Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of Solution-Focused Brief Therapy (SFBT) on Psychological Well-being and Psychological distress of mothers with Prermature Neonates hospitalized in Neonatal Intensive Care Unit (NICU)

Protocol summary

Study aim

Determining the effect of Solution-Focused Brief Therapy (SFBT) on Psychological well-being and Psychological distress of mothers with Prermature Neonates hospitalized in Neonatal Intensive Care Unit (NICU) of Afzalipour hospital, Kerman, Iran, 2020.

Design

The present study is a quasi-experimental study of clinical trial type with intervention and control group and pre-test and post-test. The sample size was 60(30 in the intervention group and 30 in the control group) of mothers with Prermature Neonates hospitalized in Neonatal Intensive Care Unit (NICU) of Afzalipour hospital in Kerman city.An available sampling method is used. At the beginning of the study, they are randomly divided into two groups (one intervention group and one control group).

Settings and conduct

The implementation area is the consultation in the midwifery room of Afzalipour hospital. The mentioned consultation will be done for the intervention group and a summary of the interventions and counseling is provided orally or educational CD for the control group after completing the post-test questionnaire. Data collection was performed by questionnaires immediately after the intervention and one month after the intervention.

Participants/Inclusion and exclusion criteria

Inclusion: Premature birth (under 37 weeks) Willingness to participate in the study Exclusion: Lack of willingness and cooperation of mothers to complete the questionnaire and not attending training sessions (maximum of two consecutive sessions)

Intervention groups

Intervention is used to Solution-Focused Brief Therapy is conducted twice a week for 90 minutes for 2 weeks in the intervention group.

Main outcome variables

Psychological well-being Psychological distress

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200728048234N1**
Registration date: **2020-09-07, 1399/06/17**
Registration timing: **prospective**

Last update: **2020-09-07, 1399/06/17**
Update count: **0**

Registration date

2020-09-07, 1399/06/17

Registrant information

Name

Fatemeh Hassanshahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3743 5964

Email address

fatemehhassanshahi1374@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2021-01-20, 1399/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigating the effect of Solution-Focused Brief Therapy (SFBT) on Psychological Well-being and Psychological distress of mothers with Prermature Neonates hospitalized in Neonatal Intensive Care Unit (NICU)

Public title
Investigating the effect of Solution-Focused Brief Therapy on Psychological Well-being and Psychological distress of mothers with Prermature Neonates hospitalized in Neonatal Intensive Care Unit

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Willingness to participate in the study Premature birth (under 37 weeks) Absence of obvious abnormalities or genetic disorders (gastrointestinal, cardiac, urinary, neurological abnormalities and trisomies 13,18,21) No history of anxiety disorders and depression Literate and fluent in Persian

Exclusion criteria:
Attending another intervention or study while participating in this study Lack of willingness and cooperation of mothers to complete the questionnaire and not attending training sessions Occurrence of anxious events while studying Maternal addiction Transfer the baby to other medical centers Infant death Care by family members other than the mother

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
How to randomize will be through random table. To use the random number table, each sample is given a code or machine number, the researcher randomly starts from a table point in a row or column, selecting the point by blindfolding and placing finger or pen tip on the table. Moves in the direction of a row or column.

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 Kerman University of Medical sciences

Street address
Fourth unit, second floor, Farhad building, Alley 25, Paeiz street

City
Shiraz

Province
Fars

Postal code
7177933354

Approval date
2020-04-13, 1399/01/25

Ethics committee reference number
IR.KMU.REC.1399.049

Health conditions studied

1

Description of health condition studied
Psychological well-being

ICD-10 code

ICD-10 code description

2

Description of health condition studied
Psychological distress

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Psychological well-being score in the Ryff Scale

Timepoint
Before intervention and after the sessions are completed and one month after the intervention

Method of measurement
Ryff Psychological Well-Being Scale

2

Description
Psychological distress score in the Depression, Anxiety and Stress Scale(21-DASS)

Timepoint
Before intervention and after the sessions are completed and one month after the intervention

Method of measurement
The Depression, Anxiety and Stress Scale - 21 Itemes(21-DASS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The method of this research is quasi-experimental and the research design is pre-test-post-test with a control group that will be performed on 60 mothers with infants admitted to the neonatal intensive care unit. For the mothers of the intervention group, after determining the score of psychological distress and psychological well-being using DASS and Ryff questionnaires, 4 sessions of Solution-Focused Brief Therapy will be held for 90 minutes and 2 times a week.(Solution-Focused Brief therapy is one of the effective and short-term counseling models that has a non-cognitive perspective on clients and helps clients find solutions to their current problems).
Category
Lifestyle

2

Description
Control group: They don't receive any intervention
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Afzalipour hospital
Full name of responsible person
Fatemeh Hassanshahi
Street address
Fourth unit, Second floor, Farhad building, Alley 25, Paeiz street
City
Shiraz
Province
Fars
Postal code
7177933354
Phone
+98 71 3743 5964
Email
fatemehhassanshahi7374@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Abbas Pardakhty
Street address
Fourth unit, Second floor, Farhad building, Alley 25, Paeiz street
City
Shiraz
Province
Fars
Postal code
7177933354
Phone
+98 71 3743 5964
Email
fatemehhassanshahi7374@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Fatemeh Hassanshahi
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Fourth unit, Second floor, Farhad building, Alley 25, Paeiz street
City
Shiraz
Province
Fars
Postal code
7177933354
Phone
+98 71 3743 5964

Email
fatemehhassanshahi7374@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Fatemeh Hassanshahi
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Fourth unit, second floor,Farhad building,alley 25,Paeiz st
City
Shiraz
Province
Fars
Postal code
7177933354
Phone
+98 71 3743 5964
Fax
Email
fatemehhassanshahi7374@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Fatemeh Hassanshahi
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Midwifery
Street address
Fourth unit, second floor,Farhad building,alley 25,Paeiz st
City
Shiraz
Province
Fars
Postal code
7177933354
Phone
+98 71 3743 5964
Fax
Email
fatemehhassanshahi1374@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Title and more details about the data/document
Data on the main outcomes of the research after the completion of research work can be published.
When the data will become available and for how long
Starting access to the data above is immediately after publishing the results.
To whom data/document is available
Researchers in academia and scientific institute are able to access research data.
Under which criteria data/document could be used
In case of supplementary research, using data is permitted.
From where data/document is obtainable
The applicant can contact the researcher to receive information via email. nasim.shahrahmani@gmail.com fatemehhassanshahi7374@gmail.com
What processes are involved for a request to access data/document
After submitting a written request from the applicant, the data will be provided to him/her as soon as possible.
Comments