Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Aug 2026

Investigation of the effect of applying video interaction guidance on the intensity of grief in mothers with premature infant

Protocol summary

Study aim
Investigation of the effect of video interaction guidance on the intensity of grief in mothers with premature infant

Design
The research is a quantitative interventional study of semi-experimental method, two groups of control and intervention on mothers with premature babies hospitalized under 37 weeks of pregnancy in the neonatal intensive care unit

Settings and conduct
Sampling will be done as available and every day in a rotating shift at Yas Hospital located in Tehran according to the entry criteria of mothers, a total of 72 people, 36 people will be in the control group and 36 people will be in the intervention group, and the sampling will be done simultaneously.

Participants/Inclusion and exclusion criteria
1) Over the age of 18 2) Literate to read and write 3) Having a premature baby girl or boy born under 37 weeks of pregnancy and admitted to the neonatal intensive care unit 4) Absence of known physical and psychological diseases 5) Absence of alcohol and drug addiction 6) Not having a history of divorce and separation from spouse during pregnancy 7) Having relative familiarity with mass communication tools 8) Absence of anomalies at the time of birth in the baby 9) Mothers will not be included in the study if they do not want to cooperate

Intervention groups
In the intervention group, Intervention of the Video Interaction Guidance (VIG) will be implemented for one week, which includes filming 5 for up to 10 minutes three times and editing and re-showing moments of positive interaction between mother and baby three times. Mothers in the control group will receive just routine care and no more additional intervention.

Main outcome variables
The severity of mothers' grief

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180429039464N6**
Registration date: **2023-02-15, 1401/11/26**
Registration timing: **prospective**

Last update: **2023-02-15, 1401/11/26**
Update count: **0**

Registration date
2023-02-15, 1401/11/26

Registrant information
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Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-03-21, 1402/01/01
Expected recruitment end date
2023-08-23, 1402/06/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Investigation of the effect of applying video interaction guidance on the intensity of grief in mothers with premature infant

Public title

Investigation of the effect of applying video interaction guidance on the intensity of grief in mothers with premature infant

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Over the age of 18 Literate to read and write Having a premature baby girl or boy born under 37 weeks of pregnancy and admitted to the neonatal intensive care unit Absence of known physical and psychological diseases (cancer, chronic and acute diseases, depression, etc.) in the initial evaluation as self-reported by mothers Absence of alcohol and drug addiction in the initial assessment and as self-reported by mothers Not having a history of divorce and separation from spouse during pregnancy Having relative familiarity with mass communication tools such as mobile phones and working with mass communication software and social networks to connect the researcher with mothers Absence of anomalies at the time of birth in the baby due to the prolonged grief process in mothers

Exclusion criteria:

The mother's unwillingness to continue participating in the study at any stage of the research Sudden deterioration and infant death at every stage of research and intervention implementation Early discharge (less than one week of intervention) of the baby from the neonatal intensive care unit

Age

From **18 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Mothers with premature baby hospitalized in the neonatal intensive care unit will be selected by Convenience sampling method and will be assigned to the intervention and control groups by 4 block randomization method. Allocation of groups is based on randomization with 18 groups of 4 people (72 people in total) who will be randomly assigned to group A (control group) and group B (intervention group).

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Sampling of the intervention and control groups will be done at the same time, mothers will be randomly assigned to the intervention and control groups. After giving informed consent and completing the pre-test pre-maturity grief questionnaire, the mothers of the intervention group will have three sessions video interaction guide and feedback intervention during the first week of the newborn's hospitalization in the neonatal intensive care unit. After the end of the first week, the post-test questionnaire will be administered. After the first test and after the end of the second week, the second post-test questionnaire will be provided to the mothers. In the control group, after informed consent and collecting the pre-test questionnaire from the mothers, one week and two weeks after the admission of the newborn in the neonatal intensive care unit, the first post-test and the second post-test will be provided to mothers and will be collected after completion. There will be no intervention on the mothers of the control group, but it should be noted that the mothers of the control group will receive the usual care during the intervention.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Nursing and Midwifery & Rehabilitation - Tehran University o

Street address

Room 604, 6th floor, central building of Tehran University of Medical Sciences, intersection of Qods St., Keshavarz Blvd., Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2022-12-11, 1401/09/20

Ethics committee reference number

IR.TUMS.FNM.REC.1401.118

Health conditions studied

1

Description of health condition studied

Intensity of Grief in Mothers with Premature Infant

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Intensity of Grief in Mothers with Premature Infant
Timepoint
The first assessment of the severity of grief of mothers with premature babies before the start of the intervention will be by Hasanpour, Zarezadeh's Pre-maturity Grief Questionnaire. The second measurement will be one week after the start of the intervention and the third measurement will be two weeks after the start of the intervention.
Method of measurement
Hasanpour, Zarezadeh's Pre-maturity Grief Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Before the start of the intervention, the informed consent form and the pre-maturity grief pre-test questionnaire will be completed after the first interaction with the baby in the neonatal intensive care unit, on the first day of the intervention, the first filming of mother-baby interactions will be done, on the second day of the intervention, the videos will be edited by the researcher and selected Better moments than usual will be done, on the third day of the intervention, the first video interaction guidance session (watching the golden moments of mother-baby interaction by the researcher and the mother, positive feedback to the mother by the researcher) + the second filming, on the fourth day of the editing intervention Videos by the researcher, on the fifth day of the intervention, the second session of the video interaction guidance + the third filming, on the sixth day of the intervention, editing of the videos by the researcher, on the seventh day of the intervention, the third session of the video interaction guidance + completion of the first post-test questionnaire, at the end of the second week The questionnaire will be completed.
Category
Behavior

2

Description
Control group: Before starting the intervention, the informed consent form and the completion of the pre-test questionnaire of pre-maturity grief will be done by the mother after the first interaction with the baby in the neonatal intensive care unit, at the end of the first week, the completion of the post-test questionnaire and at the end of the second week The second will be done.
Category
Behavior

Recruitment centers

1

Recruitment center
Name of recruitment center
Yas Hospital Complex
Full name of responsible person
Dr. Arash Jafarieh
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North Nejat Elahi St., Mirzai Shirazi St., next to Sarvo St., Tehran., Iran
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Web page address
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Hossein Ghenaati
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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
40
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

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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
Not applicable
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
Not applicable