the order of the list and number them in order. Then the envelopes will be given to the person in charge of the delivery room. After obtaining informed consent from the bereaved mothers, the first thick sealed envelope will be given to the principal researcher by the delivery room manager from the numbered box.

Participants/Inclusion and exclusion criteria
Inclusion criterion: mothers with pregnancy loss. Exclusion criteria: Voluntary or legal abortion of pregnancy with clearly abnormal fetus, Having a mental illness or a history of it

Intervention groups
The intervention group: they will have a face-to-face consultation at the time of discharge from the hospital, and a virtual group counseling session will be conducted 20 to 35 days after discharge. From the time of discharge, they have been a member of the virtual information network for 2 months and will be able to receive training and advice. Control group: At the time of discharge, they are not aware of their group and will receive only a pamphlet.

Main outcome variables
Maternal grief, psychological well-being

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230907059370N1**
Registration date: **2023-10-10, 1402/07/18**
Registration timing: **registered_while_recruiting**

Last update: **2023-10-10, 1402/07/18**
Update count: **0**

Registration date
2023-10-10, 1402/07/18

Registrant information

Name
giti Atashsokhan

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 23 3239 5054

Email address
gitiatashsokhan@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-29, 1402/07/07

Expected recruitment end date
2024-02-09, 1402/11/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Comparing the effectiveness of integrated care versus usual care on maternal grief in mothers with perinatal loss: a randomized clinical trial

Public title
Integrated care effect on grief of bereaved mothers
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Mothers with perinatal loss Stillbirth Ectopic pregnancy Fetal death immediately after birth during the mother's hospitalization Abortion, miscarriage Having smart phone Being married
Exclusion criteria:
Suffering from mental illness Having a history of psychological illness Taking psychoactive drugs Divorce Experience a new crisis during past 6 months Pregnancy loss with abnormal fetus
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **128**
Randomization (investigator's opinion)
Randomized
Randomization description
The random allocation of mothers is done using blocks of size four and by a Statistics specialist through computer-based randomization. Based on the table obtained from the allocation, envelopes that are numbered in sequence and contain the type of intervention or control are prepared by someone outside the research. The thick envelopes in the package are placed in a box in order. This box is given to the person in charge of the delivery room who is not involved in the research. After obtaining the consent of the participant to enter the study, an envelope will be opened by the delivery room manager. The desired sample will be assigned to the specified group inside the envelope. Participants will not know about the allocation
Blinding (investigator's opinion)
Single blinded
Blinding description
Participants (bereaved mothers) will receive the usual care, but the intervention group also will receive additional care. The intervention group will have face-to-face counseling and will have access to the virtual educational counseling network. The control group will only receive an educational pamphlet at the time of discharge from the hospital. Both groups are unaware of the allocation. Clinical caregivers will perform all routine tasks for both groups and will not be informed. The person responsible for data collection is a research assistant who will complete the questionnaires over the phone for both groups and will not be informed. The statistician will analyze the data from the questionnaires and will not be informed.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahroud University of Medical Sciences
Street address
Shahroud University of Medical Sciences and Health Services, Hafte Tir Square, Taheri Ave
City
Shahroud
Province
Semnan
Postal code
3614773955
Approval date
2021-03-08, 1399/12/18
Ethics committee reference number
IR.SHMU.REC.1400.011

Health conditions studied

1

Description of health condition studied
Maternal grief, psychological well-being
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Maternal greif score in Perinatal Grief Scale (potvin)
Timepoint
Before intervention, after virtual session, 2 months after discharge
Method of measurement
Perinatal Grief Scale

2

Description
Psychological well-being

Timepoint
Before intervention, 2 months after discharge
Method of measurement
Ryff scales of psychological well-being

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: one face-to-face individual counseling session patient-centered for bereaved mother with an empathic approach before discharge from the hospital, two virtual peer group counseling sessions, and allocation of a virtual online counseling channel for bereaved mothers until the end of the sampling period.
Category
Rehabilitation

2

Description
Control group: receiving usual care and a general educational pamphlet at time of discharge
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Maternity ward at Bahar hospital in Shahroud
Full name of responsible person
Giti Atashsokhan
Street address
Bahar Hospital, 22 Bahman street
City
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Province
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Postal code
3614773955
Phone
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Fax
Email
atashsokhan@shmu.ac.ir
Web page address
https://shmu.ac.ir/bahar/fa

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahroud University of Medical Sciences
Full name of responsible person
Dr.Mohammad Hasan Imamian
Street address
7th Tir Square, Taheri St. Shahrood University of Medical Sciences.Shahroud, Iran.
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۳۶۱۴۷۷۳۹۴۳
Phone
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Fax
Email
vcr@shmu.ac.ir
Web page address
https://shmu.ac.ir/research/fa
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahroud University of Medical Sciences
Proportion provided by this source
2
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
Shahroud University of Medical Sciences
Full name of responsible person
Giti Atashsokhan
Position
faculty member
Latest degree
Master
Other areas of specialty/work
Reproductive Health
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Afsaneh Keramat

Position
Professor

Latest degree
Ph.D.

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is 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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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
Yes - There is a plan to make this available

Title and more details about the data/document
After publishing the article and anonymizing the participants, the data file can be sent via email as requested

When the data will become available and for how long
After publishing the research paper of the project for 6 months

To whom data/document is available
for all Academic Researcher

Under which criteria data/document could be used
An approved proposal whose goals indicate the need for this information

From where data/document is obtainable
By Email

What processes are involved for a request to access data/document
After the approval of the project partners, the information will be sent within two weeks

Comments