

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

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

Protocol summary

Psychological well-being Psychological distress

Study aim

Determining the effect of Solution-Focused Brief Therapy (SFBT) on Psychological well-being and Psychological distress of mothers with Premature 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 Premature 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

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 Premature 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 Premature 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 Items(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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhty

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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

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

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Person responsible for scientific inquiries

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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